



Institutional Review Board

Policies and Procedures

Revised: November 2015
Originally Adopted: July 1, 1995

Office of the Provost

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Section 1: Overview

1.2 Purpose

The purpose of Utica College's Institutional Review Board (IRB) is to assure that all human subject research associated with the College conforms to related college, state, and federal regulations. UC's IRB is charged with protecting the safety, welfare, rights, and privacy of all participants in human subjects research that proceeds under any investigator conducting research on the Utica College campus, satellite campuses, and/or using Utica College students, staff, and/or faculty. These safeguards derive from the following 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.

1.3 Ethical Guidelines Governing Research

- *Respect for Persons:* Recognition of the personal dignity and autonomy of individuals and special protection of those persons with diminished autonomy or particular vulnerabilities, including prisoners, children, those who are mentally or cognitively disabled, pregnant women, or economically or educationally disadvantaged persons. Human subjects should enter into research voluntarily and with adequate information.
- *Beneficence:* The obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks. Possible risks to human subjects should be weighed against possible benefits to the subjects, as well as against the possible improvement of knowledge.
- *Justice:* Fairness in the distribution of research benefits and burdens. In selecting human subjects for research, investigators should ensure that no group of participants is either consistently selected to participate in research, or consistently deprived of the opportunity to do so.

1.4 Charge of the IRB and Definition of terms

The procedures for review described below adhere to the regulations of the Department of Health and Human Services (45 CFR 46, as amended and published in the Federal Register on June 18, 1991).

The IRB is charged with reviewing human subject research proposals before the research begins. College campus.

1.4.2 Definition of terms

"*Research*" is defined as "systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalized knowledge" (45 CFR 46.102d).

"*Human Subject*" is a living individual about whom an investigator (whether Professional or student) conducting research obtains [either]

- Data through intervention or interaction with the individual, or
- 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 that 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)." If the private information is not individually identifiable (i.e., if the identity of the subject is not known and cannot readily be ascertained by the investigator or associated with the information), the research does not constitute research involving human subjects.

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."

Principal Investigator (PI) – the person designated as having primary responsibility for the coordination of the research procedures and ensuring compliance with relevant policies by all participating researchers.

Co-Investigator(s) – any individual assisting the PI with the gathering and recording of data. This must be disclosed on the IRB application.

Faculty Advisor – any student conducting research needs to do so under the direct supervision of a faculty member. This must be disclosed on the IRB application.

Section 2: Researcher Responsibilities

IRB policies are intended to protect the rights of human subject participants. However, researchers are also responsible for protecting those rights. In addition to the ethical guidelines from Section 1, researchers must abide by the Principles and Ethics summarized below, and they are encouraged to consult additional guidelines provided by their respective disciplinary groups.

2.1 Compliance

Faculty, staff, and students who participate in human subject research must act in compliance with federal, state, and college regulations. In addition, professional disciplinary guidelines governing the conduct of human subject research should inform researchers as they plan and conduct their research. As required by IRB policies, researchers are required to obtain institutional approval prior to conducting research.

2.2 Informed Consent

Prior to conducting research with human participants (except when the research involves only anonymous surveys, naturalistic observations, or similar procedures), researchers enter into a social contract with participants, clarifying the nature of the research and what participants can expect to experience during the course of the study. Participants are informed of all features of the research that might influence their decision to participate. Researchers are to respect participant decisions to decline or discontinue participating in the research at any time for any reason and without penalty. Where possible, researchers make reference to participants' rights along these lines in their consent forms (see <https://www.utica.edu/irb/Media/Informed%20Consent%20Checklist.pdf>).

2.3 Minimizing Negative Effects of Participation (e.g., Intrusiveness, Harm)

Researchers protect participants from physical and psychological discomfort, harm and/or danger to the extent possible. Risks to participants are minimized and explained to the participant before he or she is asked to give consent. If the research inflicts undesirable side effects on participants, the researcher should find ways to remedy these effects. When human participants are younger than 18 years of age, the adult (e.g., parent or guardian) giving consent shall be fully informed of all risks on the child-participant's behalf. However, if it is reasonable to do so, the researcher shall explain the risks to the child-participant as well and provide them the opportunity to decline participation.

2.4 Deception in Research

Researchers conduct studies involving deception only when they have determined that the use of deceptive techniques is justified by the study's prospective scientific, educational or applied value and that equally effective alternative approaches that do not involve deception are not feasible. Researchers will never deceive participants about significant aspects of the procedure that might affect participants' willingness to participate (e.g., physical discomfort, physical risks, unpleasant emotional experiences).

Any other deception that is central to the design and implementation of the study must be explained to participants as early as is feasible, preferably at the conclusion of their participation, but no later than at the conclusion of the research.

There may be instances in which deception is not involved but participants are not fully informed about the purpose of a study. For example, in the study of memory (e.g., for faces, conversation, news releases), it may be important not to inform participants at the outset that the purpose of the study is to test the accuracy of memory. In these instances, the use of cover tasks (or instructions for processing materials) need not make mention of subsequent memory tests. Although these cover tasks do not necessarily involve deception (i.e., telling participants information that is not true), for adult participants, their role in the research should be mentioned in debriefing statements.

2.5 Confidentiality and Privacy

All personally identifiable information about participants' is kept confidential. When there is a possibility that others may have access to this information, participants should be informed of this possibility prior to giving their consent. All information is processed, stored and destroyed in a manner that preserves the confidentiality of the participant. Researchers include reference to the way(s) in which confidentiality is safeguarded in their consent forms. Issues related to confidentiality and length of time for data storage will be reviewed on a case-by-case basis depending on the nature of the data, e.g. verbal recordings and video. Typically, data are maintained for a period of five years, but this can vary according to academic discipline.

Section 3: IRB Functions and Operations

3.1 Responsibilities

Responsibility for the protection of human subjects of research at Utica College is in large part vested in the Institutional Review Board. The Board, therefore, is responsible not only for reviewing, regulating, and monitoring such research, but also for educating the College community in the protection of human subjects. Specific responsibilities of the Board include the following.

- Meet on an as-needed basis to review proposals.
- Advise investigators on improvements to research protocols.
- Monitor the research it has approved, through review of the annual reports.
- Maintain records of its activities.
- Report to the Provost all actions pertaining to research supported by external funding or proposed for such support.
- Report at once to the Provost any action to suspend or terminate approved research.
- Assist the Provost, as requested, in interpreting College research with human subjects for any of the College's constituencies or for the general public.
- Devise and conduct programs of education in matters relevant to research with human subjects for the benefit of students and employees of the College.
- Review annually the College's policies and procedures for the protection of human subjects and report any inadequacies or suggested improvements to the Provost.
- Report its activities to the Provost annually, or more frequently if so requested.

3.2 Authority

The Board is authorized to:

- Approve, disapprove, or require modifications in the research protocols submitted.
- Monitor the research it has approved by any means it deems appropriate, including observation of the consent process and the research, and appointment of a third party to undertake such observation.
- Suspend or terminate approved research, whenever the research is not being conducted in accordance with the Board's requirements or whenever it has been associated with unexpected harm to human subjects.

3.3 IRB Membership

IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of human subject research activities conducted by College faculty, staff, and students. The 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. The 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.

The Director of Graduate Program Operations (also the IRB Coordinator) also sits on the IRB as a non-voting (ex officio) member.

The IRB may, in its discretion, invite individuals with competence in special areas to aid the review of issues which require expertise beyond that available on the IRB. These individuals may not vote with the IRB.

No member of the IRB may 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. When an IRB member's proposal is discussed during an IRB meeting in which that member is present, he/she must not be involved in the discussion and cannot vote.

The Provost will appoint the members of the IRB in accordance with College, state, and federal regulations and in compliance with the IRB Policy and Procedures. Members will generally serve a three-year term.

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3.4 Qualifications

The Board shall be sufficiently qualified through the experience and expertise of its members, diversity of the members, including consideration of race, gender, and cultural backgrounds, and their sensitivity to such issues as community attitudes, to adequately review research proposals, safeguard the rights and welfare of human subjects particularly vulnerable populations, and to promote respect for its advice and counsel.

The Board shall always include at least one member whose primary concerns are in nonscientific areas, one whose primary concerns are in scientific areas, and one community member who is not otherwise affiliated with the College and who is not part of the immediate family of a person who is affiliated with the College. A single member of the Board may fill more than one representational role.

3.5 Duties of Specific Positions

Chair

- Report to the Provost
- Serve as contact person for and communicate with principal investigators and instructors
- Prepare annual memoranda and reports
- Respond to inquiries from interested parties
- Remain informed about news bulletins and releases from the Office for Human Research Protections (OHRP), National Institutes of Health (NIH), Department of Health and Human Services (HHS)
- Meet with new faculty

IRB Coordinator

- Oversee maintenance of all records
- Review, edit, and distribute minutes of meetings
- Serve as a resource for investigators with procedural questions
- Coordinate educational programs

IRB Administrator

- Assists with maintenance of all records
- Take, edit, and distribute minutes of meetings

3.6 Training

IRB members (voting and ex-officio) and others charged with responsibility for reviewing and approving research will receive detailed training in the regulations, guidelines, and policies applicable to human subjects research. Attending workshops and other educational opportunities focused on IRB functions is encouraged and supported to the extent possible.

During their first year of service, IRB members will complete one appropriate training activity. Appropriate training may include workshops, web-based modules, CD ROMs, books, articles, and relevant videos.

Documentation of training should be submitted to the IRB Coordinator.

3.7 IRB Records

The IRB Coordinator shall prepare and maintain adequate documentation of IRB activities, including the following:

- Copies of all research proposals (including those classified as exempt and reviewed by individual departments), scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.
- Minutes of IRB meetings which shall be in sufficient detail to report attendance at the meetings; actions taken by the IRB; the vote on actions on proposals under review 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 disputed issues and their resolution.
- Records of continuing review activities.
- Copies of all correspondence between the IRB and the investigators.
- 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 (e.g., full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant).
- Written procedures for the IRB.

3.8 IRB Maintenance of Records

Records pertaining to human subjects that come under IRB purview will be kept on a secure computer server (electronic records) or in a locked space in an administrative office under supervision of the IRB Coordinator for three years after the completion of an approved project or declination of a proposal. Records may include: certification of completion in human subjects protection training, applications for approval to the IRB, descriptions of research protocols, sample consent forms, sample questionnaires, copies of grant proposals, minutes of IRB meetings, and related memoranda and correspondence.

Section 4: Submitting a Proposal to the IRB

4.1 Qualified Investigators

Only qualified faculty and staff investigators with appropriate credentials related to human subjects research may submit a proposal to the IRB. Students and other members of the UC community who do not have the appropriate credentials are required to have a research sponsor (most often a member of the faculty) who will assume responsibility for the research activities outlined in the proposal.

4.2 Roles and Responsibilities of Researchers

4.2.1 Principal Investigator (PI)

- The PI shall design and present to the authorized review body a protocol of the research to be conducted. The authorized body of first review is the Utica College Institutional Review Board.
- The PI shall not nor let any other investigators or faculty advisor initiate any research with human subjects until the Board has approved the protocol.
- The PI shall make no, or let any other investigators or faculty advisor, alterations to the approved protocol without the prior approval of such alterations by the Board.
- The PI shall report at once to the Board any unanticipated harm to human subjects.
- The PI shall report to the Board on the conduct of the research and shall seek approval for continuation of the research at least annually, and more frequently if the Board so requires.
- The PI shall cooperate fully with the Board in monitoring the progress of the research.
- PIs are responsible for reporting unethical research behaviors to the faculty advisor, or IRB as appropriate

4.2.2 Co-Investigators

- Co-investigators are responsible for reviewing the research and understanding what they are agreeing to.
- Understand that the PI's, from the IRB's perspective, only additional responsibility is to be the point of contact and liaison to the IRB.
- Co-investigators are responsible for reporting unethical research behaviors to the PI, faculty advisor, or IRB as appropriate.

4.2.3 Faculty Advisors

- Faculty advisors must ensure PIs and co-investigators understand and acknowledge roles and responsibilities.
- Make sure that the student researchers understand the principles of ethical research.
- Understand that they cannot change IRB applications but can make their concerns and suggestions known to the PI, who then can edit the IRB application.

4.2.4 Instructors of Research Methods Courses

- An instructor or professor that teaches a Research Methods course for the first time must complete a Teaching Research Methods Form Part I. For every term the approved course is taught the instructor or professor must submit a Teaching Research Methods Part II form to the IRB. This form must be accompanied by a list of the students' names and titles of research.
- Make sure that the students understand that they DO NOT have to complete an IRB application. If the instructor or professor would like the students to complete an application for experience, a Word template is available and can be disbursed, completed, and submitted

- back to the instructor or professor.
- Ensure that the students in the course understand the principles of ethical research.

4.3 Use of Utica College IRB Forms

Investigators are to utilize the Utica College IRB standardized templates for proposal submission and development of informed consent forms. These templates are found on the IRB's website.

4.3.1 Guidelines for Informed Consent Forms (see Appendix J and K)

Except under special conditions specified in the IRB Policy and Procedures, researchers are required to obtain written informed consent from all adult participants. Investigators are required to provide prospective adult participants with sufficient information and opportunity to consider that information. Every consent form should obtain a statement of the participants' rights (see <https://www.utica.edu/irb/Media/Informed%20Consent%20Checklist.pdf> for a list of required and additional elements)

4.3.2 An IRB may approve a consent procedure that does not include, or which alters, some of the guidelines listed above under certain circumstances:

- The research could not be carried out without the waiver of consent
- Waiver of consent: The IRB may approve a consent procedure that does not involve the guidelines specified above when:
 - The research involves no more than minimal risk
 - The waiver does not adversely affect the rights and welfare of the participants
 - The research could not be carried out in any other way practically
 - Whenever possible, participants will provide additional information and/or consent after participating (e.g., releasing use of video)

4.3 Consent of Child Participants

4.4.1 *Parental Consent*

When the participants are under 18 years of age, parental (or guardian) consent must be obtained. This consent could be specific to an individual project or inclusive of all projects receiving IRB approval for a given year. Parents and guardians may sign a consent form giving permission for their child(ren) to participate in a series of projects conducted over a period of an academic year. It is understood that although parental consent is obtained, child participants are free to decline invitations to participate without any penalty. Parent consent letters should provide information about the purpose of the research as well as information about the procedure itself from the child's point of view. As with research involving adult participants, this letter should indicate how confidentiality would be maintained.

4.4.2 *Child Assent*

Child participants should be given an age-appropriate explanation about the procedures used and what to expect by way of participation. Children should be asked if they want to participate. Mere failure to object on the child participant's part should not, in the absence of an affirmative response, be interpreted as assent. In the proposal, the

researcher should indicate how assent would be obtained and documented. The researcher should also indicate how parental consent would be obtained including an example of the letter of consent (if relevant).

4.4.3 *Debriefing Statement*

Debriefing statements are required for some research projects. The purpose of debriefing is to inform the participants of the goal(s) of the study and to remove (or minimize) any negative effects of the study. When course credit is offered for participation (e.g., by way of extra credit), the debriefing should also be educational in that it informs the participants of some of the issues (e.g., psychological) of concern in the study. Debriefing is of particular importance if deception is involved and/or if the study involved sensitive or potentially embarrassing issues. It is the researcher's responsibility to remove any negative feelings that a participant might experience as a result of his or her participation. Note: Materials submitted to the IRB Committee should include a script of the debriefing statement.

When there are potential risks (e.g., inducing negative emotional reactions) even if minimal in nature, participants should be provided with appropriate contact information (e.g., counseling center, disabilities specialists) in the debriefing form. In studies where deception used, the researcher has the obligation to allow participants to learn about the nature of the deception (and its purpose) upon completing the session or study.

Section 5: IRB Review of Proposals

5.1 Introduction

Qualified investigators (see section 4.1) who are planning research projects involving human subjects are responsible for initiating the review process by submitting their research proposals electronically to the IRB. Only electronic submissions are accepted. Typically, the Chair of the IRB will determine the category of review for all proposals.

5.2 Categories of Review

Depending on the level of risk associated with the research, a protocol may be classified as exempt from review, eligible for expedited review, or require a full review. A proposal can be deemed exempt from IRB review only through the IRB Chair. The Chair and/or another IRB member complete expedited reviews. A full review requires a review by all IRB members.

5.2.1 Criteria for Non-human subjects research

See Appendix A

5.2.2 Criteria for Exempt Proposals

Exempt Proposals Part A (all items must apply) (see appendix B):

- The research does not involve as subjects prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults, including economically or educationally disadvantaged persons.
- The research does not involve the collection or recording of behavior which, if known outside of the research, could reasonably place subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.
- The research does not involve the collection of information regarding sensitive aspects of subjects' behavior (e.g., drug or alcohol, use illegal conduct, sexual behavior).
- The research does not involve subjects under the age of 18 (except as they are participating in projects that fall under categories 1, 3, 4, and/or 5 in Part B).
- The research does not involve deception.
- The procedures of this research are generally free of foreseeable risk to the subject.

Exempt Proposals Part B (at least one item should apply):

- Research conducted in established or commonly accepted educational settings, such as: Research on regular and special education, instructional strategies, or cognitive processes, or research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.
- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects, or 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.
- Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

- 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: Public benefit or service programs; procedures for obtaining benefits or services under those programs; possible changes in, or alternatives to, those programs or procedures; possible changes in methods or levels of payment for payment for benefits or services under those programs.
- Taste and food quality evaluation and consumer acceptance studies: if wholesome foods without chemical additives are consumed, or if a food is consumed that contains a food ingredient at or below the level of safety and for a use found to be safe, or agricultural chemical or environmental contaminant at or below a 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.

5.2.3 Criteria for Delegated/Expedited Review

Expedited Part A (all items must apply) (see Appendix H)

- The research does not involve as subjects prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults, including economically or educationally disadvantaged persons.
- The research does not involve the collection or recording of behavior which, if known outside of the research, could reasonably place subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.
- The research does not involve the collection of information regarding sensitive aspects of subjects' behavior (e.g., drug or alcohol, use illegal conduct, sexual behavior).
- The procedures of this research present no more than minimal risk to the subject. (Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.)

Expedited Part B (at least one item should apply)

- Research that collects data from voice, video, digital, or image recordings;
- Research on individual or group characteristics or behavior, including but not limited to survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodology as follows:
- Involving adults, where (i) the research does not involve stress to subjects, and (ii) identification of the subjects and/or their responses would not reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation;
- Involving children where (i) the research involves neither stress to subjects nor sensitive information about themselves or their family; (ii) no alteration or waiver of regulatory requirements for parental permission has been proposed; and (iii) identification of the subjects and/or their responses would not reasonably place them or their family members at risk of criminal or civil liability or be damaging to the financial standing, employability, or reputation of themselves or their family members.
- Continuations of projects previously approved by the IRB if (a) no new human subjects are enrolled in the study, all research-related interventions on human subjects have been

completed, and the research remains active only for long- term follow-up of subjects; OR
 (b) no additional risks to subjects have been identified or the remaining research activities are limited to data analysis;

- Certain classes of clinical studies of drugs or medical devices (i.e., clinical studies of drugs for which a new investigational drug application is not required; or research on medical devices for which an investigational device application is not required or the device is approved for marketing and is being used according to approved labeling);
- Research involving existing identifiable data, documents, records, or biological specimens (including pathological or diagnostic specimens), where these materials, in their entirety, have been collected prior to the research for a purpose other than the proposed research. These sources are not publicly available and, although confidentiality will be strictly maintained, information will not be recorded anonymously (e.g., use will be made of audio or video tapes, names will be recorded, even if they are not directly associated with the data);
- Collection of data through use of the following procedures: (a) non-invasive procedures routinely employed in clinical practice and not involving exposure to electromagnetic exposure or electromagnetic radiation outside the visible range (i.e., not involving x-rays, microwaves, etc.); (b) 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; (c) weighing, testing sensory acuity, electrocardiography,
- Electroretinography, echography, sonography, ultrasound, magnetic resonance imaging (MRI), diagnostic infrared imaging, doppler blood flow, and echocardiography; (d) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing involving subjects; (e) collection of blood samples by finger stick or venipuncture.
- Continuations of projects that do not fall into the above categories, and have been previously subject to the Full Review process by the IRB, which has determined that the research involved poses not more than minimal risk, and no additional risks have been identified.

5.2.4 Criteria for Convened/Full Review If ANY of these apply:

- The research involves as subjects prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults, including economically or educationally disadvantaged persons.
- The research involves the collection or recording of behavior, which, if known 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.
- The research involves the collection of information regarding sensitive aspects of the subjects' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).
- The procedures of the research involve more than minimal risk to the subject (where "more than minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the proposed research is greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests).
- Any research that does not fall into any of the categories explicitly identified as qualifying for exempt or expedited status.

5.3 Review Process

All research proposals are submitted through the [Utica College online IRB application](#).

The IRB Coordinator reviews the application for missing or unclear information. The IRB coordinator works with the PI to prepare the application for official IRB review. The IRB coordinator then routes the application to the IRB chair with a recommendation for type of review.

The IRB Chair then determines if the review will be exempt, expedited/delegated, or convened/full board.

Under the expedited review process, members of the IRB selected by the Coordinator will review the proposal. Under full review, all members of the IRB will receive a link to review and/or post comments and decisions. Members may request to discuss the application at the next scheduled IRB meeting.

For all research proposals, official written (e-mail) IRB approval is necessary before data collection can begin.

5.4 Proposal Review Timeline and Deadlines

As a committee, the IRB meets on a regular basis during the academic year. The IRB attempts to review proposals in a timely manner. The full IRB meets every month, providing there is a need to meet. Specific IRB meeting dates change each semester and are listed on the IRB website. Investigators whose proposals are exempt from review will be notified about exempt status within two weeks after the IRB Coordinator receives the proposal.

5.5 Review Outcomes

Researchers will be notified in writing as to the outcome of the review. The possible outcomes are as follows:

- **Approved:** No further action is required from the investigator prior to initiating the study.
- **Approval with Conditions:** If minor changes are requested by the IRB, the principal investigator will write a memo to the Coordinator indicating that such changes were made. The memo will be uploaded and attached to the original application.
- **Returned for Revisions:** In order to fully protect subjects, changes have been identified by the IRB and must be addressed in writing before the study activities may begin. The IRB Coordinator will summarize the changes and communicate those in writing to the investigator. Every effort will be made to have the resubmission reviewed by the members who originally read the proposal and provided initial feedback. Once the proposal has been re-reviewed, the Chair will communicate with the investigator as to the outcome of the review (approved, approval pending, revise and resubmit, or denied).
- **Denied:** The proposed research, due to the benefit to risk ratio and/or ethical concerns, cannot be initiated.

5.6 Review of Continuing Research

IRB-approved research that is continuing or has been changed must be re-reviewed by the IRB at least annually depending on level of risk. Approximately one month prior to the year anniversary of the IRB approval date, the investigator will be sent a letter regarding the need for [Continuing Review](#) (see Appendix I). The investigator is expected to complete the Review of Continuing Research form and submit it to the IRB Coordinator by the date indicated in the notice letter. The continuing review will be designated as exempt, expedited, or full and will be subjected to the review process delineated above. Continuing review is required for all proposals.

If the scope of the research changes or deviates from the description originally provided to the IRB, investigators must submit a [Modifications to Approved IRB Protocol form](#) to the IRB Coordinator describing such changes. The changes will be reviewed under the exempt, expedited, or full review process.

Failure to comply with the Continuing Review process can result in suspension or termination of IRB approval for the project.

After a proposal is underway, investigators must promptly report to the IRB Chair any unanticipated problems or adverse events that pose risks to subjects or others.

Complaints/Questions/Concerns: Questions, complaints, or concerns regarding compliance with UC's IRB Policy and Procedures should be directed to the Chair.

5.7 Research Approved by IRBs at Other Institutions

UC faculty and/or student research that has been approved by an IRB at another institution where the data collection will occur under the auspices of that institution does not require additional review by UC's IRB. Principal investigators of such research are required to submit the protocol and official IRB approval to the IRB Coordinator. Research approved at another institution that utilizes UC community members as subjects does require IRB review according to the procedures described herein.

5.7 IRB Appeals Process

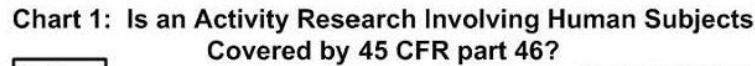
The decision of the IRB may be appealed. The principal investigator(s) initiates the appeal in writing to the Chair of the IRB. The investigator may submit information pertinent to the proposal and may request a meeting with the IRB. The IRB may request additional information relevant to the proposal from either the investigator or others. The appeal will be considered by the full IRB and the decision will be determined by the majority vote of all voting members of the IRB.

Appendices

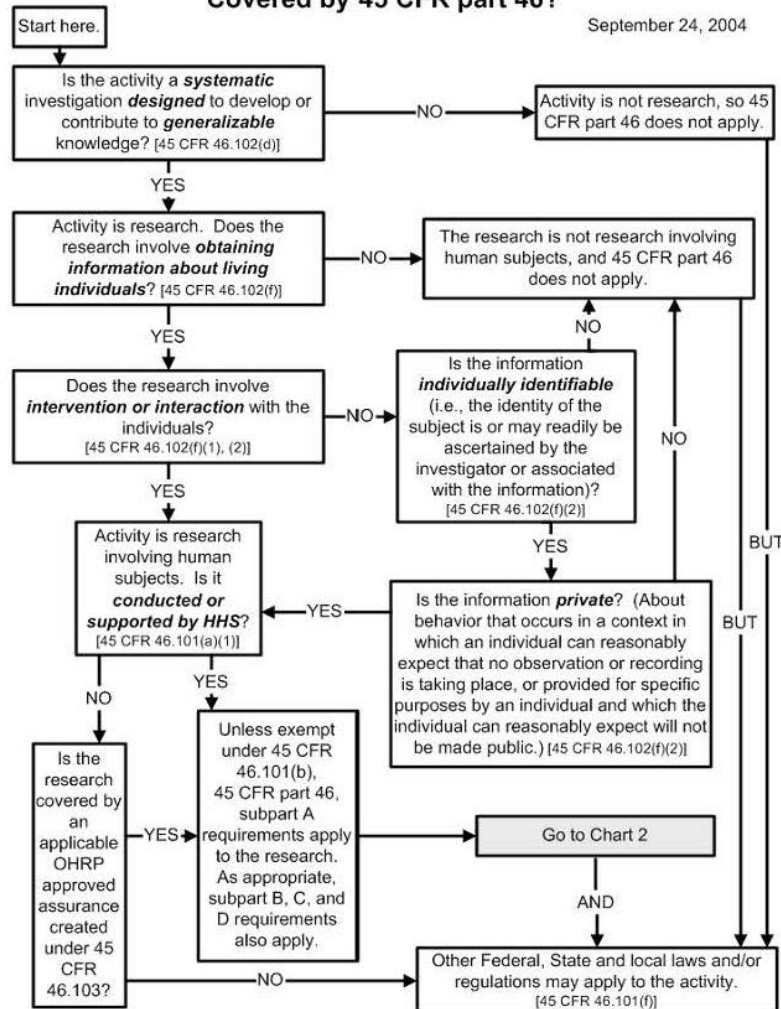
Appendix A – Chart 1

Human Subject Regulations Decision Charts

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



September 24, 2004



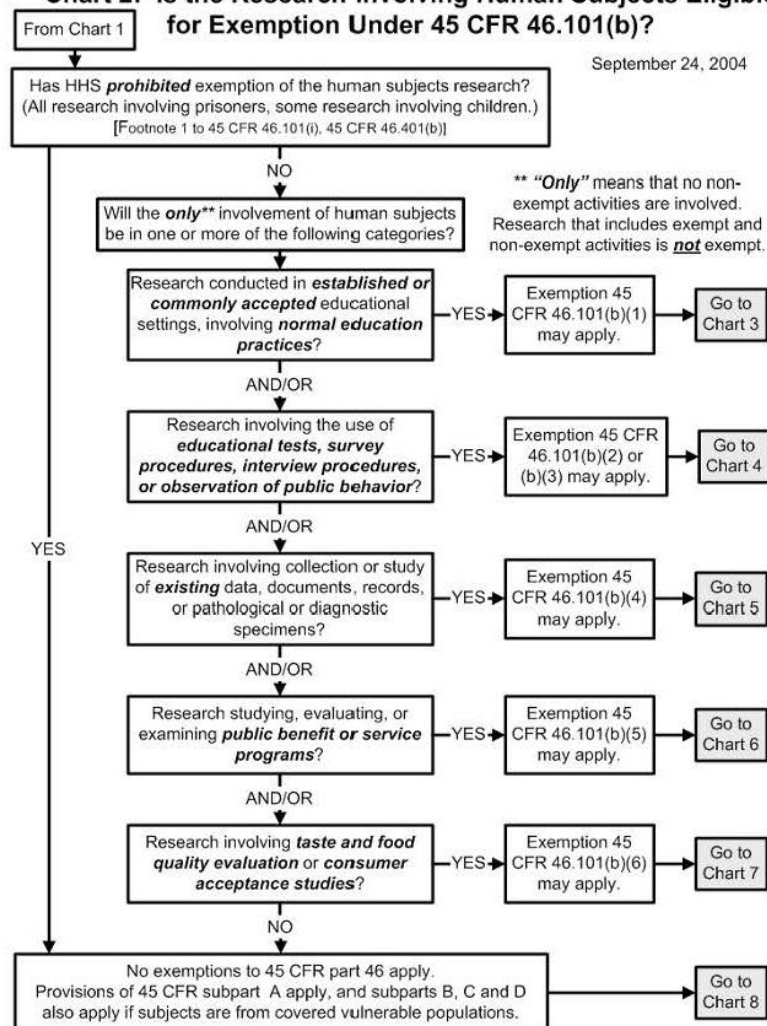
Appendix B – Chart 2

Human Subject Regulations Decision Charts

<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)?

September 24, 2004

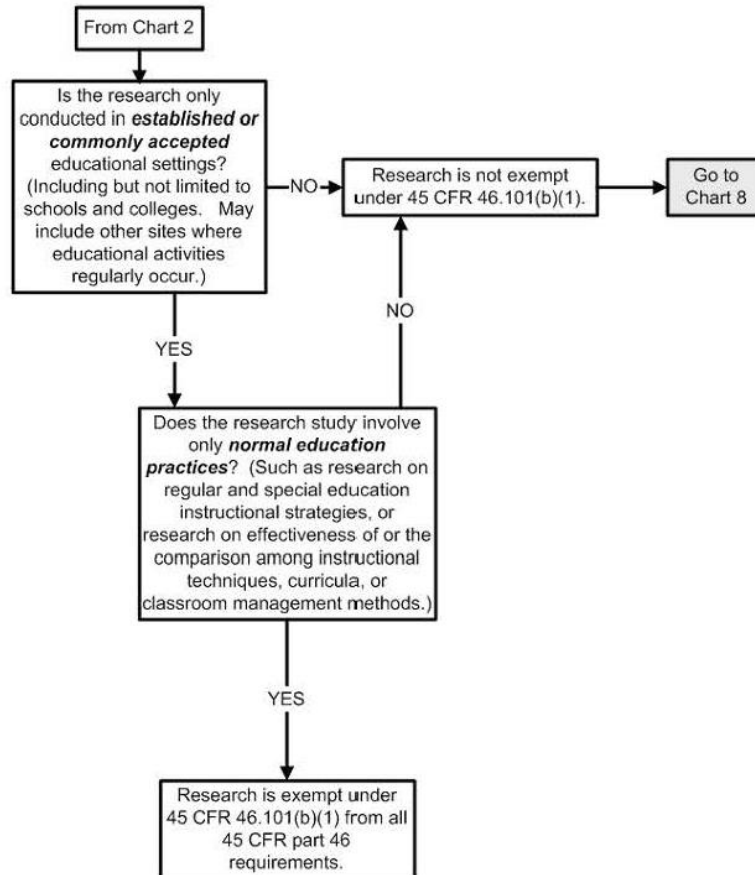


Appendix C – Chart 3

Human Subject Regulations Decision Charts

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

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

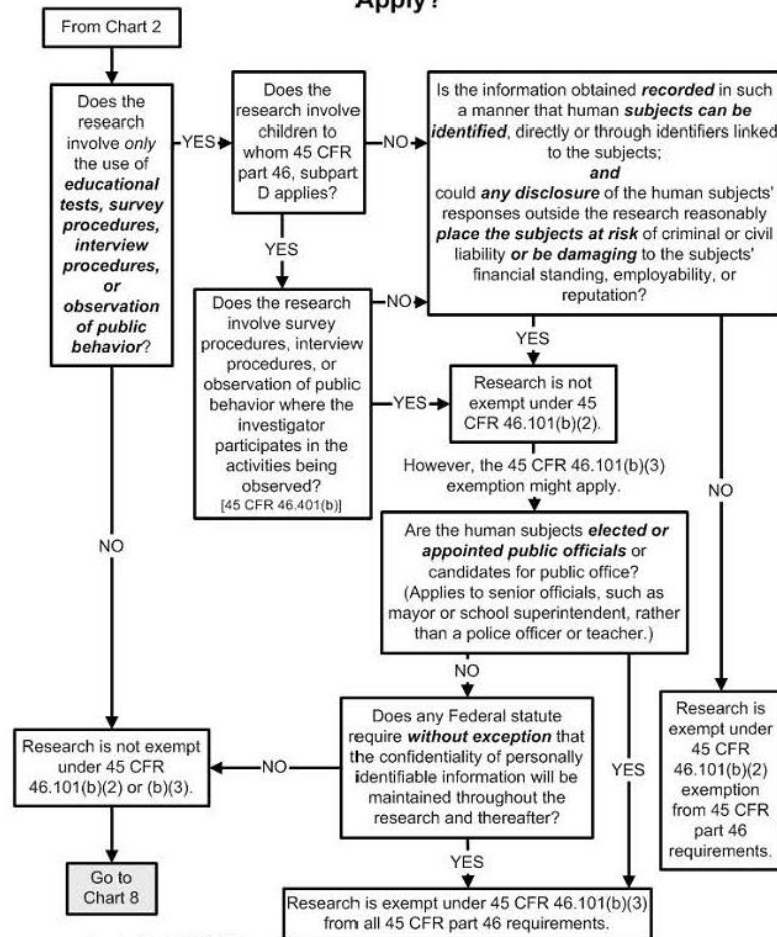


Appendix D – Chart 4

Human Subject Regulations Decision Charts

<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?**



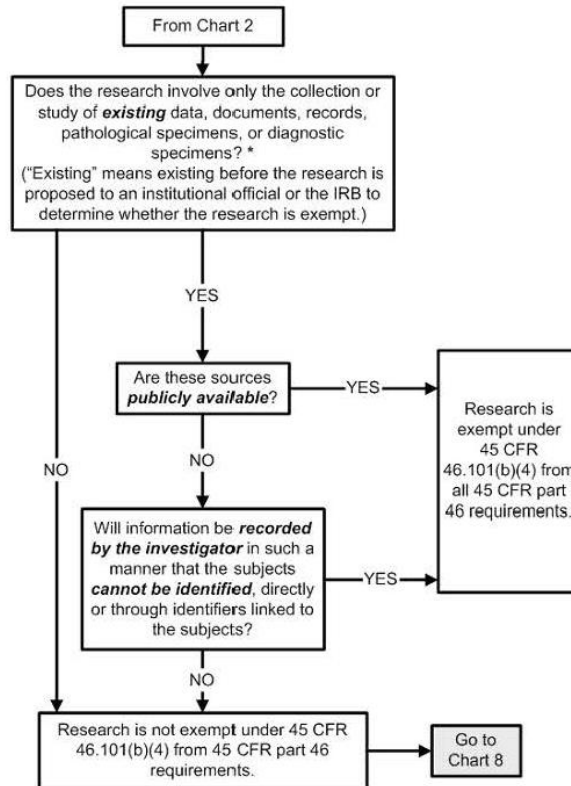
September 24, 2004

Appendix E – Chart 5

Human Subject Regulations Decision Charts

<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.

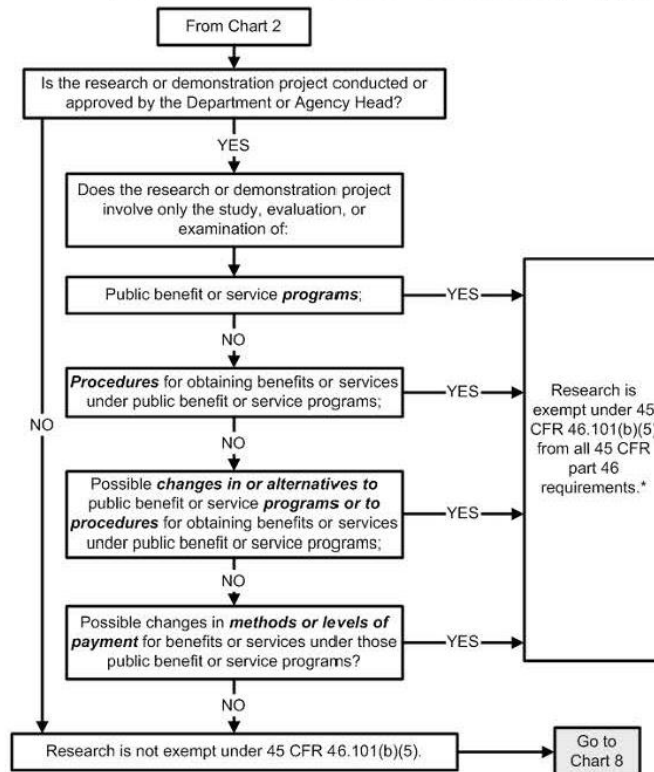
September 24, 2004

Appendix F – Chart 6

Human Subject Regulations Decision Charts

<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.

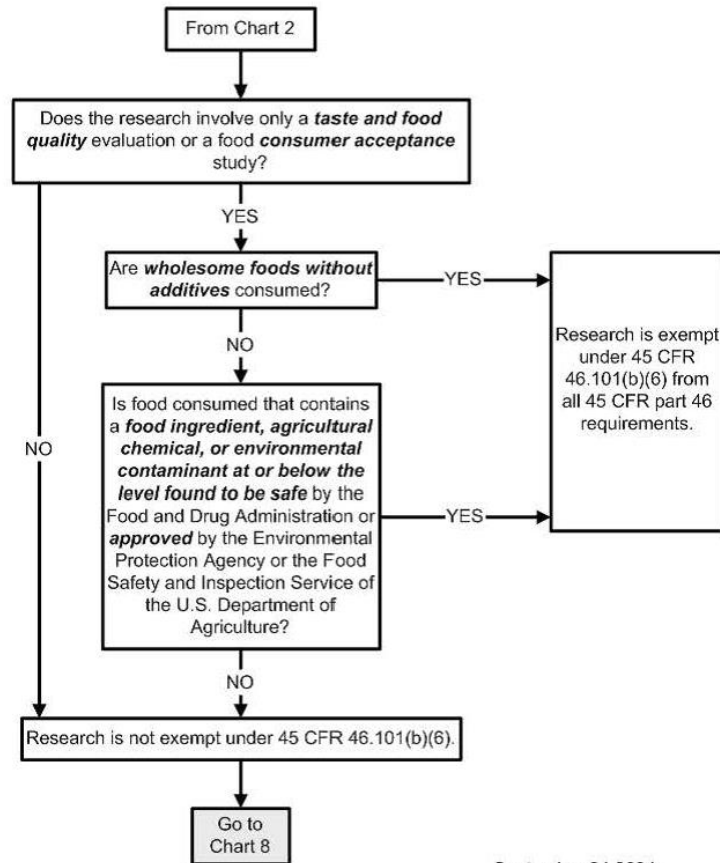
September 24, 2004

Appendix G – Chart 7

Human Subject Regulations Decision Charts

<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?**



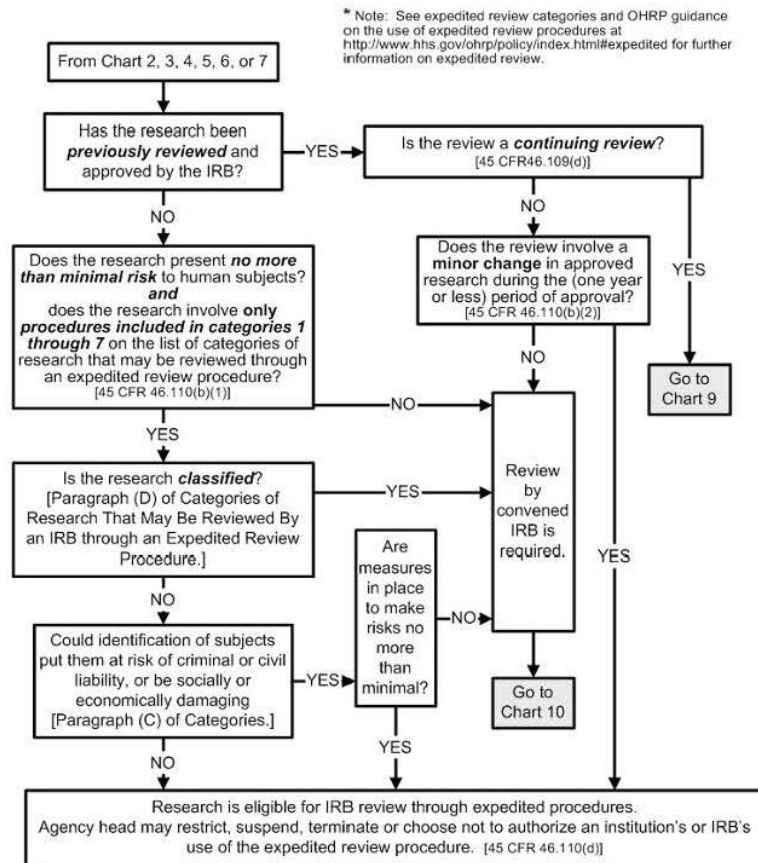
September 24 2004

Appendix H – Chart 8

Human Subject Regulations Decision Charts

<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?*



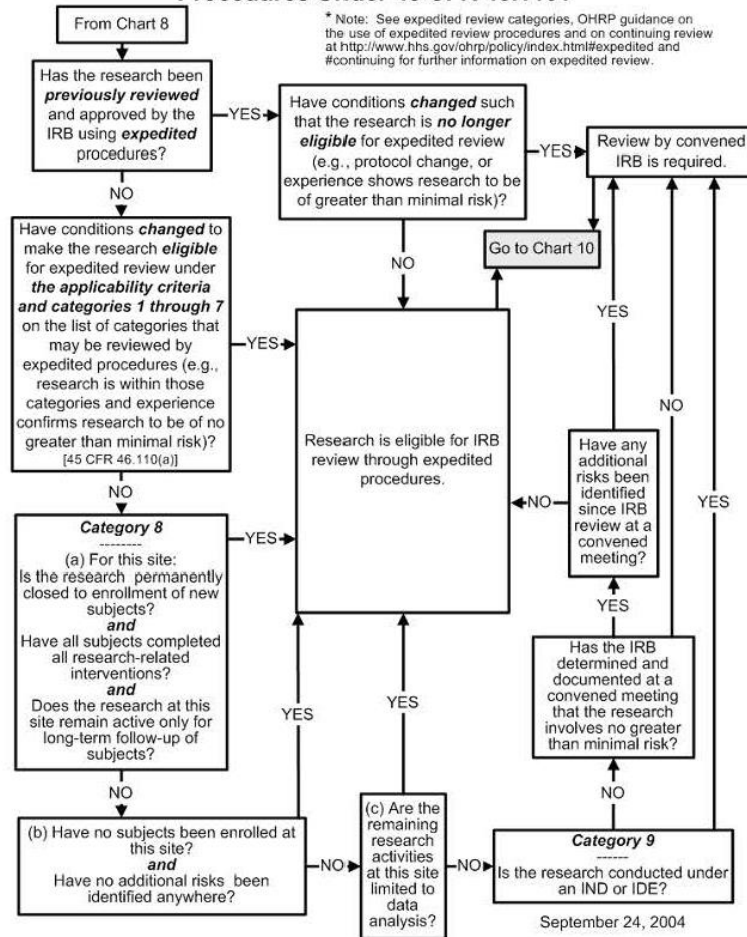
September 24, 2004

Appendix I – Chart 9

Human Subject Regulations Decision Charts

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

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



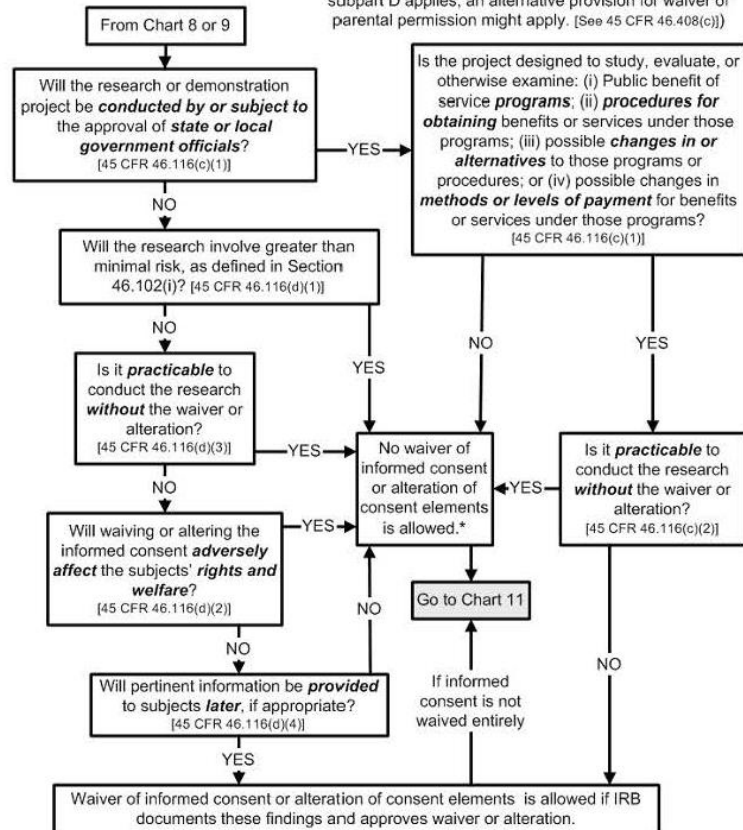
Appendix J – Chart 10

Human Subject Regulations Decision Charts

<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.

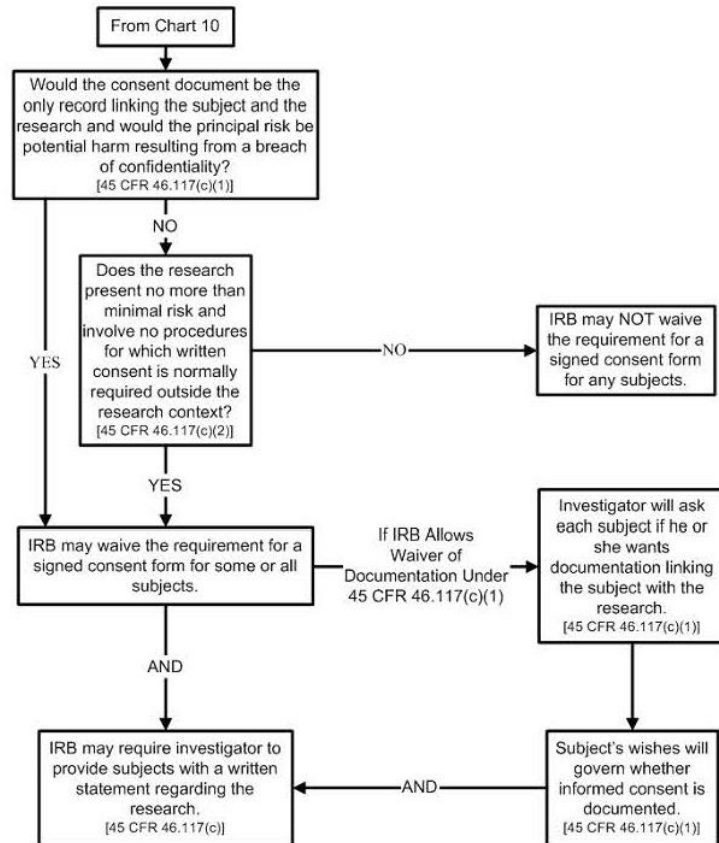
September 24, 2004

Appendix K – Chart 11

Human Subject Regulations Decision Charts

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

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



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