

Institutional Review Board (IRB) Policy and Standard Operating Procedures Manual

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LETTER FROM THE VICE-PRESIDENT

As an institution of higher education, Suffolk County Community understands the value of research performed for a variety of purposes. Suffolk County Community College also is committed to safeguarding the welfare, rights, and privacy of all persons who participate as subjects in research projects conducted under its auspices, and to ensuring that the subjects of such research are aware of their rights and the protections available to them. In compliance with federal regulations, Suffolk maintains an Institutional Review Board (IRB) to review all research requests to make sure they conform to human subject protection standards. These safeguards derive from the ethical principles, which were first articulated in the Belmont Report issued by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979, which are described later in this document.

This manual provides the College's policies, procedures and review guidelines for research involving human subjects as well as the process for obtaining approval from Suffolk's IRB. Any person conducting a research project using human subjects will need to obtain approval of the IRB *prior* to collecting data. The purpose of this policy is to provide a single, comprehensive standard of protection for human subjects of research conducted by students, staff, faculty, or visiting researchers at Suffolk County Community College. The intent is to assure that researchers do not unduly put at risk or harm the subjects of research, and that the subjects of such research are aware of their rights as defined in Title 45, part 46 of the Code of Federal Regulations. IRB approval must precede commencement of any work involving human subjects.

Suffolk County Community College receives many requests for permission to perform research studies. Our IRB policy has been developed to encourage research while maintaining protections for those who take part in any research activities.

Jeffrey M. Pedersen, Ed. D.
Vice President for Planning and Institutional Effectiveness

INTRODUCTION

Importance of the IRB[1]

Suffolk County Community College, as a comprehensive, public community college, not only provides a quality education to its students, enhances local economic development, and engages in community outreach, but also supports faculty, staff, students, and administrators in conducting research and engaging in educational projects. Additionally, where appropriate, the College allows external constituents to conduct appropriate and beneficial research at one of the three campuses or two off-campus centers. While these efforts are supported, the College is, first and foremost, concerned with and dedicated to the protection of its faculty, staff, and students.

For practical and legal, but primarily ethical reasons, the College is committed to protecting the rights of all individuals involved with either research or educational projects that depend upon interaction with members of the college community. To ensure institutional accountability, responsibility, and oversight over research efforts, the Institutional Review Board (IRB) was established and operates as the institutional board charged with assurance of human subjects' protection. This board is responsible for ensuring that all research projects protect the rights and well-being of individuals involved in the studies, that informed consent is provided, that risks have been minimized, and that participants understand the voluntary nature of the activities. The body ensures these protections through a thorough review of protocols to determine if they meet the criteria for research, are eligible for exemption or expedited review, or whether a full review is necessary. At its core, the IRB exists to ensure that individuals are treated ethically, with respect, and in accordance with the mission and vision of the College. Given the technical nature of this document, a list of acronyms (Appendix A) and a glossary of terms (Appendix B) is included.

In discussing the importance of the IRB, it is important to speak to two issues that are not addressed by the review board. First, there are a number of activities that occur at the College as a part of the "normal educational practices" of the institution and are not subject to review by the board. These areas are explained in detail later, however, they include regular assessment of student learning and the support of student learning, institutional reporting, and faculty projects not designed to expand generalizable knowledge. Secondly, it is not the policy of the SCCC IRB to review the soundness of the research studies. Through the College's IRB Policy (Appendix C), a process has been established to approve research studies. After approval, the IRB reviews the protocol and proposal to ensure human subject's protection, review other institutional IRB approvals, and authorize the study.

[1] Three documents were very helpful in the development of this manual and include The American Psychological Association's *The Institutional Review Board (IRB);A Community College Planning Guide*, Columbus State Community College's *Institutional Review Board Standard Operating Procedures*, and Maricopa County Community College District's *Institutional Review Board Handbook: Standard Procedures of Operation*.

IRB Purpose and Principles

The IRB exists for one primary reason – to ensure that research participants are treated ethically, protected from undo risk, and informed of their rights which includes the right to withdraw without any penalties. This purpose, as well as the guiding principles for ensuring human subjects protection, is found within the 1979 *Belmont Report* (Appendix D). This report summarized the findings from the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research; a group tasked with establishing national standards designed to protect research participants.

As a result of the Commission's work, three basic ethical principles emerged. These include:

1. **Respect for Persons** – The report calls for researchers to respect individuals and to treat them as "autonomous agents" and for those unable to act with full autonomy (vulnerable subjects), it requires that special review be put in place to ensure that they are not subjected to situations which they cannot fully comprehend
2. **Beneficence** – Rather than focusing on "kindness" the report requires researchers to treat individuals with dignity, respect, and in an ethical manner that protects subjects from harm while also seeking to "secure their well-being." Even when benefits may not be readily or ever apparent to participants, studies should seek to "maximize possible benefits and minimize possible harms."
3. **Justice** – For the purposes of behavioral research, the commission implores researchers to ensure a "fairness of distribution" in regards to the selection of participants, especially where benefits are direct and readily apparent.

The report also explores the boundaries between practice and research and applications. This information is summarized into the following series of principles to ensure human subject protection[2]:

1. Subjects' legal rights will be respected; their rights to privacy, dignity, and comfort will also be considered in approving proposed research,
2. Risks to subjects must be reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result,
3. Adequate provision(s) must be made for all facilities, procedures, and professional attention necessary for the protection of the individual as a research subject,
4. Adequate provisions should be made for recruiting a subject population that is

[2] This summation was taken from both Columbus State Community College and the Maricopa County Community College District IRB Handbooks

representative of the population base in terms of gender and minority representation, unless the nature of the study justifies a specific subject population,

5. Research involving human subjects must be supervised by qualified persons,
6. Participation of a human subject in research must be voluntary, and the right to withdraw at any time must be provided. Information provided to gain subject consent must be adequate, appropriate, and presented in lay language appropriate to the subject population.

IRB Policy

The College's most recent IRB Policy was approved by the Board of Trustees on 8/21/2014 and is the basis for this manual. The full policy can be found in both appendix C and on the Legal Affairs webpage

Authorization and Registration of the IRB

Suffolk County Community College is registered with and authorized by the U.S. Department of Health and Human Services (HHS) to operate and institutional review board. The purpose of the board is to review "research involving human subjects conducted or supported by the Department of Health and Human Services, or other federal departments or agencies that apply the Federal Policy for the Protection of Human Subjects to such research…" Accordingly, the board is empowered to make decisions regarding what projects are considered research and whether the rights and safety of human subjects are adequately protected along with other responsibilities stated in the IRB responsibilities section. The College has one committee registered with HHS and the official institution/organization number is IORG0006694.

ROLE OF THE IRB

Operations

Meetings

IRB meetings are scheduled once in the fall and once in the spring semesters. If an emergency meeting is required (e.g. violation of policy, urgent request), members will be given ten days' notice. Agendas and all paperwork associated with current IRB requests will be provide at least five business days prior to meetings, either regularly scheduled or emergency, and sign-in sheets will be distributed at each meeting.

Membership

The membership of the review board includes the following:

- IRB Chairperson (Representative from the Office of Planning and Institutional Effectiveness);
- An instructional faculty member from each campus (selected by Campus Governance representatives);
- A faculty or staff member selected by the President;
- A faculty or staff member selected by the Office of Planning and Institutional Effectiveness; and
- One external representative.

In addition to this membership, one representative from the Office of Grants Development, Legal Affairs, Academic Affairs, and Student Affairs will serve as *ex-officio* members. In accordance with federal guidelines, membership of the IRB is chosen to ensure:

1. Diversity of research expertise
2. Diversity of representation
3. Diversity of gender
4. Diversity of profession

To ensure a membership with the education, experience, and expertise to evaluate research projects, the following criteria must be adhered to:

- Instructional faculty representatives are selected from either a physical or social science and, where possible, should have human subjects research experience and a terminal degree;
- The Chair and appointed members should have human subjects research experience, when possible; and
- The external representative is not related to any employee of the College but represents community interest, the population from which human subjects are commonly drawn, and/or has a background in ethics or human rights advocacy.

Prior to serving on the College's IRB, all members must submit the following documentation

a. Confidentiality agreement
b. Conflict of interest form
c. Belmont report agreement form

Management

Given the role of the IRB, the College has determined that oversight and accountability are the responsibility of the Office of Planning and Institutional Effectiveness (OPIE). In his/her role as the Vice-President of OPIE, he/she recommends both a Chairperson and Vice-chairperson of the IRB to the President for approval. The chairperson will be a staff member from OPIE while the Vice-chair will represent another office and will be selected from the current membership. In the absence of the Chairperson, the Vice-chair will conduct business during regularly scheduled meetings. If a change in Chair is required, the Vice-President will name a replacement and ensure that accurate information is sent to HHS.

Faculty membership is important to the board and given the three-campus structure of the College, one faculty member, appointed by the campus governance representatives, from each campus will serve on the board. These individuals should have a physical science/hard science degree and experience with social science research at the graduate level. Ideally, these individuals will possess terminal degrees.

To ensure diversity of experiences, positions, and research experience, the President and the Vice-President of OPIE will each appoint one member to serve on the IRB. These individuals can represent faculty, staff, students, or administrators, however, it is important that the membership not be overly represented by administrators.

In accordance with guidance from HHS, the College selects one external member to serve as a voting member of the IRB. This individual will, ideally, have an advanced degree in a research field, will have a background in ethics or advocacy, and will have a demonstrated research record. Additionally, this individual must not be related to any College employee given that their task is to represent the community interest.

With the exception of the Chair, internal members are appointed on a two-year basis. The external member, in contrast, serves for a three-year period.

Voting

In order to conduct business during a regularly scheduled or emergency meeting, the IRB must convene a quorum of its membership (a simple majority). In the case of either exempting a study from IRB review or granting an expedited review, a formal board vote is not required as stated in 45 CFR 46.110. In these cases, paperwork accompanying the decision will be sent forward to the remainder of the board for review. Should a majority of members vote during the next regularly scheduled meeting that a full review is necessary (as opposed to the expedited review), the decision by the full body will supersede the original decision. Additional information and formal procedures are provided later in the document. In the case of approval for a study requiring a full review, authorization can only be granted by majority vote from those present at the meeting.

The IRB meetings are open to the public and operate as a forum where additional information can be provided on the projects. This can include presentations from the Project Directors, Primary Investigators, or other concerned parties. If an IRB member wishes to offer information, they must assure the board that their presence as a voting member on the study does not represent a conflict of interest. If the membership determines that sensitive matters need to be discussed, the Chair will call the meeting into an executive session and will close the meeting to the public.

Conflict of Interest

Under no circumstance should any member of the IRB be involved with the initial review nor continuing review of a study in which they are directly or indirectly connected. They may offer information and respond to questions from the remainder of the body, however, they must recuse themselves from the formal voting process.

PROCEDURES

Approval of Projects

The IRB does not provide approval for research projects, but rather authorizes that approved projects can be conducted based on exemption or acceptance of the research protocol. Upon receipt of a proposal, the information will be forwarded to the Office of Academic Affairs or the Office of Student Affairs, depending upon the content. When necessary, these offices will confer with the Office of Legal Affairs. After approval from the appropriate administrator, the IRB Chair is permitted, if necessary, to submit a letter of support to the requestor. The approval process takes between 3 and 4 weeks.

Project Authorization

The IRB does not provide approval for research projects, but rather authorizes that approved projects can be conducted either through exemption or as a result of an expedited or full review. The IRB is not a committee, but rather a board and is empowered by HHS, the College, and this operational manual to either authorize or reject research projects that impact the faculty, students, staff, and administrators at the College. Authorization times vary by type of review with exemption and expedition of the projects taking 2-3 weeks after approval and authorization from a full review coming 2-3 weeks after the IRB's regularly scheduled meetings. The IRB application for authorization can be found in Appendix E.

IRB Review

The IRB exists to review approved projects to ensure that human subjects are protected from unnecessary risk or harm. There are three decisions that can be made regarding review: exempting the study or project from review, expediting the review, or requiring a full review.

Exempt Activities

The majority of the data collected within a college does not meet the definition of research and therefore does not require an IRB review. If an activity uses human subjects data that is regularly and routinely gathered at the institution, does not require new, additional, or significantly altered data gathering procedures, or if the activity is not sponsored by an external agency or does not test a hypothesis, it probably is **not** research (e.g. assessment of student learning). Specifically, the following activities at Suffolk County Community College are always exempt from IRB review even though they involve human subjects:

- Assessment of student learning at the classroom or program level;
- Analysis of existing data sets when 1) all identifiable information has been removed or 2) the activity does not meet the criteria for research;
- Collection of data to fulfill county, state, federal, or system requirements; or
- Institutional analyses

These activities do not require an IRB review and are, instead, subject to the official, formal approval and authorization protocols. In addition to these common data collection activities, numerous other projects are eligible for exemption. According to HHS[3], the following scenarios represent activities that are exempt

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the

[3] www.hhs.gov/ohrp/humansubjects/guidance/hsdc95-02.htm

personally identifiable information will be maintained throughout the research and thereafter.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
5. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental

The decision chart provided by HHS and utilized by the IRB to render decisions about exempt status can be found in Appendix F. When in doubt, the primary investigator should contact the IRB chair to determine if the project is exempt. Under three conditions, however, the primary investigator is required to complete an exemption form (Appendix E) which can be found on the OPIE website. The conditions are:

- The study is being conducted by a party external to the college
- Research is being conducted as part of a dissertation
- A previously exempted study has undergone a change to the protocol.

In accordance with CFR 45, the decision to exempt a study falls under the purview of the IRB Chair. All documentation associated with the decision will be shared via e-mail with all members of the board and will be up for discussion at the subsequent, regularly scheduled meeting. If a project is authorized as exempt, the Primary Investigator or Project Director should still expect to wait between 4 and 6 weeks for formal approval by the appropriate College administrator and subsequent authorization by the IRB.

Expedited Review

When the educational activity is designated as research and does not meet any of the exemptions identified by HHS, the study may undergo an expedited review at the discretion of the IRB chair. The IRB is committed to providing responses to the Primary Investigators

or Project Directors in a reasonable time frame and, where possible, seeks to expedite the review. As was the case with exempting studies, the decision to expedite the review is handled by the IRB Chair. HHS provides a listing of the criteria that allow for an expedited review and these include[4]:

- Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories [listed below], may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects

- Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

  Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject=s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

- Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

[4] www.hhs.gov/ohrp/policy/expedited98.html

- Collection of data from voice, video, digital, or image recordings made for research purposes.

- Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

- Continuing review of research previously approved by the convened IRB as follows: where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or where no subjects have been enrolled and no additional risks have been identified; or where the remaining research activities are limited to data analysis.

There are numerous other categories of research listed on the site, however, per the College's IRB policy, research involving clinical trials, drug trials, or testing of medical equipment are not permitted and will not be authorized. As a result, these categories were not included within this manual.

Full Review

In the event that a proposal is approved, but is not eligible for either exemption or an expedited review, it will be sent to the full membership for review. The full review meeting is a working meeting that is open to the public with the exception of an executive session if necessary[5]. The Primary Investigator or Project Director will be alerted as to the date of the next IRB meeting and should expect to wait for two weeks after the meeting date to receive a final decision on authorization.

Completion of the IRB authorization process is highly recommended if there is any question or doubt about whether a project or study involving human subjects or the analysis of potentially sensitive requires IRB authorization. Should the IRB be made aware of a project that should have been authorized before initiation, a letter will be sent from the IRB noting that the project or study must be halted while a review is conducted. While the project is halted, it will undergo the full approval and authorization process

[5] Should the board need to discuss sensitive information regarding a project under review, the Chair will call an executive session which closes that portion of the meeting to the public.

and if approved, the IRB chair will determine if the project meets the exempt or expedited criteria.

IRB Actions

Initial Review

Upon receiving a completed IRB application for authorization form, the IRB Chair sends the form to either Academic or Student Affairs for review and approval. After approval from the appropriate administrator, the request is sent back to the IRB (within 2-3 weeks of receipt). If the project is deemed to be either exempt or eligible for an expedited review, the Chair of the IRB will send an authorization letter to the Primary Investigator or Project Director. This letter will only be sent, however, if appropriate documentation has been sent along with the application form. As noted on the form, this includes a copy of the home institution's IRB approval, the research protocol, and, if appropriate, the consent form. Should a letter of support be required, the letter will be sent for either exempt or expedited projects in lieu of the authorization letter. The authorization letter, which is also sent to members of the IRB and filed in the Office of Planning and Institutional Effectiveness, can only be sent after the form is completed and all documentation is included.

In the event that a full review is necessary, applicants must follow these same steps:

- Submission of the authorization form and documentation
- Obtain approval from Academic or Student Affairs
- Obtain a letter of authorization from the IRB

Although the process is different, a letter of support can still be sent with the same, aforementioned caveats. If a project is subject to full review, the following questions have not been sufficiently addressed:

- The extent to which individuals participating in the study are protected from unnecessary risks and harm
- The extent to which the protocol explicitly addresses the protection of participant rights
- The extent to which the protocol explicitly addresses the ethical treatment of the human subjects
- The degree to which confidentiality of participation and the protection and security of data is addressed

- The degree to which the potential benefits to the participants and/or contribution to greater generalized knowledge outweighs the potential risks to the subject or the college
- Rationale for why informed consent is being withheld (per regulations in 45 CFR 46) or insufficiency of the informed consent documentation
- The adequacy of facilities and resources necessary for conducting the study

Only after any and all concerns are adequately addressed with the IRB authorize a research study.

Should a full review be required, the Primary Investigator, Project Director, or members of the research team are invited to attend the meeting to discuss their proposal and to respond to questions from the board. After the board is satisfied that all concerns have been addressed, they will authorize the study.

In the event that additional or revised documentation is required (minor revision), the board will authorize the study with restrictions. Under this condition, the study can only start after submission of any new documentation and a letter of authorization from the IRB Chair. Should the IRB deem that the required changes are "substantial", but that the project is viable with the Primary Investigator or Project Director will be required to resubmit the entire project for a new review. Under this scenario, discussion about the project is tabled until resubmission and discussion at the next, regularly scheduled IRB meeting.

In the event that substantial questions remain regarding the project and the board determines that a complete resubmission of all materials is required (significant revision), the project will be disapproved. As with projects deemed to require substantial change, the Primary Investigator or Project Director can resubmit the entire application packet and submit the proposal for a full IRB review.

Continuing Review

In accordance with guidelines provided by HHS, the College maintains a systematic approach to the IRB's authorization period. It is the responsibility of the board to ensure that research projects are reviewed and reauthorized to ensure the continued protection of both human subjects' safety and rights. Regardless of the type of review conducted by the IRB, all projects are subject to continuing review. The timelines are as follows:

- **Exempt** – Projects or studies deemed to be exempt from IRB review are authorized without a predetermined review date. Should changes to the protocol or study occur, however, the Primary Investigator or Project Director must resubmit the proposal and based on changes, an official continuing review date may be established.

- **Expedited** – If a study is authorized with an expedited review, the review date is established as one calendar year from the official authorization act. Should changes to the protocol or study occur, however, the Primary Investigator or Project Director is expected to immediately resubmit the proposal for review. If the proposal is accepted on an expedited basis, the review date is extended one year from the date of the reauthorization letter. If the study is required to go through a full review, the new review date is one year from authorization by the full board.
- **Full Review** - If a study is authorized under a full review, the review date is established as one calendar year from the official authorization act. Should changes to the protocol or study occur, however, the Primary Investigator or Project Director is expected to immediately resubmit the proposal for review. If the proposal is accepted on an expedited basis (based on limited adjustments to a previous authorization by the full board), the review date is extended one year from the date of the reauthorization letter. If the study is required to go through a full review, the new review date is one year from authorization by the full board.

Documentation

The Primary Investigator or Project Director is expected to complete the Application for IRB Approval which is located on the College's Office of Planning and Institutional Effectiveness site. This document includes information about the researchers, the study and its procedures, and requires the inclusion of documentation of IRB approval from the home institution, the research protocol, the informed consent form, and any additional information that the submitter believes will help the board make an informed decision.

The IRB is also responsible for providing and maintaining documentation for each individual request. After project or study approval, an IRB number is assigned regardless of the type of review required. The following information is provided for each type of review:

- **Exempt** – The submitter will receive an official authorization letter with the College's expectations (i.e. notification of change), an IRB number, a review date (marked as N/A), and the College's IORG number. In addition, a signed copy of the Application for IRB approval will be sent. Should a letter of support be required after the project or study is approved by appropriate College administrators, a letter will be sent that indicates that the study will be authorized subsequent to approval from the home institutions' IRB. All correspondence will be sent electronically and in hard copy.
- **Expedited** – The submitter will receive an official authorization letter with the College's expectations (i.e. notification of change), an IRB number, a review date (one year from the date of the letter), and the College's IORG number. In addition, a

signed copy of the Application for IRB approval will be sent. Should a letter of support be required after the project or study is approved by appropriate College administrators, a letter will be sent that indicates that the study will be authorized subsequent to approval from the home institutions' IRB. All correspondence will be sent electronically and in hard copy.

- **Full Review** – After a meeting of the full board, the submitter will receive an official authorization letter with the College's expectations (i.e. notification of change), an IRB number, a review date (one year from the date of the letter), and the College's IORG number. In addition, a signed copy of the Application for IRB approval will be sent. Should a letter of support be required after the project or study is approved by appropriate College administrators, a letter will be sent that indicates that the study will be authorized subsequent to approval from the home institutions' IRB. All correspondence will be sent electronically and in hard copy.

In addition to the aforementioned documentation, the IRB is responsible for maintaining complete records for each of the projects that go through review. These records include the following:

- All correspondence identified above (including e-mail correspondence with the IRB Chair)
- Agendas, minutes (including approval of previous minutes), and sign-in sheets
- Statements of significant changes along with amended Application for IRB forms
- Updated documents (protocols, consent forms, etc.)
- Adverse event or policy violation reports
- If applicable, information regarding appeals
- Materials provided to research participants

Appeals

If a Primary Investigator or Project Director is dissatisfied with the IRB's decision to either authorize a project with restrictions or to disapprove a study, he/she may formally appeal the decision. The first step in the process is to seek mutual agreement during the IRB meeting in which the project is under discussion. Should this opportunity fail to lead to an acceptable alternative, the decision can be appealed in writing. This appeal letter is to be sent to the IRB Chair who will convene a special *ad hoc* committee to review the appeal. The process of committee review will take between 4 and 6 weeks after official receipt of the letter and the findings will be presented to the full board at the next regularly scheduled meeting. At that meeting, the IRB will make a final determination regarding the appeal and in accordance with federal regulations, the final decision by the IRB is official and cannot be appealed further.

Adverse Events

Two federal regulations (21 CFR 56.108 and 45 CFR 46.103) charge the IRB with accountability, responsibility, and oversight regarding adverse events that occur during a study. While some of this responsibility is subsumed under the standard continuing review cycle, there are instances that may occur during an authorization period that requires investigation and, potentially, intervention by the board.

An adverse event is any instance which places participants at risk or at a level or degree of potential harm outside of those indicated within the initial protocol. Should such an event occur, the College IRB must be notified within 48 hours of the event. This information will be forwarded to the Vice President for Planning and Institutional Effectiveness as well as to the Office for Human Research Protection.

Upon receipt of the adverse event report, the Chair of the IRB, in consultation with other members and administrators as appropriate, will require immediate suspension of the activity prior to review by the full membership. The body will then review the situation at an emergency meeting to determine if additional information or further investigation is required and to provide official correspondence that study must be halted until corrective action is taken. Affected supervising administrator(s) will be copied on all correspondence between the review board and the involved parties.

Policy Violations

As the institutional body charged with assurance of human subject safety, the IRB is also tasked with ensuring that research conducted at the College is conducted ethically in accordance with the principles outlined in the *Belmont Report*. Accordingly, the IRB is responsible for ensuring adherence to this policy and to the procedures and processes outlined in the IRB Manual. All projects authorized by the IRB must meet strict ethical standards in line with accepted best practices, and violations of this policy, regardless of the reason, are taken seriously and will be dealt with by the review board.

Should any violations of this policy occur, the information will be brought before the IRB at a convened meeting. The body will review the reported violation and determine if additional information or further investigation is required. Affected supervising administrator(s) will be copied on all correspondence between the review board and the involved parties. If it is determined that a violation of this policy has occurred, the IRB will require that the activity in question be halted until corrective action is taken.

In situations where participant safety is compromised, and/or the violations are apparent, the Chair of the IRB, in consultation with other members and administrators as appropriate, will require

immediate suspension of the activity prior to review by the full membership. If the IRB determines that the violation involves possible scholarly or scientific misconduct that doesn't impact human subjects protection, the Vice President for Academic and Student Affairs and the Vice President for Planning and Institutional Effectiveness will be notified by the board. While the IRB can and will assist in the investigation, the review board will adhere to the decisions made by the Vice-Presidents regarding continued institutional approval of the project. It is expected that the College administrators will determine which direction to take in accordance with established College assurances, policies, and procedures.

RESEARCH GUIDELINES

Belmont Report

The *Belmont Report* is considered the seminal federal document associated with the protection of human subjects and is the document most connected with 45 CFR 46 (Human Subjects Research). This document is required reading for all members of the IRB and is provided in totality in Appendix D. According to HHS,[6]

> *On July 12, 1974, the National Research Act (Pub. L. 93-348) was signed into law, there-by creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. One of the charges to the Commission was to identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles…The Belmont Report attempts to summarize the basic ethical principles identified by the Commission in the course of its deliberations… It is a statement of basic ethical principles and guidelines that should assist in resolving the ethical problems that surround the conduct of research with human subjects.*

Informed Consent

With the exception of therapeutic or diagnostic research, human subjects involved in a research study are entitled to informed consent. Given the scope of research reviewed by the IRB and authorized at the College, all studies must provide either direct or implied consent. Based on 45 CFR 46.116 (45 CFR 46 is found in Appendix G), informed consent must include the following[7]

- A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the

[6] www.hhs.gov/ohrp/humansubjects/guidance/belmont.html
[7] http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

procedures to be followed, and identification of any procedures which are experimental;

- A description of any reasonably foreseeable risks or discomforts to the subject;
- A description of any benefits to the subject or to others which may reasonably be expected from the research;
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Full documentation as well as a checklist that can be used to guide the development of the informed consent form can be found in Appendix H.

Vulnerable Populations

In the event where a study will be conducting research on populations identified by HHS as either special or vulnerable, a full review by the IRB will be required. The board will place extra scrutiny on the protocol, consent form, and any risks or potential for harm. Given the scope of the research approved by the College, only children under 18 are identified as part of a special population.

APPENDIX A: Acronyms

IRB – Institutional Review Board

BOT – Board of Trustees

HHS – U.S. Department of Health and Human Services

IORG – Institutional or Organizational Number

OHRP – Office of Human Research Protection

OPIE – Office of Planning and Institutional Effectiveness

CFR – Code of Federal Regulations

APPENDIX B: Definition of Terms

Adverse event – An unintended and unwanted consequence resulting in the course of research that must be reported immediately and may lead to a suspension of the project

Approval – Permission to conduct a study that is granted by College administration

Authorization – Certification by the IRB that human subjects will be treated ethically, informed, and protected from unnecessary risk

Anticipated benefits – Benefits that are accrued to some combination of the participants, researcher, or to general knowledge and understandings

Belmont Report – A report emanating from the National Commission for the Protection of Human Subjects in 1979 and seen as the seminal document offering guidelines on the ethical treatment of human subjects

Confidentiality – Assurance that the information gathered during the course of a research project will not be connected back to participants and that provisions are in place to safeguard individual records

Commonly accepted educational settings – These include spaces and facilities in which educational activities commonly occur (i.e. classroom, library, etc.)

Continuing Review – A status assigned to expedited or full review which require the researchers to submit progress reports and reapply for IRB authorization at a given time or a process that is initiated after a significant change in the research protocol

Educational projects – Activities that gather and analyze information, but which do not meet the definition of research

Ethical principles – A set of values documented in the *Belmont Report* designed to ensure that human subjects are treated equitably, ethically, and with dignity

Exempt – Educational projects that don't meet the criteria for research and which meet the standard for normal educational practices in commonly accepted educational setting and either never need to be reviewed per guidance in this manual or which are reviewed and a determination is made that further review, apart from significant protocol changes, is not necessary

Expedited review – Activities meeting the definition of research, but which include no more than minimal risk and meet one of the criteria illustrated in the Human Subjects Regulations Decision Charts for expedited review

Full review – **A**ctivities meeting the definition of research and that include more than minimal risk and/or do not meet any of the criteria illustrated in the Human Subjects Regulations Decision Charts for expedited review

Human subjects – By HHS definition these are "Living individual(s) about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with an individual, or (2) identifiable private information"

Informed consent – Assurance that participants in a study are doing so voluntarily and based upon an appropriate level of knowledge about the purpose, risks, and benefits of a stud

Institutional Review Board – An institutional board charged with authorizing research projects based on the degree to which the rights are protected for human subjects

IRB policy – The policy document approved by the Suffolk County Community College Board of Trustees that enables the IRB to authorize research studies and provides the framework for the IRB Operating Procedures Manual

Normal educational practices – Activities that take place on a routine and regular basis as part of the educational process and can include, but is not limited to, testing of student knowledge, measuring the effectiveness of pedagogical interventions, or assessing the impact of curricular change

Protocol – The document provided to the IRB that identifies the research design and includes the rationale, methodology, methods, and other information pertinent to the study

Research – By HHS definition it is "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge"

Restrictions – In reference to authorization of a study, restrictions indicate that a study is only authorized after the identified issues have been addressed and revisions have been submitted to the IRB

Risks – The likelihood that harm or injury (physical, psychological, reputational, or financial) will occur to a participant of a research study and may range from minimal to significant

Voluntary – Maintaining the choice to participate or not without the use of coercion or pressure and without fear of retribution or reprisal

Vulnerable populations – Individuals who for one reason or another are not of sound mind, able the exercise autonomy or sound judgment, are subject to special risks, or who are not empowered to make their own decisions and includes children (under age 18), prisoners, pregnant woman (depending upon the research) and other classes identified by HHS

Appendix C: Final Board Approved Policy

Policy on Institutional Review Board and Human Subjects' Protection

I. Introduction

Suffolk County Community College (the College) is committed to the protection of students, employees, and others who may conduct or participate in research or externally-funded educational projects involving human subjects, which are sponsored by, or associated with, the College. In accordance with the regulations of the United States Department of Health and Human Services, Office for Human Research Protections (OHRP), and requirements of federal grant agencies and the State of New York, the College's Institutional Review Board (IRB) is charged with ensuring this protection and rendering decisions regarding research and educational projects that impact the College community. The primary role of the IRB is to ensure that the College's students, faculty, staff, and administrators, as well as individuals involved in College-approved and sanctioned research or educational projects, are protected from unnecessary harm and risk.

II. Definitions

A. **Human Subjects.** Living individual(s) about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with an individual, or (2) identifiable private information (45 CFR 46.102[d]).

B. **Research.** A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. (45 CFR 46.102[d]) If the activity meets this standard, it is defined as research (e.g. dissertation research). If an activity uses human subjects data that is regularly and routinely gathered at the institution, does not require new, additional, or significantly altered data gathering procedures, or if the activity is not sponsored by an external agency or does not test a hypothesis, it likely does **not** constitute research (e.g. assessment of student learning).

III. Policy and Duties of the IRB

A. All proposed research or educational projects involving human subjects will be reviewed by the IRB to ensure compliance with all applicable law, rules and regulations.

B. This policy applies to the following:

1. All College faculty, staff, and students using College facilities or the facilities of an off-campus site for the purpose of conducting research or for externally funded projects involving human subjects;

2. Persons who are not College employees or students who wish to use College facilities for such projects; and

3. Persons who wish to conduct projects with College employees or students as subjects, regardless of the project's location.

C. The IRB shall be empowered and responsible to:

1. Determine whether proposed research or educational projects constitute "research." In the case of any such research project, the IRB will meet to approve, request revision, or deny approval of the research activity's protection protocol for human subjects.

2. Determine if research activities are exempt from IRB oversight.

3. Provide oversight of human subject protection for ongoing research involving human subjects.

4. Ensure adherence to this policy and to the procedures and processes outlined in the *IRB Manual* (manual is located on the OPIE section of the SCCC website).

5. Ensure that research conducted at the College is conducted ethically, in accordance with the principles outlined in the *Belmont Report* (see the IRB procedures manual on the SCCC website).

IV. Membership of the Institutional Review Board

A. The membership of the institutional review board shall include the following:

1. IRB Chairperson (Representative from the Office of Planning and Institutional Effectiveness);

2. An instructional faculty member from each campus (selected by Campus Governance representatives);

3. A faculty or staff member selected by the President;

4. A faculty or staff member selected by the Office of Planning and Institutional Effectiveness; and

5. One external representative

B. In addition to this membership, a representative from the Offices of Grants Development, Legal Affairs, Academic Affairs, and Student Affairs will serve as ex-officio members.

C. To ensure an IRB membership with the education, experience, and expertise to evaluate research projects, the following criteria must be adhered to:

1. Instructional faculty representatives are to be selected from either a physical or social science and, where possible, should have human subjects research experience and a terminal degree;

2. The Chair and appointed members should have human subjects research experience, when possible; and

3. The external representative may not be related to any officer or employee of the College. Such representative should represent a community interest, and/or have a background in ethics or human rights advocacy.

V. Mandatory Training

All members of the IRB, as well as persons who conduct research directly or indirectly with human subjects, must undergo training on the protection of human subjects. Given the limited scope of research conducted at the College, this requirement is fulfilled through mandatory review of the *Belmont Report* by the membership of the IRB.

VI. Prohibited Research

In adherence to the College's mission, the College will not engage in, nor support, research projects involving students, faculty, administration, or staff that require clinical trials, drug trials or medical device research.

VII. Policy Violations

A. Should any alleged violations of this policy occur, the allegations will be brought before the IRB at a convened meeting. The body will review the reported violation and determine if additional information or further investigation is required. Affected supervising administrator(s) will be copied on all correspondence between the review board and the involved parties. If it is determined that a violation of this policy has occurred, the IRB will require that the activity in question be halted until corrective action is taken.

B. In situations where participant safety is compromised, and/or the violations are apparent, the Chair of the IRB, in consultation with other members and administrators, as appropriate, will require immediate suspension of the activity prior to review by the full membership. If the IRB determines that the violation involves possible scholarly or scientific misconduct, the Vice President for Academic and Student Affairs and the Vice President for Planning and Institutional Effectiveness will be notified. While the IRB can and will assist in the investigation, the review board will adhere to the decisions made by the Vice-Presidents which must consider all appropriate actions in light of established College assurances, policies, and procedures.

VIII. Policy Review

A. **Annual Review.** This policy shall be reviewed on an annual basis.

B. **Comprehensive Review.** This policy shall be reviewed five (5) years from the effective date or one year from a change in CFR 45, Part 46.

IX. Effective Date

This policy shall be effective as of August 21, 2014.

The Belmont Report

Office of the Secretary

Ethical Principles and Guidelines for the Protection of Human Subjects of Research

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

April 18, 1979

AGENCY: Department of Health, Education, and Welfare.

ACTION: Notice of Report for Public Comment.

SUMMARY: On July 12, 1974, the National Research Act (Pub. L. 93-348) was signed into law, there-by creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. One of the charges to the Commission was to identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles. In carrying out the above, the Commission was directed to consider: **(i)** the boundaries between biomedical and behavioral research and the accepted and routine practice of medicine, **(ii)** the role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects, **(iii)** appropriate guidelines for the selection of human subjects for participation in such research and **(iv)** the nature and definition of informed consent in various research settings.

The Belmont Report attempts to summarize the basic ethical principles identified by the Commission in the course of its deliberations. It is the outgrowth of an intensive four-day period of discussions that were held in February 1976 at the Smithsonian Institution's Belmont Conference Center supplemented by the monthly deliberations of the Commission that were held over a period of nearly four years. It is a statement of basic ethical principles and guidelines that should assist in resolving the ethical problems that surround the conduct of research with human subjects. By publishing the Report in the Federal Register, and providing reprints upon request, the Secretary intends that it may be made readily available to scientists, members of Institutional Review Boards, and Federal employees. The two-volume Appendix, containing the lengthy reports of experts and specialists who assisted the Commission in fulfilling this part of its charge, is available as DHEW Publication No. (OS) 78-0013 and No. (OS) 78-0014, for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

Unlike most other reports of the Commission, the Belmont Report does not make specific recommendations for administrative action by the Secretary of Health, Education, and Welfare. Rather, the Commission recommended that the Belmont Report be adopted in its entirety, as a statement of the Department's policy. The Department requests public comment on this recommendation.

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

Members of the Commission

Kenneth John Ryan, M.D., Chairman, Chief of Staff, Boston Hospital for Women.
Joseph V. Brady, Ph.D., Professor of Behavioral Biology, Johns Hopkins University.
Robert E. Cooke, M.D., President, Medical College of Pennsylvania.
Dorothy I. Height, President, National Council of Negro Women, Inc.
Albert R. Jonsen, Ph.D., Associate Professor of Bioethics, University of California at San Francisco.
Patricia King, J.D., Associate Professor of Law, Georgetown University Law Center.
Karen Lebacqz, Ph.D., Associate Professor of Christian Ethics, Pacific School of Religion.
**** David W. Louisell, J.D., Professor of Law, University of California at Berkeley.*
Donald W. Seldin, M.D., Professor and Chairman, Department of Internal Medicine, University of Texas at Dallas.
****Eliot Stellar, Ph.D., Provost of the University and Professor of Physiological Psychology, University of Pennsylvania.*
**** Robert H. Turtle, LL.B., Attorney, VomBaur, Coburn, Simmons & Turtle, Washington, D.C.*

****Deceased.*

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Ethical Principles & Guidelines for Research Involving Human Subjects

Scientific research has produced substantial social benefits. It has also posed some troubling ethical questions. Public attention was drawn to these questions by reported abuses of human subjects in biomedical experiments, especially during the Second World War. During the Nuremberg War Crime Trials, the Nuremberg code was drafted as a set of standards for judging physicians and scientists who had conducted biomedical experiments on concentration camp prisoners. This code became the prototype of many later codes(1) intended to assure that research involving human subjects would be carried out in an ethical manner.

The codes consist of rules, some general, others specific, that guide the investigators or the reviewers of research in their work. Such rules often are inadequate to cover complex situations; at times they come into conflict, and they are frequently difficult to interpret or apply. Broader ethical principles will provide a basis on which specific rules may be formulated, criticized and interpreted.

Three principles, or general prescriptive judgments, that are relevant to research involving human subjects are identified in this statement. Other principles may also be relevant. These three are comprehensive, however, and are stated at a level of generalization that should assist scientists, subjects, reviewers and interested citizens to understand the ethical issues inherent in research involving human subjects. These principles cannot always be applied so as to resolve beyond dispute particular ethical problems. The objective is to provide an analytical framework that will guide the resolution of ethical problems arising from research involving human subjects.

This statement consists of a distinction between research and practice, a discussion of the three basic ethical principles, and remarks about the application of these principles.

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Part A: Boundaries Between Practice & Research

A. Boundaries Between Practice and Research

It is important to distinguish between biomedical and behavioral research, on the one hand, and the practice of accepted therapy on the other, in order to know what activities ought to undergo review for the protection of human subjects of research. The distinction between research and practice is blurred partly because both often occur together (as in research designed to evaluate a therapy) and partly because notable departures from standard practice are often called "experimental" when the terms "experimental" and "research" are not carefully defined.

For the most part, the term "practice" refers to interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success. The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment or therapy to particular individuals.(2) By contrast, the term "research' designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.

When a clinician departs in a significant way from standard or accepted practice, the innovation does not, in and of itself, constitute research. The fact that a procedure is "experimental," in the sense of new, untested or different, does not automatically place it in the category of research. Radically new procedures of this description should, however, be made the object of formal research at an early stage in order to determine whether they are safe and effective. Thus, it is the responsibility of medical practice committees, for example, to insist that a major innovation be incorporated into a formal research project.(3)

Research and practice may be carried on together when research is designed to evaluate the safety and efficacy of a therapy. This need not cause any confusion regarding whether or not the activity requires review; the general rule is that if there is any element of research in an activity, that activity should undergo review for the protection of human subjects.

Part B: Basic Ethical Principles

B. Basic Ethical Principles

The expression "basic ethical principles" refers to those general judgments that serve as a basic justification for the many particular ethical prescriptions and evaluations of human actions. Three basic principles, among those generally accepted in our cultural tradition, are particularly relevant to the ethics of research involving human subjects: the principles of respect of persons, beneficence and justice.

1. Respect for Persons. -- Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.

An autonomous person is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation. To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. To show lack of respect for an autonomous agent is to repudiate that person's considered judgments, to deny an individual the freedom to act

on those considered judgments, or to withhold information necessary to make a considered judgment, when there are no compelling reasons to do so.

However, not every human being is capable of self-determination. The capacity for self-determination matures during an individual's life, and some individuals lose this capacity wholly or in part because of illness, mental disability, or circumstances that severely restrict liberty. Respect for the immature and the incapacitated may require protecting them as they mature or while they are incapacitated.

Some persons are in need of extensive protection, even to the point of excluding them from activities which may harm them; other persons require little protection beyond making sure they undertake activities freely and with awareness of possible adverse consequence. The extent of protection afforded should depend upon the risk of harm and the likelihood of benefit. The judgment that any individual lacks autonomy should be periodically reevaluated and will vary in different situations.

In most cases of research involving human subjects, respect for persons demands that subjects enter into the research voluntarily and with adequate information. In some situations, however, application of the principle is not obvious. The involvement of prisoners as subjects of research provides an instructive example. On the one hand, it would seem that the principle of respect for persons requires that prisoners not be deprived of the opportunity to volunteer for research. On the other hand, under prison conditions they may be subtly coerced or unduly influenced to engage in research activities for which they would not otherwise volunteer. Respect for persons would then dictate that prisoners be protected. Whether to allow prisoners to "volunteer" or to "protect" them presents a dilemma. Respecting persons, in most hard cases, is often a matter of balancing competing claims urged by the principle of respect itself.

2. Beneficence. -- Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. The term "beneficence" is often understood to cover acts of kindness or charity that go beyond strict obligation. In this document, beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: **(1)** do not harm and **(2)** maximize possible benefits and minimize possible harms.

The Hippocratic maxim "do no harm" has long been a fundamental principle of medical ethics. Claude Bernard extended it to the realm of research, saying that one should not injure one person regardless of the benefits that might come to others. However, even avoiding harm requires learning what is harmful; and, in the process of obtaining this information, persons may be exposed to risk of harm. Further, the Hippocratic Oath requires physicians to benefit their patients "according to their best judgment." Learning what will in fact benefit may require exposing persons to risk. The problem posed by these imperatives is to decide when it is justifiable to seek certain benefits despite the risks involved, and when the benefits should be foregone because of the risks.

The obligations of beneficence affect both individual investigators and society at large, because they extend both to particular research projects and to the entire enterprise of research. In the case of particular projects, investigators and members of their institutions are obliged to give forethought to the maximization of benefits and the reduction of risk that might occur from the research investigation. In the case of scientific research in general, members of the larger society are obliged to recognize the longer term benefits and risks that may result from the improvement of knowledge and from the development of novel medical, psychotherapeutic, and social procedures.

The principle of beneficence often occupies a well-defined justifying role in many areas of research involving human subjects. An example is found in research involving children. Effective ways of treating childhood diseases and fostering healthy development are benefits that serve to justify research involving children -- even when individual research subjects are not direct beneficiaries. Research also makes it possible to avoid the harm that may result from the application of previously accepted routine practices that on closer investigation turn out to be dangerous. But the role of the principle of beneficence is not always so unambiguous. A difficult ethical problem remains, for example, about research that presents more than minimal risk without immediate prospect of direct benefit to the children involved. Some have argued that such research is inadmissible, while others have pointed out that this limit would rule out much research promising great benefit to children in the future. Here again, as with all hard cases, the different claims covered by the principle of beneficence may come into conflict and force difficult choices.

3. Justice. -- Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of "fairness in distribution" or "what is deserved." An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. Another way of conceiving the principle of justice is that equals ought to be treated equally. However, this statement requires explication. Who is equal and who is unequal? What considerations justify departure from equal distribution? Almost all commentators allow that distinctions based on experience, age, deprivation, competence, merit and position do sometimes constitute criteria justifying differential treatment for certain purposes. It is necessary, then, to explain in what respects people should be treated equally. There are several widely accepted formulations of just ways to distribute burdens and benefits. Each formulation mentions some relevant property on the basis of which burdens and benefits should be distributed. These formulations are **(1)** to each person an equal share, **(2)** to each person according to individual need, **(3)** to each person according to individual effort, **(4)** to each person according to societal contribution, and **(5)** to each person according to merit.

Questions of justice have long been associated with social practices such as punishment, taxation and political representation. Until recently these questions have not generally been associated with scientific research. However, they are foreshadowed even in the earliest reflections on the ethics of research involving human subjects. For example, during the 19th and early 20th centuries the burdens of serving as research subjects fell largely upon poor ward patients, while the benefits of improved medical care flowed primarily to private patients. Subsequently, the exploitation of unwilling prisoners as research subjects in Nazi concentration camps was condemned as a particularly flagrant injustice. In this country, in the 1940's, the Tuskegee

syphilis study used disadvantaged, rural black men to study the untreated course of a disease that is by no means confined to that population. These subjects were deprived of demonstrably effective treatment in order not to interrupt the project, long after such treatment became generally available.

Against this historical background, it can be seen how conceptions of justice are relevant to research involving human subjects. For example, the selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g., welfare patients, particular racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied. Finally, whenever research supported by public funds leads to the development of therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.

Part C: Applications

C. Applications

Applications of the general principles to the conduct of research leads to consideration of the following requirements: informed consent, risk/benefit assessment, and the selection of subjects of research.

1. Informed Consent. -- Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied.

While the importance of informed consent is unquestioned, controversy prevails over the nature and possibility of an informed consent. Nonetheless, there is widespread agreement that the consent process can be analyzed as containing three elements: information, comprehension and voluntariness.

Information. Most codes of research establish specific items for disclosure intended to assure that subjects are given sufficient information. These items generally include: the research procedure, their purposes, risks and anticipated benefits, alternative procedures (where therapy is involved), and a statement offering the subject the opportunity to ask questions and to withdraw at any time from the research. Additional items have been proposed, including how subjects are selected, the person responsible for the research, etc.

However, a simple listing of items does not answer the question of what the standard should be for judging how much and what sort of information should be provided. One standard frequently invoked in medical practice, namely the information commonly provided by practitioners in the field or in the locale, is inadequate since research takes place precisely when a common

understanding does not exist. Another standard, currently popular in malpractice law, requires the practitioner to reveal the information that reasonable persons would wish to know in order to make a decision regarding their care. This, too, seems insufficient since the research subject, being in essence a volunteer, may wish to know considerably more about risks gratuitously undertaken than do patients who deliver themselves into the hand of a clinician for needed care. It may be that a standard of "the reasonable volunteer" should be proposed: the extent and nature of information should be such that persons, knowing that the procedure is neither necessary for their care nor perhaps fully understood, can decide whether they wish to participate in the furthering of knowledge. Even when some direct benefit to them is anticipated, the subjects should understand clearly the range of risk and the voluntary nature of participation.

A special problem of consent arises where informing subjects of some pertinent aspect of the research is likely to impair the validity of the research. In many cases, it is sufficient to indicate to subjects that they are being invited to participate in research of which some features will not be revealed until the research is concluded. In all cases of research involving incomplete disclosure, such research is justified only if it is clear that **(1)** incomplete disclosure is truly necessary to accomplish the goals of the research, **(2)** there are no undisclosed risks to subjects that are more than minimal, and **(3)** there is an adequate plan for debriefing subjects, when appropriate, and for dissemination of research results to them. Information about risks should never be withheld for the purpose of eliciting the cooperation of subjects, and truthful answers should always be given to direct questions about the research. Care should be taken to distinguish cases in which disclosure would destroy or invalidate the research from cases in which disclosure would simply inconvenience the investigator.

Comprehension. The manner and context in which information is conveyed is as important as the information itself. For example, presenting information in a disorganized and rapid fashion, allowing too little time for consideration or curtailing opportunities for questioning, all may adversely affect a subject's ability to make an informed choice.

Because the subject's ability to understand is a function of intelligence, rationality, maturity and language, it is necessary to adapt the presentation of the information to the subject's capacities. Investigators are responsible for ascertaining that the subject has comprehended the information. While there is always an obligation to ascertain that the information about risk to subjects is complete and adequately comprehended, when the risks are more serious, that obligation increases. On occasion, it may be suitable to give some oral or written tests of comprehension.

Special provision may need to be made when comprehension is severely limited -- for example, by conditions of immaturity or mental disability. Each class of subjects that one might consider as incompetent (e.g., infants and young children, mentally disable patients, the terminally ill and the comatose) should be considered on its own terms. Even for these persons, however, respect requires giving them the opportunity to choose to the extent they are able, whether or not to participate in research. The objections of these subjects to involvement should be honored, unless the research entails providing them a therapy unavailable elsewhere. Respect for persons also requires seeking the permission of other parties in order to protect the subjects from harm. Such persons are thus respected both by acknowledging their own wishes and by the use of third parties to protect them from harm.

The third parties chosen should be those who are most likely to understand the incompetent subject's situation and to act in that person's best interest. The person authorized to act on behalf of the subject should be given an opportunity to observe the research as it proceeds in order to be able to withdraw the subject from the research, if such action appears in the subject's best interest.

Voluntariness. An agreement to participate in research constitutes a valid consent only if voluntarily given. This element of informed consent requires conditions free of coercion and undue influence. Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance. Undue influence, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance. Also, inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable.

Unjustifiable pressures usually occur when persons in positions of authority or commanding influence -- especially where possible sanctions are involved -- urge a course of action for a subject. A continuum of such influencing factors exists, however, and it is impossible to state precisely where justifiable persuasion ends and undue influence begins. But undue influence would include actions such as manipulating a person's choice through the controlling influence of a close relative and threatening to withdraw health services to which an individual would otherwise be entitle.

2. Assessment of Risks and Benefits. -- The assessment of risks and benefits requires a careful arrayal of relevant data, including, in some cases, alternative ways of obtaining the benefits sought in the research. Thus, the assessment presents both an opportunity and a responsibility to gather systematic and comprehensive information about proposed research. For the investigator, it is a means to examine whether the proposed research is properly designed. For a review committee, it is a method for determining whether the risks that will be presented to subjects are justified. For prospective subjects, the assessment will assist the determination whether or not to participate.

The Nature and Scope of Risks and Benefits. The requirement that research be justified on the basis of a favorable risk/benefit assessment bears a close relation to the principle of beneficence, just as the moral requirement that informed consent be obtained is derived primarily from the principle of respect for persons. The term "risk" refers to a possibility that harm may occur. However, when expressions such as "small risk" or "high risk" are used, they usually refer (often ambiguously) both to the chance (probability) of experiencing a harm and the severity (magnitude) of the envisioned harm.

The term "benefit" is used in the research context to refer to something of positive value related to health or welfare. Unlike, "risk," "benefit" is not a term that expresses probabilities. Risk is properly contrasted to probability of benefits, and benefits are properly contrasted with harms rather than risks of harm. Accordingly, so-called risk/benefit assessments are concerned with the probabilities and magnitudes of possible harm and anticipated benefits. Many kinds of possible harms and benefits need to be taken into account. There are, for example, risks of psychological harm, physical harm, legal harm, social harm and economic harm and the corresponding

benefits. While the most likely types of harms to research subjects are those of psychological or physical pain or injury, other possible kinds should not be overlooked.

Risks and benefits of research may affect the individual subjects, the families of the individual subjects, and society at large (or special groups of subjects in society). Previous codes and Federal regulations have required that risks to subjects be outweighed by the sum of both the anticipated benefit to the subject, if any, and the anticipated benefit to society in the form of knowledge to be gained from the research. In balancing these different elements, the risks and benefits affecting the immediate research subject will normally carry special weight. On the other hand, interests other than those of the subject may on some occasions be sufficient by themselves to justify the risks involved in the research, so long as the subjects' rights have been protected. Beneficence thus requires that we protect against risk of harm to subjects and also that we be concerned about the loss of the substantial benefits that might be gained from research.

The Systematic Assessment of Risks and Benefits. It is commonly said that benefits and risks must be "balanced" and shown to be "in a favorable ratio." The metaphorical character of these terms draws attention to the difficulty of making precise judgments. Only on rare occasions will quantitative techniques be available for the scrutiny of research protocols. However, the idea of systematic, nonarbitrary analysis of risks and benefits should be emulated insofar as possible. This ideal requires those making decisions about the justifiability of research to be thorough in the accumulation and assessment of information about all aspects of the research, and to consider alternatives systematically. This procedure renders the assessment of research more rigorous and precise, while making communication between review board members and investigators less subject to misinterpretation, misinformation and conflicting judgments. Thus, there should first be a determination of the validity of the presuppositions of the research; then the nature, probability and magnitude of risk should be distinguished with as much clarity as possible. The method of ascertaining risks should be explicit, especially where there is no alternative to the use of such vague categories as small or slight risk. It should also be determined whether an investigator's estimates of the probability of harm or benefits are reasonable, as judged by known facts or other available studies.

Finally, assessment of the justifiability of research should reflect at least the following considerations: **(i)** Brutal or inhumane treatment of human subjects is never morally justified. **(ii)** Risks should be reduced to those necessary to achieve the research objective. It should be determined whether it is in fact necessary to use human subjects at all. Risk can perhaps never be entirely eliminated, but it can often be reduced by careful attention to alternative procedures. **(iii)** When research involves significant risk of serious impairment, review committees should be extraordinarily insistent on the justification of the risk (looking usually to the likelihood of benefit to the subject -- or, in some rare cases, to the manifest voluntariness of the participation). **(iv)** When vulnerable populations are involved in research, the appropriateness of involving them should itself be demonstrated. A number of variables go into such judgments, including the nature and degree of risk, the condition of the particular population involved, and the nature and level of the anticipated benefits. **(v)** Relevant risks and benefits must be thoroughly arrayed in documents and procedures used in the informed consent process.

3. Selection of Subjects. -- Just as the principle of respect for persons finds expression in the requirements for consent, and the principle of beneficence in risk/benefit assessment, the principle of justice gives rise to moral requirements that there be fair procedures and outcomes in the selection of research subjects.

Justice is relevant to the selection of subjects of research at two levels: the social and the individual. Individual justice in the selection of subjects would require that researchers exhibit fairness: thus, they should not offer potentially beneficial research only to some patients who are in their favor or select only "undesirable" persons for risky research. Social justice requires that distinction be drawn between classes of subjects that ought, and ought not, to participate in any particular kind of research, based on the ability of members of that class to bear burdens and on the appropriateness of placing further burdens on already burdened persons. Thus, it can be considered a matter of social justice that there is an order of preference in the selection of classes of subjects (e.g., adults before children) and that some classes of potential subjects (e.g., the institutionalized mentally infirm or prisoners) may be involved as research subjects, if at all, only on certain conditions.

Injustice may appear in the selection of subjects, even if individual subjects are selected fairly by investigators and treated fairly in the course of research. Thus injustice arises from social, racial, sexual and cultural biases institutionalized in society. Thus, even if individual researchers are treating their research subjects fairly, and even if IRBs are taking care to assure that subjects are selected fairly within a particular institution, unjust social patterns may nevertheless appear in the overall distribution of the burdens and benefits of research. Although individual institutions or investigators may not be able to resolve a problem that is pervasive in their social setting, they can consider distributive justice in selecting research subjects.

Some populations, especially institutionalized ones, are already burdened in many ways by their infirmities and environments. When research is proposed that involves risks and does not include a therapeutic component, other less burdened classes of persons should be called upon first to accept these risks of research, except where the research is directly related to the specific conditions of the class involved. Also, even though public funds for research may often flow in the same directions as public funds for health care, it seems unfair that populations dependent on public health care constitute a pool of preferred research subjects if more advantaged populations are likely to be the recipients of the benefits.

One special instance of injustice results from the involvement of vulnerable subjects. Certain groups, such as racial minorities, the economically disadvantaged, the very sick, and the institutionalized may continually be sought as research subjects, owing to their ready availability in settings where research is conducted. Given their dependent status and their frequently compromised capacity for free consent, they should be protected against the danger of being involved in research solely for administrative convenience, or because they are easy to manipulate as a result of their illness or socioeconomic condition.

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(1) Since 1945, various codes for the proper and responsible conduct of human experimentation in medical research have been adopted by different organizations. The best known of these codes

are the Nuremberg Code of 1947, the Helsinki Declaration of 1964 (revised in 1975), and the 1971 Guidelines (codified into Federal Regulations in 1974) issued by the U.S. Department of Health, Education, and Welfare Codes for the conduct of social and behavioral research have also been adopted, the best known being that of the American Psychological Association, published in 1973.

(2) Although practice usually involves interventions designed solely to enhance the well-being of a particular individual, interventions are sometimes applied to one individual for the enhancement of the well-being of another (e.g., blood donation, skin grafts, organ transplants) or an intervention may have the dual purpose of enhancing the well-being of a particular individual, and, at the same time, providing some benefit to others (e.g., vaccination, which protects both the person who is vaccinated and society generally). The fact that some forms of practice have elements other than immediate benefit to the individual receiving an intervention, however, should not confuse the general distinction between research and practice. Even when a procedure applied in practice may benefit some other person, it remains an intervention designed to enhance the well-being of a particular individual or groups of individuals; thus, it is practice and need not be reviewed as research.

(3) Because the problems related to social experimentation may differ substantially from those of biomedical and behavioral research, the Commission specifically declines to make any policy determination regarding such research at this time. Rather, the Commission believes that the problem ought to be addressed by one of its successor bodies.

Appendix E: IRB Authorization Form

INSTITUTIONAL REVIEW BOARD APPLICATION FOR IRB AUTHORIZATION

INSTRUCTIONS

Individuals seeking to conduct research studies that involve either the faculty, staff, students, or administration of the college or utilize the College's facilities ***must*** get both project approval and IRB authorization before the collection of data commences. Per definition by the U.S. Department of Health and Human Services (HHS), research is defined as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge" If an activity uses human subjects data that is regularly and routinely gathered at the institution, does not require new, additional, or significantly altered data gathering procedures, or if the activity is not sponsored by an external agency or does not test a hypothesis, it probably is **not** research (e.g. assessment of student learning). Specifically, the following activities conducted by the College's internal constituents at Suffolk County Community College are always exempt from IRB review even though they involve human subjects:

- Assessment of student learning at the classroom or program level
- Analysis of existing data sets
- Collection of data to fulfill county, state, federal, or system requirements
- Institutional analyses

Although the educational projects or research studies may meet the criteria for exemption, ***all*** external constituents ***must*** complete an application for IRB authorization form. In addition, all internal constituents engaged in activities that meet the definition for research (i.e. dissertation) must complete a form. Completion of this form is ***highly*** recommended if there is any question or doubt about whether a project or study involving human subjects or the analysis of potentially sensitive data requires IRB authorization. Should the IRB be made aware of a project that should have been authorized before initiation, a letter will be sent from the IRB noting that the project or study must be halted while a review is conducted. The types of reviews and timelines are presented in the IRB Policy and Standard Operating Procedures Manual.

ACTIVITIES EXEMPT FROM COMMITTEE REVIEW

Federally funded Education/Research activities involving human subjects in the following categories may be exempt from review by SCCC's Institutional Review Board. The principal investigator/project director is authorized to make the first determination of eligibility for exemption, however, the College makes the final determination on exemption prior to providing authorization.

*The following exemptions do **NOT** apply when (a) **deception** of subjects may be an element of the research; (b) subjects are **under the age of eighteen**; (c) the activity may **expose the subject to discomfort or harassment** beyond levels encountered in daily life; or (d) **fetuses, pregnant women, human in vitro fertilization, children, or individuals involuntarily confined or detained in penal institutions** are subjects of the activity.*

EXCEPT FOR THE ABOVE EXCLUSIONS, the federally-approved Categories of Exemption are:

1. Research conducted in established or commonly accepted educational settings involving normal educational practices, such as: (a) research on regular and special education instructional strategies; (b) research on the effectiveness of or the comparison among instructional techniques curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; **and** (b) any disclosure of the human subjects' responses outside the research reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under Category 2 if: (a) the human subjects are elected or appointed public officials, or candidates for public office, **or** (b) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.

5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies: (a) if wholesome foods without additives are consumed, or (b) if a food is consumed that contains a food ingredient or at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe by the U.S. Food and Drug Administration or approved by the U.S. Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Exempting an activity from review does not absolve investigator(s) from ensuring that the welfare of human subjects in the activity is protected and methods used and information provided to gain subject consent are appropriate to the activity.

Please submit this form to Dr. Christopher Shults, IRB Chair, at shultsc@sunysuffolk.edu. For any questions, please contact Dr. Shults via e-mail or phone at 631-451-4885.

Educational Project/Research Protocol Summary Form

Title of Education or Research Grant Project

Principal Investigator/Project Director	**Phone Extension**	**Email address**
Co-investigator	**Phone Extension**	**Email address**
Co-investigator	**Phone Extension**	**Email address**

Projected Duration of Project: **Projected Starting Date:**

Form Submission Date

Exempt? (see definitions on page one – check one) 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ N/A ☐

SUMMARY ABSTRACT: Please supply the following information below: BRIEFLY describe the study participants, location(s) of the project, procedures to be used for data collection, whether data will be confidential or anonymous, disposition of the data, who will have access to the data. <u>Attach copy</u> of the home institution's IRB Approval (if applicable), research protocol, and informed consent form.

Limit 1000 Characters

Are the following included as attachments (**required**)?

	Yes	N/A
Home institution's IRB Approval	○	○
Research protocol	○	○
Informed consent form	○	○

	Yes	No
Is a letter of support from SCCC required?	○	○

To be completed by Chair of the SCCC IRB

Project Reviewed by IRB Chair ☐ **Name:** **Title:**			**Date**
Project Approved by Executive Administrator ☐ **Name:** **Title:**			**Date**
IRB Chair: Check 1 box:	☐ **Authorized as Exempt**	☐ **Authorized through an Expedited Review**	☐ **Referred to Board for full Review**
IRB Number			
Notes:			

Human Subject Regulations Decision Charts

Human Subject Regulations Decision Charts

September 24, 2004

The Office for Human Research Protections (OHRP) provides the following graphic aids as a guide for institutional review boards (IRBs), investigators, and others who decide if an activity is research involving human subjects that must be reviewed by an IRB under the requirements of the U.S. Department of Health and Human Services (HHS) regulations at 45 CFR part 46. OHRP welcomes comment on these decision charts. The charts address decisions on the following:

- whether an activity **is research** that must be reviewed by an IRB
- whether the review may be performed by **expedited procedures**, and
- whether **informed consent** or its documentation may be waived.

Considerations

The charts are intended to assist IRBs, institutions, and investigators in their decision-making process and should not be used as substitutes for consulting the regulations. OHRP cautions that the full text of applicable regulatory provisions should be considered in making final decisions.

These charts are necessarily generalizations and may not be specific enough for particular situations. Other guidance documents are available related to specific topics, at OHRP Policy Guidance by Topic. OHRP invites inquiries for additional information.

The charts do not address requirements that may be imposed by other organizations, such as the Food and Drug Administration, National Institutes of Health, other sponsors, or state or local governments.

Chart 1: Is an Activity Research Involving Human Subjects?

Chart 2: Is the Human Subjects Research Eligible for Exemption?

Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?

Chart 4: Does exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?

Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data, Documents, Records and Specimens) Apply?

Chart 6: Does Exemption 45 CFR 46.101(b)(5) (for Public Benefit or Service Programs) Apply?

Chart 7: Does Exemption 45 CFR 46.101(b)(6) (for Food Taste and Acceptance Studies) Apply?

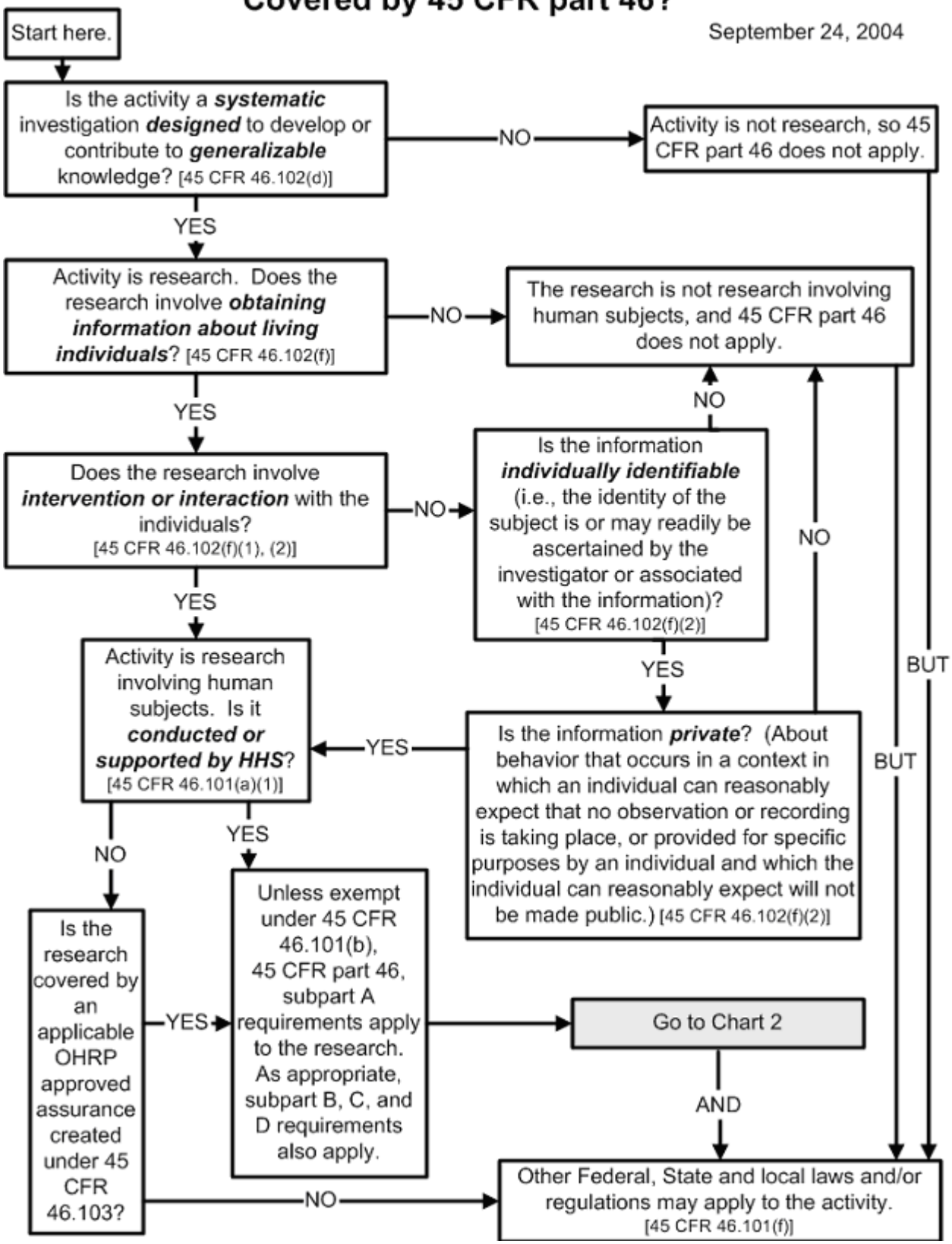
Chart 8: May the IRB Review Be Done by Expedited Procedures?

Chart 9: May the IRB Continuing Review Be Done by Expedited Procedures?

Chart 10: May Informed Consent Be Waived or Consent Elements Be Altered under 45 CFR 46.116(d)?

Chart 11: May Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?

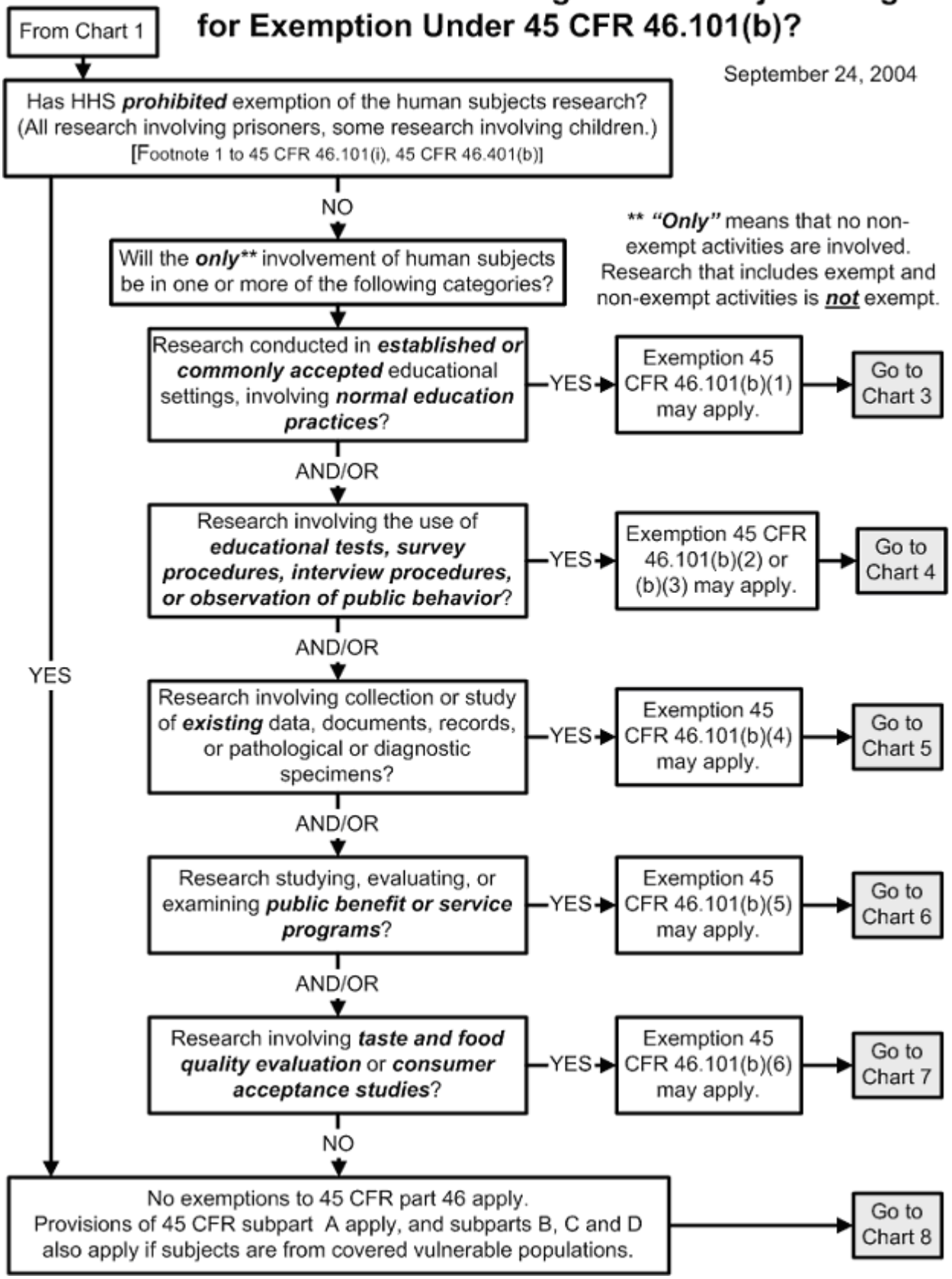
Chart 1: Is an Activity Research Involving Human Subjects Covered by 45 CFR part 46?



http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html

http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html

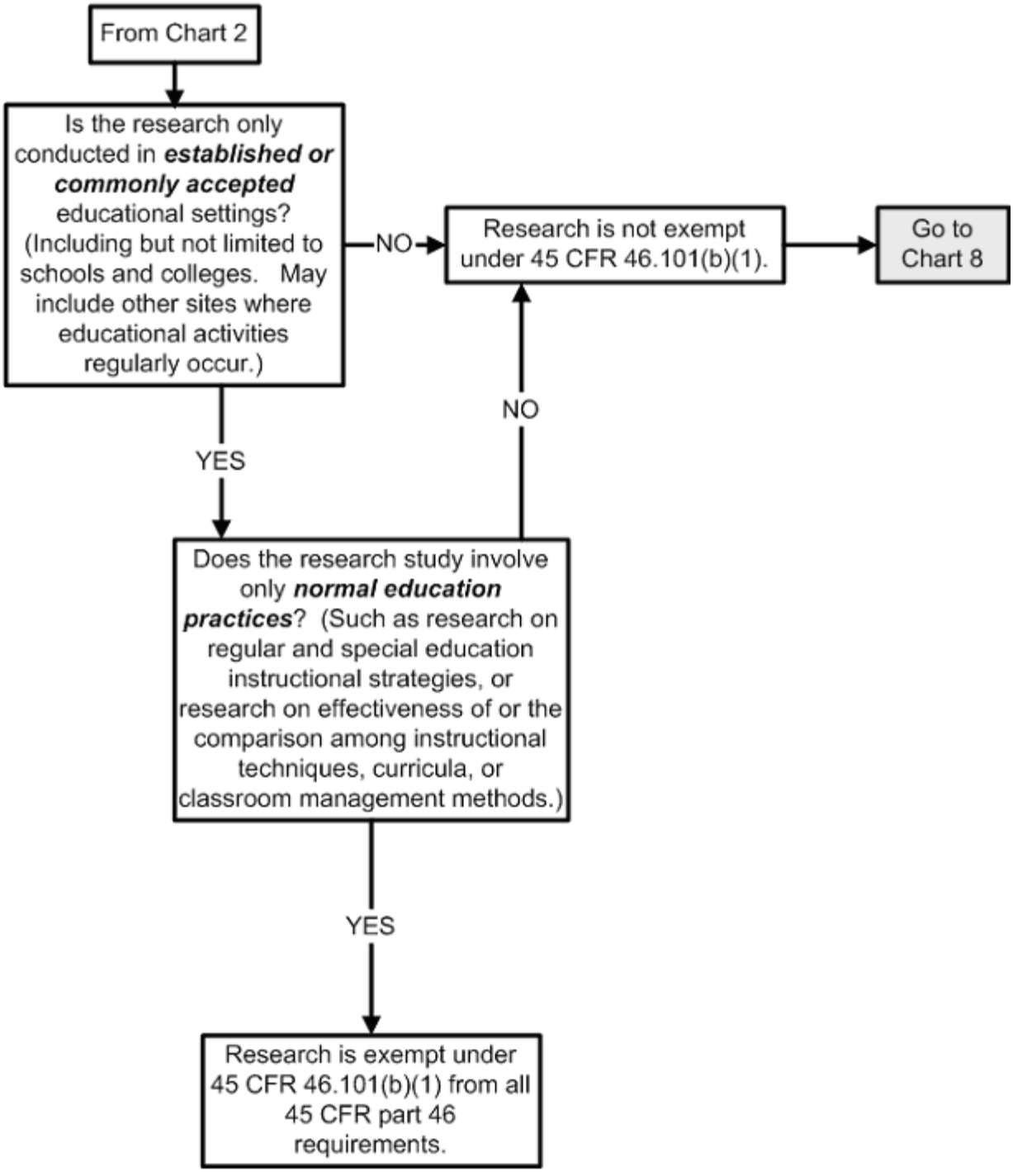
Chart 2: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.101(b)?



http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html

http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html

Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?

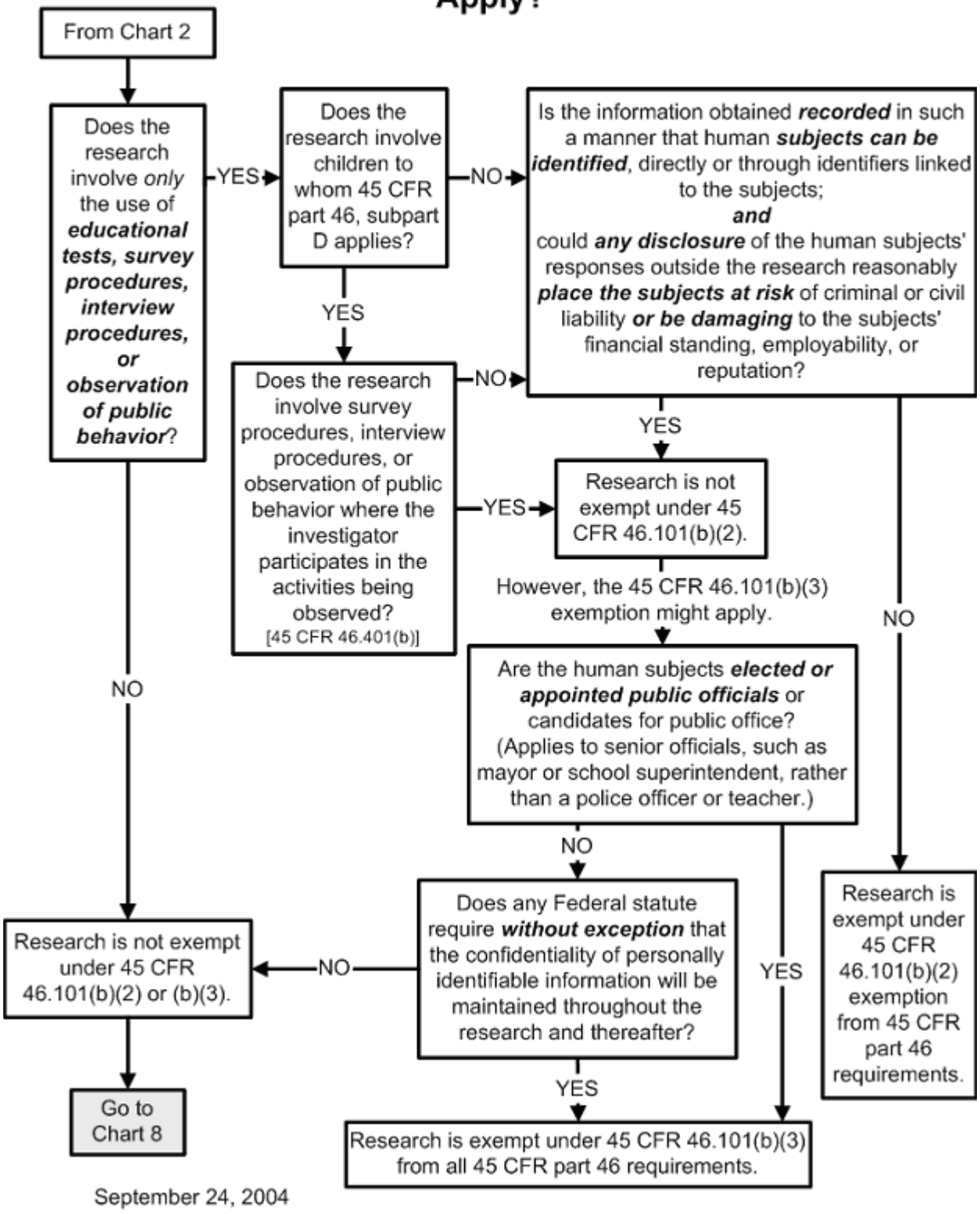


September 24, 2004

http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html

http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html

Chart 4: Does Exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?



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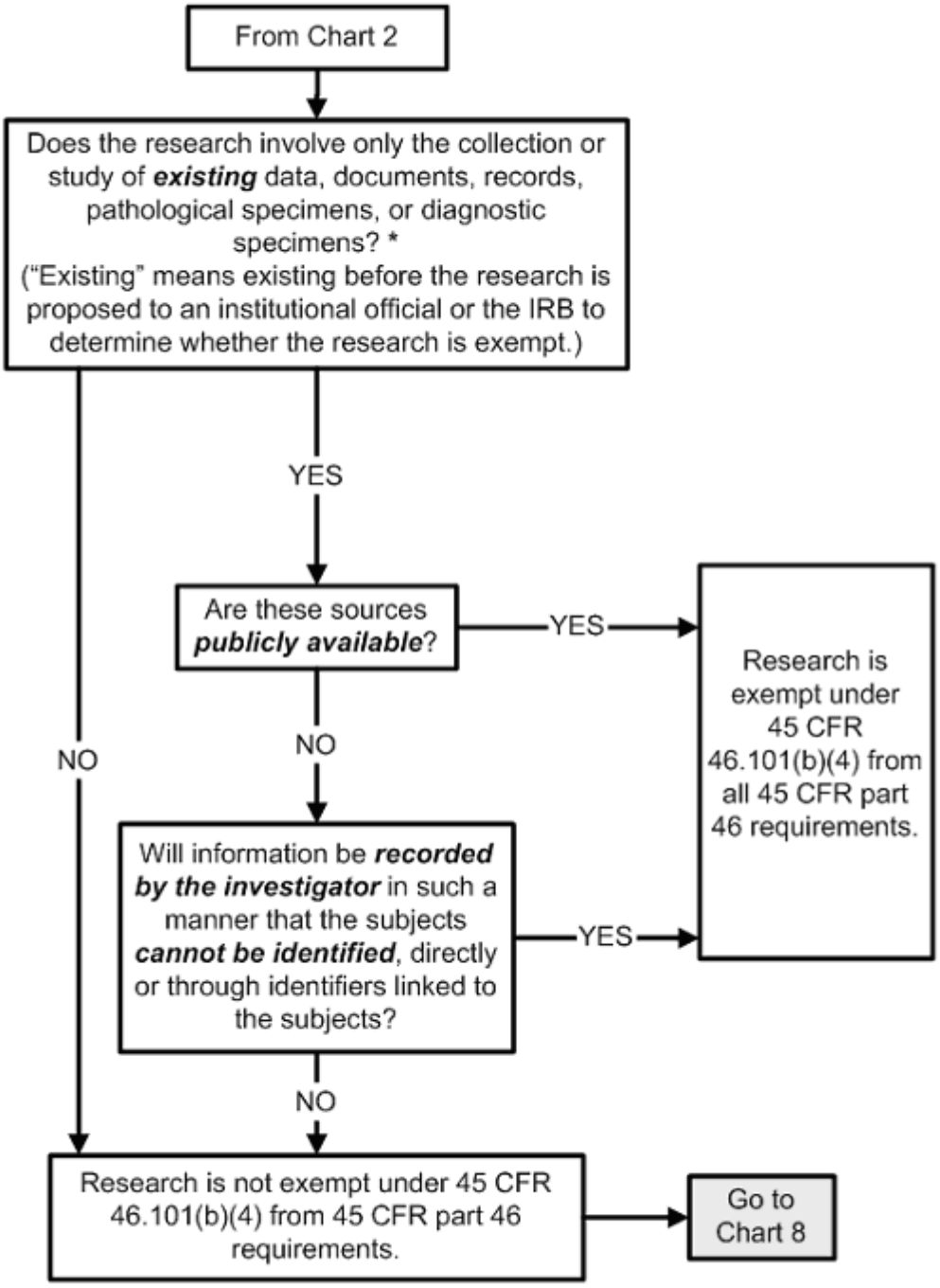
http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html

Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data Documents and Specimens) Apply?



* Note: See **OHRP** guidance on research use of stored data or tissues and on stem cells at http://www.hhs.gov/ohrp/policy/index.html#tissues and #stem, and on coded data or specimens at #coded for further information on those topics.

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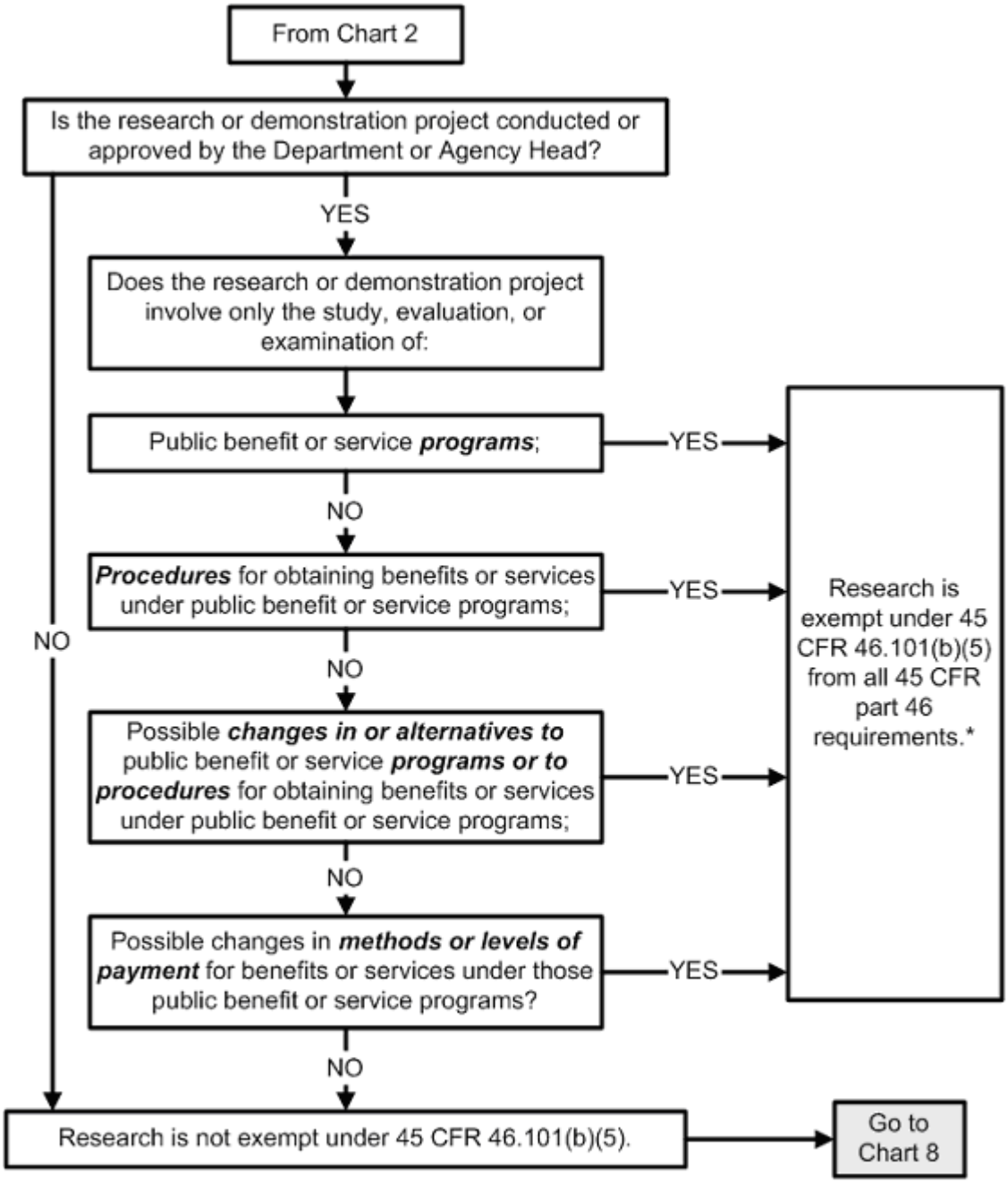
http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html

http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html

Chart 6: Does Exemption 45 CFR 46.101(b)(5) (for Public Benefit or Service Programs) Apply?



* Note: See **OHRP** guidance on exemptions at http://www.hhs.gov/ohrp/policy/index.html#exempt for further description of requirements for this exemption.

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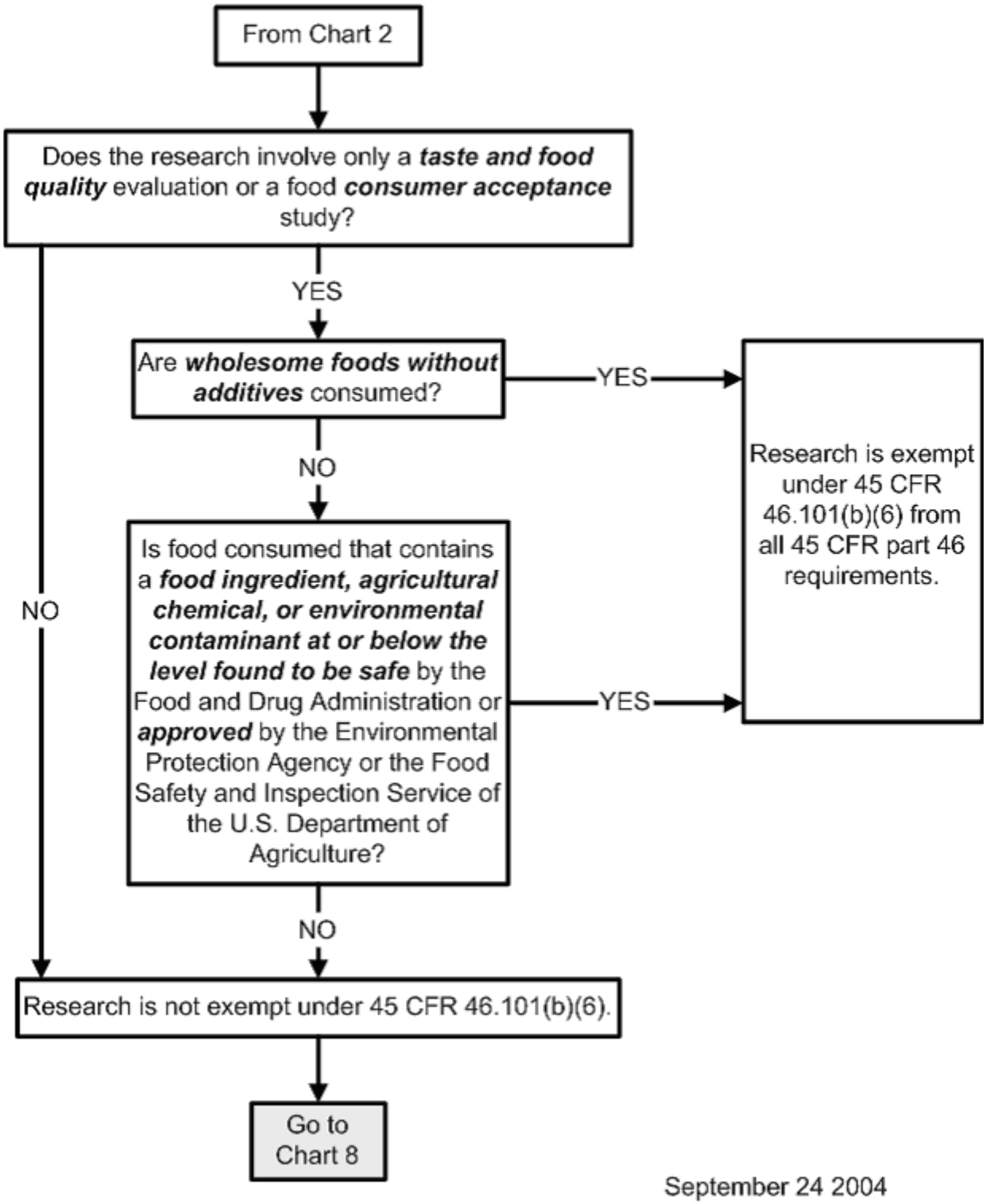
http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html

http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html

Chart 7: Does Exemption 45 CFR 46.101(b)(6) (for Food Taste and Acceptance Studies) Apply?



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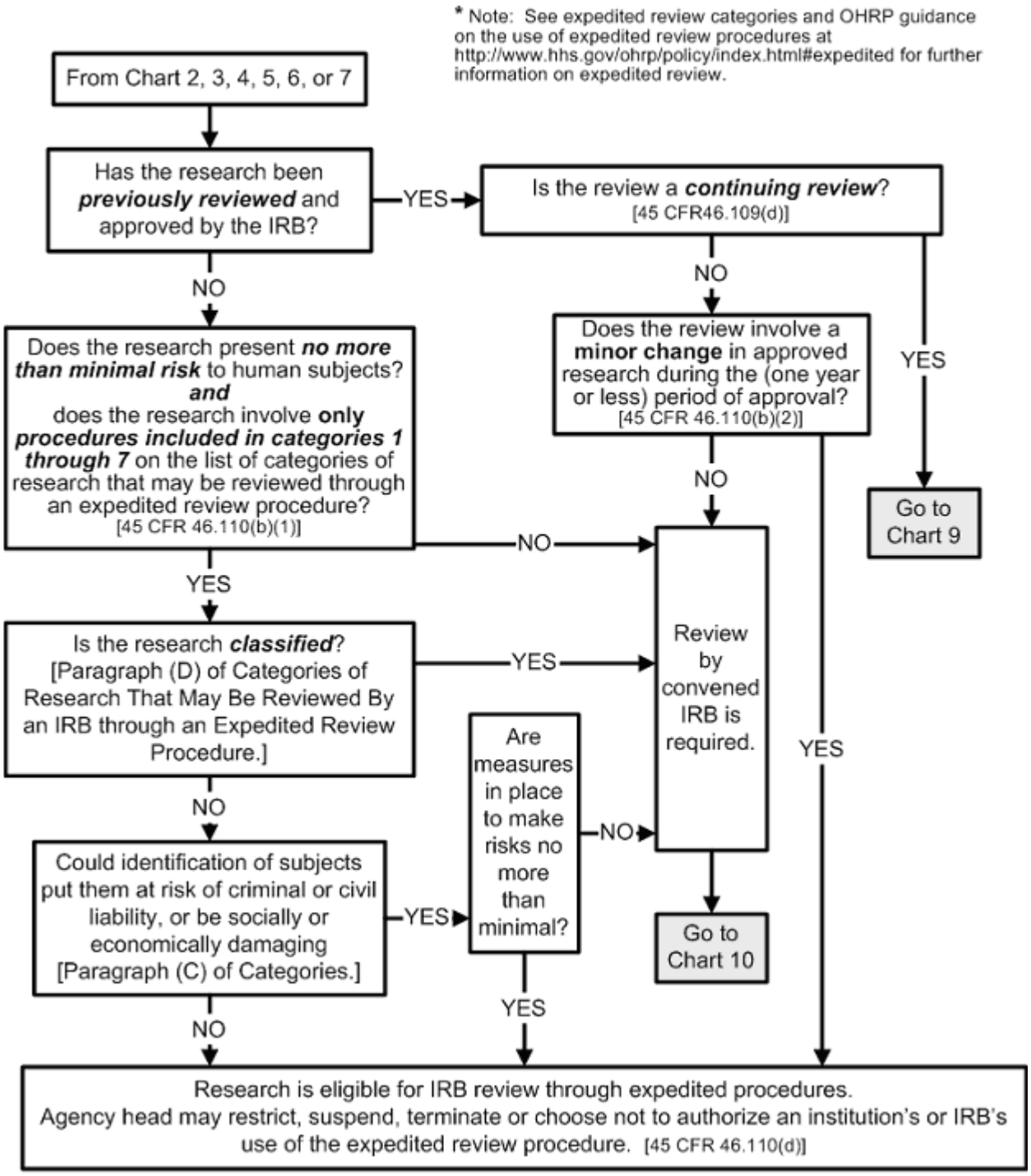
http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html

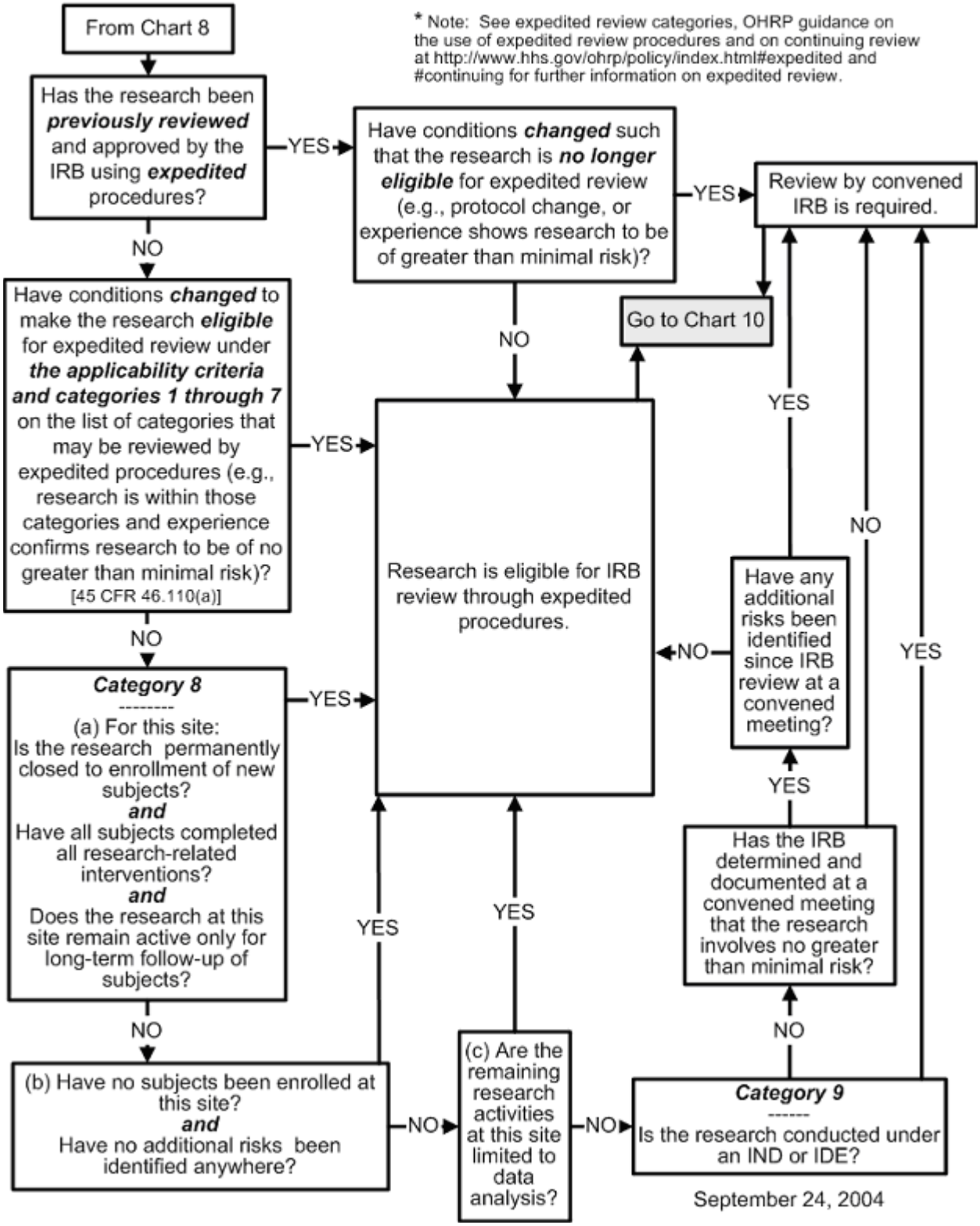
Chart 8: May the IRB Review Be Done by Expedited Procedures Under 45 CFR 46.110?*



September 24, 2004

http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html

Chart 9: Can Continuing Review be Done by Expedited Procedures Under 45 CFR 46.110?

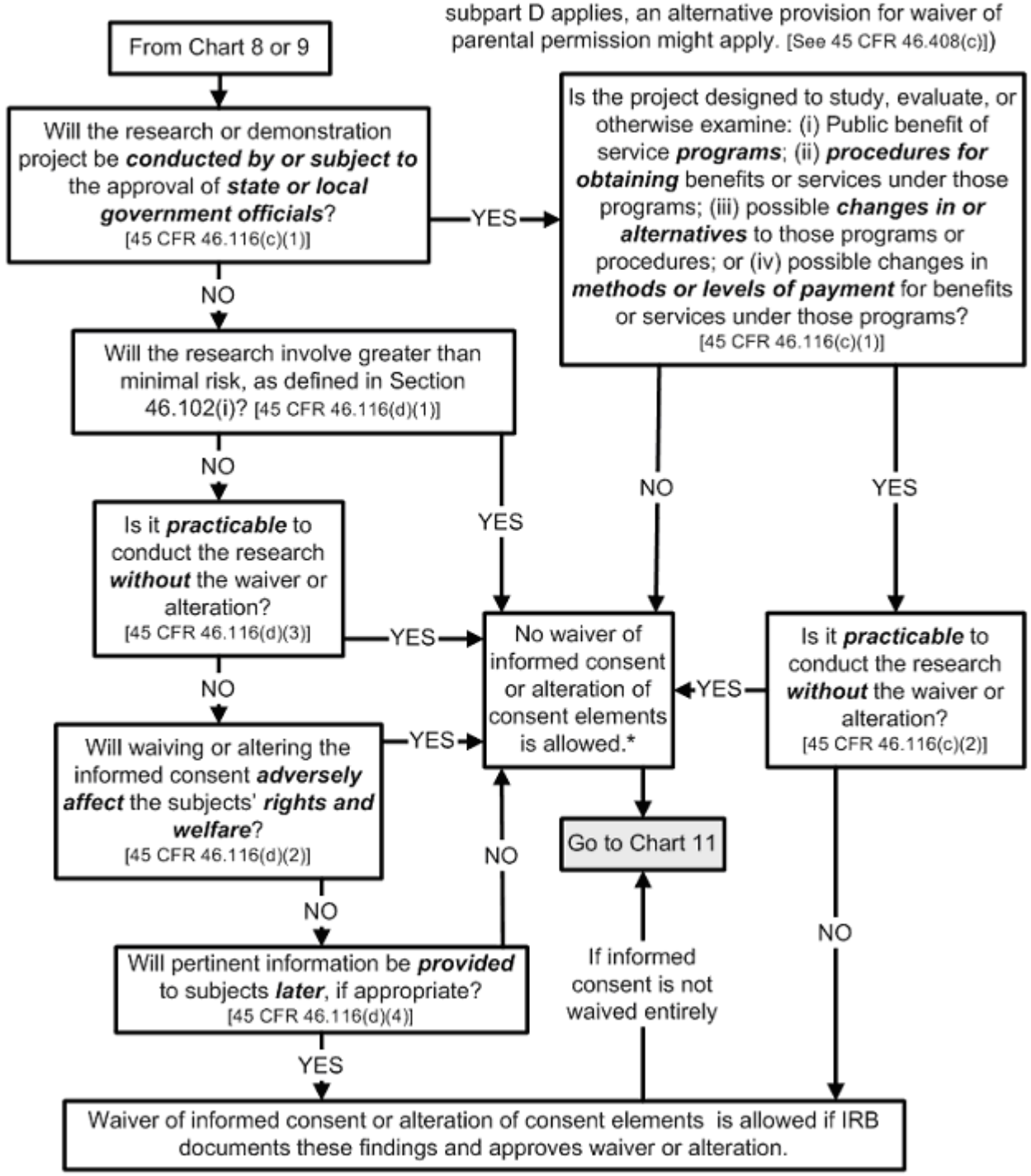


http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html

http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html

Chart 10: Can Informed Consent Be Waived or Consent Elements Be Altered Under 45 CFR 46.116(c) or (d)?**

**(Note: If subjects include children to whom 45 CFR part 46, subpart D applies, an alternative provision for waiver of parental permission might apply. [See 45 CFR 46.408(c)])



* Note: See OHRP guidance on informed consent requirements in emergency research at http://www.hhs.gov/ohrp/policy/index.html#emergency for further information on emergency research informed consent waiver.

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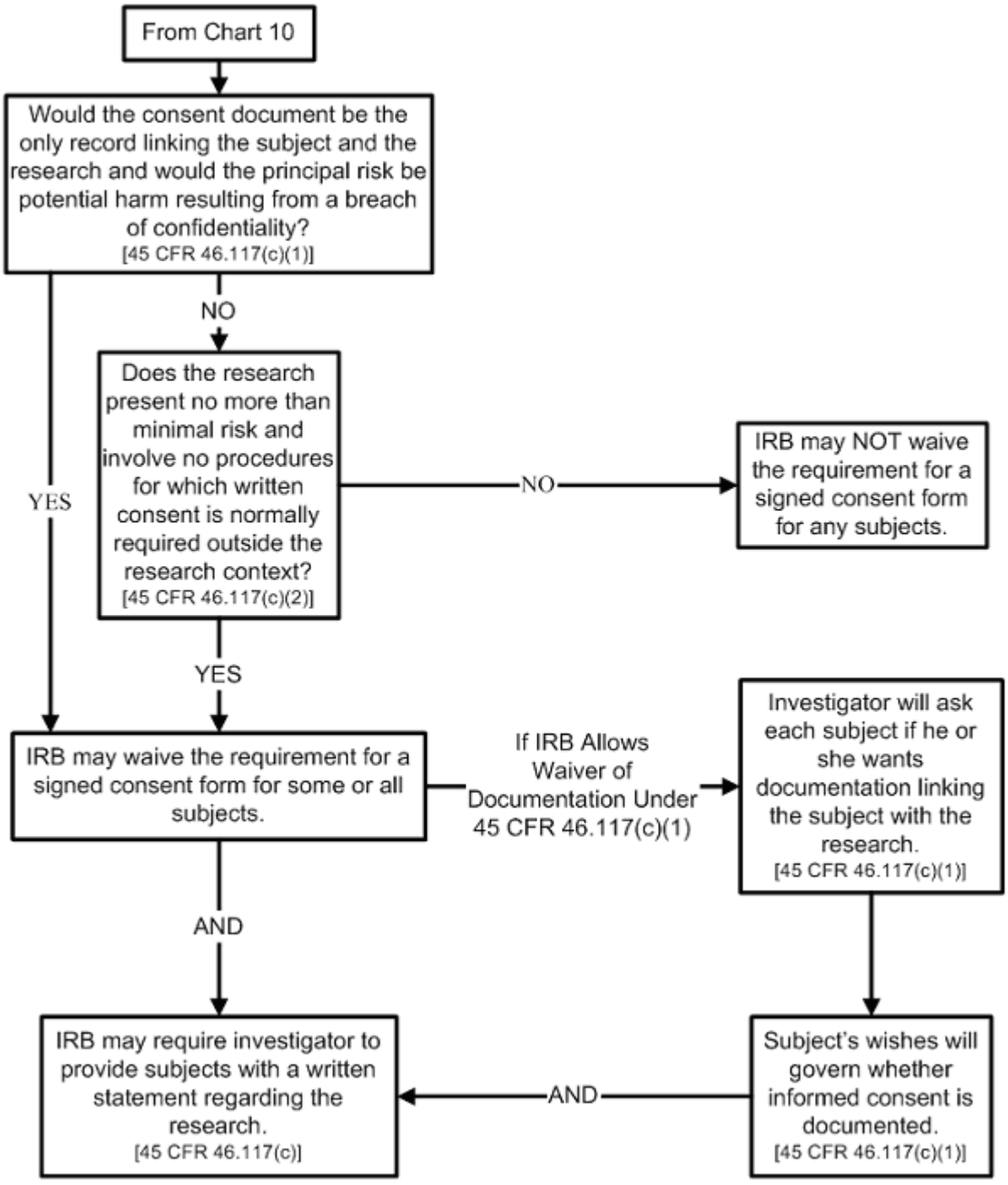
http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html

http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html

Chart 11: Can Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?



September 24, 2004

http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html

Code of Federal Regulations

TITLE 45
PUBLIC WELFARE

Department of Health and Human Services

PART 46
PROTECTION OF HUMAN SUBJECTS

* * *

Revised January 15, 2009
Effective July 14, 2009

SUBPART A—
Basic HHS Policy for Protection of Human Research Subjects

Sec.

46.101 To what does this policy apply?

46.102 Definitions.

46.103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.

46.104- [Reserved]
46.106

46.107 IRB membership.

46.108 IRB functions and operations.

46.109 IRB review of research.

46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

46.111 Criteria for IRB approval of research.

46.112 Review by institution.

46.113 Suspension or termination of IRB approval of research.

46.114 Cooperative research.

46.115 IRB records.

46.116 General requirements for informed consent.

46.117 Documentation of informed consent.

46.118 Applications and proposals lacking definite plans for involvement of human subjects.

46.119 Research undertaken without the intention of involving human subjects.

46.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.

46.121 [Reserved]

46.122 Use of Federal funds.

46.123 Early termination of research support: Evaluation of applications and proposals.

46.124 Conditions.

SUBPART B—
Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research

Sec.

46.201 To what do these regulations apply?

46.202 Definitions.

46.203 Duties of IRBs in connection with research involving pregnant women, fetuses, and neonates.

46.204 Research involving pregnant women or fetuses.

46.205 Research involving neonates.

46.206 Research involving, after delivery, the placenta, the dead fetus or fetal material.

46.207 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.

SUBPART C— Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

Sec.

46.301 Applicability.

46.302 Purpose.

46.303 Definitions.

46.304 Composition of Institutional Review Boards where prisoners are involved.

46.305 Additional duties of the Institutional Review Boards where prisoners are involved.

46.306 Permitted research involving prisoners.

SUBPART D— Additional Protections for Children Involved as Subjects in Research

Sec.

46.401 To what do these regulations apply?

46.402 Definitions.

46.403 IRB duties.

46.404 Research not involving greater than minimal risk.

46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

46.408 Requirements for permission by parents or guardians and for assent by children.

46.409 Wards.

Authority: 5 U.S.C. 301; 42 U.S.C. 289 (a).

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SUBPART E — Registration of Institutional Review Boards

Sec.

46.501 What IRBs must be registered?

46.502 What information must be provided when registering an IRB?

46.503 When must an IRB be registered?

46.504 How must an IRB be registered?

46.505 When must IRB registration information be renewed or updated?

Editorial Note: The Department of Health and Human Services issued a notice of waiver regarding the requirements set forth in part 46, relating to protection of human subjects, as they pertain to demonstration projects, approved under section 1115 of the Social Security Act, which test the use of cost-sharing, such as deductibles, copayment and coinsurance, in the Medicaid program. For further information see 47 FR 9208, Mar. 4, 1982.

SUBPART A
Basic HHS Policy for Protection of Human Research Subjects

Authority: 5 U.S.C. 301; 42 U.S.C. 289; 42 U.S.C. 300v-1(b).

Source: 56 FR 28012, 28022, June 18, 1991, unless otherwise noted.

§46.101 To what does this policy apply?

(a) Except as provided in paragraph (b) of this section, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the federal government outside the United States.

(1) Research that is conducted or supported by a federal department or agency, whether or not it is regulated as defined in §46.102(e), must comply with all sections of this policy.

(2) Research that is neither conducted nor supported by a federal department or agency but is subject to regulation as defined in §46.102(e) must be reviewed and approved, in compliance with §46.101, §46.102, and §46.107 through §46.117 of this policy, by an institutional review board (IRB) that operates in accordance with the pertinent requirements of this policy.

(b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

(i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:(i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(c) Department or agency heads retain final judgment as to whether a particular activity is covered by this policy.

(d) Department or agency heads may require that specific research activities or classes of research activities conducted, supported, or otherwise subject to regulation by the department or agency but not otherwise covered by this policy, comply with some or all of the requirements of this policy.

(e) Compliance with this policy requires compliance with pertinent federal laws or regulations which provide additional protections for human subjects.

(f) This policy does not affect any state or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects.

(g) This policy does not affect any foreign laws or regulations which may otherwise be applicable and which provide additional protections to human subjects of research.

h) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. [An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration (Declaration of Helsinki amended 1989) issued either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.] In these circumstances, if a department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or the department or agency head, notices of these actions as they occur will be published in the FEDERAL REGISTER or will be otherwise published as provided in department or agency procedures.

(i) Unless otherwise required by law, department or agency heads may waive the applicability of some or all of the provisions of this policy to specific research activities or classes of research activities otherwise covered by this policy. Except when otherwise required by statute or Executive Order, the department or agency head shall forward advance notices of these actions to the Office for Human Research Protections, Department of Health and Human Services (HHS), or any successor office, and shall also publish them in the FEDERAL REGISTER or in such other manner as provided in department or agency procedures.[1]

[56 FR 28012, 28022, June 18, 1991; 56 FR 29756, June 28, 1991, as amended at 70 FR 36328, June 23, 2005]

§46.102 Definitions.

(a) *Department or agency head* means the head of any federal department or agency and any other officer or employee of any department or agency to whom authority has been delegated.

(b) *Institution* means any public or private entity or agency (including federal, state, and other agencies).

(c) *Legally authorized representative* means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

(d) *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

(e) *Research subject to regulation*, and similar terms are intended to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity (for example, Investigational New Drug requirements administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (for example, Wage and Hour requirements administered by the Department of Labor).

(f) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains

(1) Data through intervention or interaction with the individual, or

(2) Identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context

in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

(g) *IRB* means an institutional review board established in accord with and for the purposes expressed in this policy.

(h) *IRB approval* means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

(i) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

h) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. [An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration (Declaration of Helsinki amended 1989) issued either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.] In these circumstances, if a department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or the department or agency head, notices of these actions as they occur will be published in the FEDERAL REGISTER or will be otherwise published as provided in department or agency procedures.

[1]Institutions with HHS-approved assurances on file will abide by provisions of Title 45 CFR part 46 subparts A-D. Some of the other departments and agencies have incorporated all provisions of Title 45 CFR part 46 into their policies and procedures as well. However, the exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, subpart C. The exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

§46.103 Assuring compliance with this policy -- research conducted or supported by any Federal Department or Agency.

(a) Each institution engaged in research which is covered by this policy and which is conducted or supported by a federal department or agency shall provide written assurance satisfactory to the department or agency head that it will comply with the requirements set forth in this policy. In lieu of requiring submission of an assurance, individual department or agency heads shall accept the existence of a current assurance, appropriate for the research in question, on file with the Office for Human Research Protections, HHS, or any successor office, and approved for federalwide use by that office. When the existence of an HHS-approved assurance is accepted in lieu of requiring submission of an assurance, reports (except certification) required by this policy to be made to department and agency heads shall also be made to the Office for Human Research Protections, HHS, or any successor office.

(b) Departments and agencies will conduct or support research covered by this policy only if the institution has an assurance approved as provided in this section, and only if the institution has certified to the department or agency head that the research has been reviewed and approved by an IRB provided for in the assurance, and will be subject to continuing review by the IRB. Assurances applicable to federally supported or conducted research shall at a minimum include:

(1)A statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether the research is subject to Federal regulation. This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself. This requirement does not preempt provisions of this policy applicable to department- or agency-supported or regulated research and need not be applicable to any research exempted or waived under §46.101(b) or (i).

(2)Designation of one or more IRBs established in accordance with the requirements of this policy, and for which provisions are made for meeting space and sufficient staff to support the IRB's review and recordkeeping duties.

(3)A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant. Changes in IRB membership shall be reported to the department or agency head, unless in accord with §46.103(a) of this policy, the existence of an HHS-approved assurance is accepted. In this case, change in IRB membership shall be reported to the Office for Human Research Protections, HHS, or any successor office.

(4)Written procedures which the IRB will follow (i) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (ii) for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and (iii) for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

(5)Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and (ii) any suspension or termination of IRB approval.

(c) The assurance shall be executed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by this policy and shall be filed in such form and manner as the department or agency head prescribes.

(d) The department or agency head will evaluate all assurances submitted in accordance with this policy through such officers and employees of the department or agency and such experts or consultants engaged for this purpose as the department or agency head determines to be appropriate. The department or agency head's evaluation will take into consideration the adequacy of the proposed IRB in light of the anticipated scope of the institution's research activities and the types of subject populations likely to be involved, the appropriateness of the proposed initial and continuing review procedures in light of the probable risks, and the size and complexity of the institution.

(e) On the basis of this evaluation, the department or agency head may approve or disapprove the assurance, or enter into negotiations to develop an approvable one. The department or agency head may limit the period during which any particular approved assurance or class of approved assurances shall remain effective or otherwise condition or restrict approval.

(f) Certification is required when the research is supported by a federal department or agency and not otherwise exempted or waived under §46.101(b) or (i). An institution with an approved assurance shall certify that each application or proposal for research covered by the assurance and by §46.103 of this Policy has been reviewed and approved by the IRB. Such certification must be submitted with the application or proposal or by such later date as may be prescribed by the department or agency to which the application or proposal is submitted. Under no condition shall research covered by §46.103 of the Policy be supported prior to receipt of the certification that the research has been reviewed and approved by the IRB. Institutions without an approved assurance covering the research shall certify within 30 days after receipt of a request for such a certification from the department or agency, that the application or proposal has been approved by the IRB. If the certification is not submitted within these time limits, the application or proposal may be returned to the institution.

(Approved by the Office of Management and Budget under Control Number 0990-0260.)

[56 FR 28012, 28022, June 18, 1991; 56 FR 29756, June 28, 1991, as amended at 70 FR 36328, June 23, 2005]

§§46.104--46.106 [Reserved]

§46.107 IRB membership.

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

(b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.

(c) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB

§46.108 IRB functions and operations.

In order to fulfill the requirements of this policy each IRB shall:

(a) Follow written procedures in the same detail as described in §46.103(b)(4) and, to the extent required by, §46.103(b)(5).

(b) Except when an expedited review procedure is used (see §46.110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

§46.109 IRB review of research.

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.

(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with §46.116. The IRB may require that information, in addition to that specifically mentioned in §46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent or may waive documentation in accordance with §46.117.

(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(e) An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

(Approved by the Office of Management and Budget under Control Number 0990-0260.)

[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

(a) The Secretary, HHS, has established, and published as a Notice in the FEDERAL REGISTER, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate, after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the FEDERAL REGISTER. A copy of the list is available from the Office for Human Research Protections, HHS, or any successor office.

(b) An IRB may use the expedited review procedure to review either or both of the following:

(1) some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,

(2) minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the nonexpedited procedure set forth in §46.108(b).

(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

(d) The department or agency head may restrict, suspend, terminate, or choose not to authorize an institution's or IRB's use of the expedited review procedure.

[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§46.111 Criteria for IRB approval of research.

(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

§46.112 Review by institution.

Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

§46.113 Suspension or termination of IRB approval of research.

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.

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[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§46.114 Cooperative research.

Cooperative research projects are those projects covered by this policy which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. With the approval of the department or agency head, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

§46.115 IRB records.

(a) An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members in the same detail as described in §46.103(b)(3).

(6) Written procedures for the IRB in the same detail as described in §46.103(b)(4) and §46.103(b)(5).

(7) Statements of significant new findings provided to subjects, as required by §46.116(b)(5).

(b) The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.

(Approved by the Office of Management and Budget under Control Number 0990-0260.)

[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§46.116 General requirements for informed consent.

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

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[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§46.117 Documentation of informed consent.

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by §46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

(Approved by the Office of Management and Budget under Control Number 0990-0260.)

[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§46.118 Applications and proposals lacking definite plans for involvement of human subjects.

Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research exempted or waived under §46.101(b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the department or agency.

§46.119 Research undertaken without the intention of involving human subjects.

In the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in this policy, a certification submitted, by the institution, to the department or agency, and final approval given to the proposed change by the department or agency.

§46.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.

(a) The department or agency head will evaluate all applications and proposals involving human subjects submitted to the department or agency through such officers and employees of the department or agency and such experts and consultants as the department or agency head determines to be appropriate. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.

(b) On the basis of this evaluation, the department or agency head may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

§46.121 [Reserved]

§46.122 Use of Federal funds.

Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

§46.123 Early termination of research support: Evaluation of applications and proposals.

(a) The department or agency head may require that department or agency support for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the department or agency head finds an institution has materially failed to comply with the terms of this policy.

(b) In making decisions about supporting or approving applications or proposals covered by this policy the department or agency head may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragraph (a) of this section and whether the applicant or the person or persons who would direct or has/have directed the scientific and technical aspects of an activity has/have, in the judgment of the department or agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to federal regulation).

§46.124 Conditions.

With respect to any research project or any class of research projects the department or agency head may impose additional conditions prior to or at the time of approval when in the judgment of the department or agency head additional conditions are necessary for the protection of human subjects.

Subpart B

Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research

Source: 66 FR 56778, Nov. 13, 2001, unless otherwise noted.

§46.201 To what do these regulations apply?

(a) Except as provided in paragraph (b) of this section, this subpart applies to all research involving pregnant women, human fetuses, neonates of uncertain viability, or nonviable neonates conducted or supported by the Department of Health and Human Services (DHHS). This includes all research conducted in DHHS facilities by any person and all research conducted in any facility by DHHS employees.

(b) The exemptions at §46.101(b)(1) through (6) are applicable to this subpart.

(c) The provisions of §46.101(c) through (i) are applicable to this subpart. Reference to State or local laws in this subpart and in §46.101(f) is intended to include the laws of federally recognized American Indian and Alaska Native Tribal Governments.

(d) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§46.202 Definitions.

The definitions in §46.102 shall be applicable to this subpart as well. In addition, as used in this subpart:

(a) Dead fetus means a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.

(b) Delivery means complete separation of the fetus from the woman by expulsion or extraction or any other means.

(c) Fetus means the product of conception from implantation until delivery.

(d) Neonate means a newborn.

(e) Nonviable neonate means a neonate after delivery that, although living, is not viable.

(f) Pregnancy encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

(g) Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

(h) Viable, as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration. The Secretary may from time to time, taking into account medical advances, publish in the FEDERAL REGISTER guidelines to assist in determining whether a neonate is viable for purposes of this subpart. If a neonate is viable then it may be included in research only to the extent permitted and in accordance with the requirements of subparts A and D of this part.

§46.203 Duties of IRBs in connection with research involving pregnant women, fetuses, and neonates.

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart and the other subparts of this part.

§46.204 Research involving pregnant women or fetuses.

Pregnant women or fetuses may be involved in research if all of the following conditions are met:

(a) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;

(b) The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;

(c) Any risk is the least possible for achieving the objectives of the research;

(d) If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of subpart A of this part;

(e) If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of subpart A of this part, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.

(f) Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;

(g) For children as defined in §46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D of this part;

(h) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;

(i) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and

(j) Individuals engaged in the research will have no part in determining the viability of a neonate.

§46.205 Research involving neonates.

(a) Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met:

(1) Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.

(2) Each individual providing consent under paragraph (b)(2) or (c)(5) of this section is fully informed regarding the reasonably foreseeable impact of the research on the neonate.

(3) Individuals engaged in the research will have no part in determining the viability of a neonate.

(4) The requirements of paragraph (b) or (c) of this section have been met as applicable.

(b) Neonates of uncertain viability. Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this subpart unless the following additional conditions have been met:

(1) The IRB determines that:

(i) The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or

(ii) The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research; and

(2) The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with subpart A of this part, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

(c) Nonviable neonates. After delivery nonviable neonate may not be involved in research covered by this subpart unless all of the following additional conditions are met:

(1) Vital functions of the neonate will not be artificially maintained;

(2) The research will not terminate the heartbeat or respiration of the neonate;

(3) There will be no added risk to the neonate resulting from the research;

(4) The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and

(5) The legally effective informed consent of both parents of the neonate is obtained in accord with subpart A of this part, except that the waiver and alteration provisions of §46.116(c) and (d) do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements of this paragraph (c)(5), except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph (c)(5).

(d) Viable neonates. A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements of subparts A and D of this part.

§46.206 Research involving, after delivery, the placenta, the dead fetus or fetal material.

(a) Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable federal, state, or local laws and regulations regarding such activities.

(b) If information associated with material described in paragraph (a) of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent subparts of this part are applicable.

§46.207 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.

The Secretary will conduct or fund research that the IRB does not believe meets the requirements of §46.204 or §46.205 only if:

(a) The IRB finds that the research presents

a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates; and

(b) The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law) and following opportunity for public review and comment, including a public meeting announced in the FEDERAL REGISTER, has determined either:

(1) That the research in fact satisfies the conditions of §46.204, as applicable; or

(2) The following:

(i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates;

(ii) The research will be conducted in accord with sound ethical principles; and

(iii) Informed consent will be obtained in accord with the informed consent provisions of subpart A and other applicable subparts of this part.

Subpart C

Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

Source: 43 FR 53655, Nov. 16, 1978, unless otherwise noted.

§46.301 Applicability.

(a) The regulations in this subpart are applicable to all biomedical and behavioral research conducted or supported by the Department of Health and Human Services involving prisoners as subjects.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will authorize research involving prisoners as subjects, to the extent such research is limited or barred by applicable State or local law.

(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§46.302 Purpose.

Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, it is the purpose of this subpart to provide additional safeguards for the protection of prisoners involved in activities to which this subpart is applicable.

§46.303 Definitions.

As used in this subpart:

(a) *Secretary* means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

(b) *DHHS* means the Department of Health and Human Services.

(c) *Prisoner* means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

(d) *Minimal risk* is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

§46.304 Composition of Institutional Review Boards where prisoners are involved.

In addition to satisfying the requirements in §46.107 of this part, an Institutional Review Board, carrying out responsibilities under this part with respect to research covered by this subpart, shall also meet the following specific requirements:

(a) A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.

(b) At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one Board only one Board need satisfy this requirement.

[43 FR 53655, Nov. 16, 1978, as amended at 46 FR 8366, Jan. 26, 1981]

§46.305 Additional duties of the Institutional Review Boards where prisoners are involved.

(a) In addition to all other responsibilities prescribed for Institutional Review Boards under this part, the Board shall review research covered by this subpart and approve such research only if it finds that:

(1) The research under review represents one of the categories of research permissible under §46.306(a)(2);

(2) Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;

(3) The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;

(4) Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;

(5) The information is presented in language which is understandable to the subject population;

(6) Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

(7) Where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

(b) The Board shall carry out such other duties as may be assigned by the Secretary.

(c) The institution shall certify to the Secre-

tary, in such form and manner as the Secretary may require, that the duties of the Board under this section have been fulfilled.

§46.306 Permitted research involving prisoners.

(a) Biomedical or behavioral research conducted or supported by DHHS may involve prisoners as subjects only if:

(1) The institution responsible for the conduct of the research has certified to the Secretary that the Institutional Review Board has approved the research under §46.305 of this subpart; and

(2) In the judgment of the Secretary the proposed research involves solely the following:

(i) Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(ii) Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(iii) Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research; or

(iv) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of the intent to approve such research.

(b) Except as provided in paragraph (a) of this section, biomedical or behavioral research conducted or supported by DHHS shall not involve prisoners as subjects.

Subpart D

Additional Protections for Children Involved as Subjects in Research

Source: 48 FR 9818, March 8, 1983, unless otherwise noted.

§46.401 To what do these regulations apply?

(a) This subpart applies to all research involving children as subjects, conducted or supported by the Department of Health and Human Services.

(1) This includes research conducted by Department employees, except that each head of an Operating Division of the Department may adopt such nonsubstantive, procedural modifications as may be appropriate from an administrative standpoint.

(2) It also includes research conducted or supported by the Department of Health and Human Services outside the United States, but in appropriate circumstances, the Secretary may, under paragraph (i) of §46.101 of subpart A, waive the applicability of some or all of the requirements of these regulations for research of this type.

(b) Exemptions at §46.101(b)(1) and (b)(3) through (b)(6) are applicable to this subpart. The exemption at §46.101(b)(2) regarding educational tests is also applicable to this subpart. However, the exemption at §46.101 (b)(2) for research involving survey or interview procedures or observations of public behavior does not apply to research covered by this subpart, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

(c) The exceptions, additions, and provisions for waiver as they appear in paragraphs (c) through (i) of §46.101 of subpart A are applicable to this subpart.

[48 FR 9818, Mar.8, 1983; 56 FR 28032, June 18, 1991; 56 FR 29757, June 28, 1991.]

§46.402 Definitions.

The definitions in §46.102 of subpart A shall be applicable to this subpart as well. In addition, as used in this subpart:

(a) *Children* are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

(b) *Assent* means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

(c) *Permission* means the agreement of parent (s) or guardian to the participation of their child or ward in research.

(d) *Parent* means a child's biological or adoptive parent.

(e) *Guardian* means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

§46.403 IRB duties.

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart.

§46.404 Research not involving greater than minimal risk.

HHS will conduct or fund research in which the IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in §46.408.

§46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the IRB finds that:

(a) The risk is justified by the anticipated benefit to the subjects;

(b) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and

(c) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in §46.408.

§46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that:

(a) The risk represents a minor increase over minimal risk;

(b) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;

(c) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and

(d) Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in §46.408.

§46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

HHS will conduct or fund research that the IRB does not believe meets the requirements of §46.404, §46.405, or §46.406 only if:

(a) the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and

(b) the Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either:

(1) that the research in fact satisfies the conditions of §46.404, §46.405, or §46.406, as applicable, or (2) the following:

(i) the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;

(ii) the research will be conducted in accordance with sound ethical principles;

(iii) adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in §46.408.

§46.408 Requirements for permission by parents or guardians and for assent by children.

(a) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with §46.116 of Subpart A.

(b) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by §46.116 of Subpart A, that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under §46.404 or §46.405. Where research is covered by §§46.406 and 46.407 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

(c) In addition to the provisions for waiver contained in §46.116 of subpart A, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with federal, state, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

(d) Permission by parents or guardians shall be documented in accordance with and to the extent required by §46.117 of subpart A.

(e) When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

§46.409 Wards.

(a) Children who are wards of the state or any other agency, institution, or entity can be included in research approved under §46.406 or §46.407 only if such research is:

(1) Related to their status as wards; or

(2) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

(b) If the research is approved under paragraph (a) of this section, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

Subpart E

Registration of Institutional Review Boards

Source: 74 FR 2399, January 15, 2009, unless otherwise noted.

§46.501 What IRBs must be registered?

Each IRB that is designated by an institution under an assurance of compliance approved for federalwide use by the Office for Human Research Protections (OHRP) under §46.103(a) and that reviews research involving human subjects conducted or supported by the Department of Health and Human Services (HHS) must be registered with HHS. An individual authorized to act on behalf of the institution or organization operating the IRB must submit the registration information.

§46.502 What information must be provided when registering an IRB?

The following information must be provided to HHS when registering an IRB:

(a) The name, mailing address, and street address (if different from the mailing address) of the institution or organization operating the IRB(s); and the name, mailing address, phone number, facsimile number, and electronic mail address of the senior officer or head official of that institution or organization who is responsible for overseeing activities performed by the IRB.

(b) The name, mailing address, phone number, facsimile number, and electronic mail address of the contact person providing the registration information.

(c) The name, if any, assigned to the IRB by the institution or organization, and the IRB's mailing address, street address (if different from the mailing address), phone number, facsimile number, and electronic mail address.

(d) The name, phone number, and electronic mail address of the IRB chairperson.

(e)(1) The approximate numbers of:

(i) All active protocols; and

(ii) Active protocols conducted or supported by HHS.

(2) For purpose of this regulation, an ``active protocol'' is any protocol for which the IRB conducted an initial review or a continuing review at a convened meeting or under an expedited review procedure during the preceding twelve months.

(f) The approximate number of full-time equivalent positions devoted to the IRB's administrative activities.

§46.503 When must an IRB be registered?

An IRB must be registered before it can be designated under an assurance approved for federalwide use by OHRP under §46.103(a).

IRB registration becomes effective when reviewed and accepted by OHRP.

The registration will be effective for 3 years.

§46.504 How must an IRB be registered?

Each IRB must be registered electronically through http://ohrp.cit.nih.gov/efile unless an institution or organization lacks the ability to register its IRB(s) electronically. If an institution or organization lacks the ability to register an IRB electronically, it must send its IRB registration information in writing to OHRP.

§46.505 When must IRB registration information be renewed or updated?

(a) Each IRB must renew its registration every 3 years.

(b) The registration information for an IRB must be updated within 90 days after changes occur regarding the contact person who provided the IRB registration information or the IRB chairperson. The updated registration information must be submitted in accordance with §46.504.

(c) Any renewal or update that is submitted to, and accepted by, OHRP begins a new 3-year effective period.

(d) An institution's or organization's decision to disband a registered IRB which it is operating also must be reported to OHRP in writing within 30 days after permanent cessation of the IRB's review of HHS-conducted or -supported research.

Office for Human Research Protections (OHRP)

§46.116 Informed Consent Checklist - Basic and Additional Elements

- A statement that the study involves research
- An explanation of the purposes of the research
- The expected duration of the subject's participation
- A description of the procedures to be followed
- Identification of any procedures which are experimental
- A description of any reasonably foreseeable risks or discomforts to the subject
- A description of any benefits to the subject or to others which may reasonably be expected from the research
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
- For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained
- **Research, Rights or Injury:** An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled

Additional Elements as Appropriate

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
- Any additional costs to the subject that may result from participation in the research
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
- A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject
- The approximate number of subjects involved in the study

§46.117 Documentation of Informed Consent Checklist

a. Except as provided in paragraph "c" of this section, informed consent shall be documented by the use of a written consent form approved by the IRB, and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

Written
The consent form may be either of the following:

1. A **written consent** document that embodies the elements of informed consent required by §46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator should give either the subject or the representative adequate opportunity to read it before it is signed.

Done Orally

2. A **short form written consent** document, stating that the elements of informed consent required by §46.116 have been presented **orally** to the subject or the subject's legally authorized representative. When this method is used, there shall be a **witness** to the oral presentation. Also, the IRB shall approve a **written summary** of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

Waiver of Requirement for Signed Form

c. An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects, if it finds either:

1. That the only record linking the subject and the research would be the consent document, and the **principal risk** would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

2. That the research presents **no more than minimal risk** of harm to subjects, and involves no procedures, for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

IRB Latitude to Approve a Consent Procedure that Alters or Waives some or all of the Elements of Consent

http://www.hhs.gov/ohrp/policy/consentckls.html

§ 46.116 - An IRB may approve a consent procedure, which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent, provided the IRB finds and documents that:

- C: 1.The research or demonstration project is to be conducted by, or subject to the approval of, state or local government officials, and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and
- C: 2.The research could not practicably be carried out without the waiver or alteration.
- D: 1. The research involves no more than minimal risk to the subjects;
- D: 2.The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- D: 3.The research could not practicably be carried out without the waiver or alteration; and
- D: 4.Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Special Requirements - 45 CFR 46 Subpart D - Additional DHHS Protections for Children Involved as Subjects in Research

Assent/Waiver

The IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted, or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children, and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances, in which consent may be waived in accord with §46.116 of Subpart A.

Parents

- The IRB may find that the permission of one parent is sufficient for research to be conducted under §46.404 or §46.405.
- Where research is covered by §46.406 and §46.407, and permission is to be obtained from parents, both parents must give their permission, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
- If the IRB determines that a research protocol is designed for conditions or for a subject population, for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part and paragraph (b) of this section, provided an

appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, state or local law.

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