UNIVERSITY OF MEDICINE AND HEALTH SCIENCES

POLICIES AND PROCEDURES

FOR THE

REVIEW OF RESEARCH INVOLVING HUMAN SUBJECTS

This manual is believed to be in full compliance with all applicable U.S. and St. Kitts-Nevis Federal laws and regulations. Revisions will be issued from time to time that reflect changes in federal and state laws and regulations and changes in University procedures, which experience shows to be needed or desirable. Comments from users of this manual are welcome and will be given full consideration in the preparation of revisions and changes in procedures for the review of research involving human subjects. Please forward your comments to the IRB chairperson care of the Dean of Basic Sciences.

TABLE OF CONTENTS

A. STATEMENT OF PRINCIPLES

The University of Medicine and Health Sciences is committed to protecting the rights and welfare of human subjects in research. All activities related to human subjects research will be guided by the ethical principles in the Belmont Report and applicable U.S. and St. Kitts-Nevis Federal laws and regulations. The University of Medicine and Health Sciences IRB supports human subjects research with no or minimal harm, good consent processes, no deception or debriefed deception, confidentiality or anonymity and the use of fairly chosen participants who can refuse to participate if they choose so as to minimize the risks of injury to human subjects and maximum protection for the rights and welfare of subjects.

B. INTRODUCTION

Pursuant to the U.S. National Research Act (P.L. 93-348§212a) and 45 CFR 46.103, University of Medicine and Health Sciences (UMHS) of St Kitts maintains an Institutional Review Board (IRB) and has created written policy to govern its actions. At UMHS, the IRB is charged with assuring the protection of the rights and welfare of human subjects participating in research. Therefore, the IRB is required to review all research involving human subjects prior to the conducting of any research. This manual has been prepared to assist all members of the university community in complying with the stated policy and procedures of the institution regarding research involving human subjects. Appendixes contain forms, instructions, and other guidelines to assist the researcher, the various academic departments and other units of UMHS, and the IRB in carrying out the review process.

B.1 General Distribution of Responsibility

Any undertaking in which an UMHS faculty member, staff member, or student investigates or collects information on living humans for research or related activities may be considered as "involving human subjects." It is the responsibility of each investigator to seek review by the IRB for any study involving human subjects prior to beginning the project.

UMHS's IRB is responsible for the review of research or related activities involving human subjects. The respective authorities and duties of the IRB are described in this policy manual.

Consistent with U.S. federal regulations, the Research Committee Chairperson (UMHS' equivalent of a chief research officer) appoints members to the IRB.

The IRB administrator is responsible for managing the application review process, record keeping and reporting, and research training.

B.2 Abbreviations and Definitions Used in Policy and Procedures

U.S. Federal regulations and university policy use the following abbreviations:

CFR	Code of Federal Regulations
DHHS	Department of Health and Human Services – U.S.
EAP	Executive, Administrative, and Professional staff

FDA	Food and Drug Administration – U.S.
IRB	Institutional Review Board
IERC	Interim Ethics Review Committee – St. Kitts-Nevis Ministry of Health
OHRP	Office for Human Research Protection
PI	Principal Investigator
RCC	Research Committee Chairperson
UMHS	University of Medicine and Health Sciences

U.S. and St. Kitts-Nevis federal regulations, the World Medical Association Declaration of Helsinki and University policy define various terms in regard to protection of human research subjects. 45 CFR 46 is the body of regulations promulgated by DHHS. Most projects at UMHS fall under these regulations. 45 CFR 46 includes the following definitions:

B.2.1 Definitions used by the U.S. Department of Health and Human Services

(1) *Department or Agency* 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.

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

(3) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains (a) data through intervention or interaction with the individual, or (b) identifiable private information.

- Intervention includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes (e.g., cognitive experiment).
- Interaction includes communication or interpersonal contact between investigator and human subject (e.g., a telephone interview).
- *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 he or she can reasonably expect will not be made public (e.g., 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.

(4) *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.

(5) *Vulnerable population* means children, prisoners, pregnant women, mentally disabled persons, economically or educationally disadvantaged persons, individuals who are unable to give informed consent due to a physical or mental condition, or individuals whose circumstances may make them especially vulnerable to coercion (e.g., probationers).

(6) *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 that provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. Prisoners receive additional protections under 45 CFR 46, Subpart C.

(7) *Child* means a person who has not yet attained the age of consent to treatments or procedures involved in the research, under the applicable laws of the jurisdiction in which the research will be conducted. Children receive additional protections under 45 CFR 46, Subpart D.

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

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

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

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

(12) *Adverse effect* means an undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention (*e.g*., subject becomes upset following completion of a depression questionnaire, subject experiences intestinal bleeding associated with aspirin therapy) that is directly or indirectly due to participation in a research study.

Some studies may fall under the regulations promulgated by the FDA (21 CFR 50). These will generally be studies that involve the testing of an investigational medication or a medical device. Refer to 21 CFR 50 for specific definitions regarding these studies. Some FDA definitions differ from the above DHHS definitions.

B.2.2 Definitions used by University of Medicine and Health Sciences

In addition to definitions promulgated by U.S. federal agencies, UMHS policy uses the following definitions:

(1) *IRB Administrator* is the individual who has administrative responsibilities for the IRB.

(2) *Principal Investigator* is the person who leads the project and is ultimately responsible for all aspects of it. On most projects, the term has the same meaning as "project director."

(3) *Student project* means a study in which a student investigator (individually or as part of a group) gathers or analyzes information in a systematic manner, primarily for pedagogical purposes. It is not intended to contribute to generalizable knowledge and is not to be published (including publication on the Internet), presented, or archived. Research conducted for a master's thesis or doctoral dissertation does not fall under this definition.

(4) *Institutional research* is a study conducted by UMHS staff that is designed to obtain information to assist in the administration of the university. Institutional research provides information for administrative planning, policy making, decision making, and includes examinations of institutional effectiveness. It is not intended to produce generalizable knowledge.

(5) *Training* refers to a process approved by UMHS, and required by U.S. federal regulations, to instruct investigators in the conduct of research involving human subjects.

B.3 General Information on Submitting Materials to the IRB

PIs should submit their application packet directly to the IRB chairperson for review by the IRB. A new application consists of Form A, including answers to all research description questions; Form B (exempt research checklist) or Form C (expedited review research categories), if applicable; and the research grant proposal, if the PI is seeking funding or has received funding. Similarly, any submissions after IRB approval, including modification requests (Form D), continuation requests (Form E), adverse event written reports (Form F) and completion of research activities (Form G) should be submitted to the IRB administrator. Refer to Appendix 1 for more information on submission materials and for copies of the forms. The IRB chairperson will forward the materials to the IRB vice chairperson, or designated IRB member who will determine the level of review required. The IRB chairperson, vice chairperson, or designated IRB member will correspond directly with the PI regarding the submission. Correspondence of the PI regarding revisions to the submission materials or questions may be directed to the IRB chairperson, vice chairperson, or designated IRB member and may be conducted through e-mail.

Reports of adverse events must be reported immediately via phone or e-mail to the IRB chairperson or vice chairperson. A written report of the adverse event, using Form F, must then be submitted to the IRB chairperson within 5 working days after first awareness of the problem. Refer to Section G for more information.

C. RESPONSIBILITIES AND ACTIONS OF THE INSTITUTIONAL REVIEW BOARD

C.1 Composition of the IRB and Appointment of Members

U.S. federal regulations require that the IRB must be composed of at least five members (45 CFR 46.107). At UMHS, the IRB shall also be composed of seven (7) to eight (8) members plus one or two (1-2) alternates. The IRB administrator may serve as an ex-officio member without vote. Representation will include: (a) at least two members whose primary concerns are in scientific areas, such that both social and behavioral sciences and biomedical sciences are represented; (b) at least one member whose primary concerns are in non-scientific areas; and (c) a community representative who is not otherwise affiliated with UMHS nor a member of the immediate family of an UMHS employee. One member or alternate will be on the administrative staff of the Ministry of Education of the Government of St. Kitts-Nevis. One member or alternate must be able to act as an advocate for children, by virtue of experience and education. These advocates may be the same individual or different individuals. In addition, the membership shall include men and women, as well as representation of racial and ethnic minority groups. All IRB members and alternates shall serve three-year terms, which are staggered, and they may be reappointed for consecutive terms.

If a member goes on sabbatical or other leave for a semester, then an alternate will take his or her place. If a member or alternate leaves the university or goes on leave for one year or more, then the RCC will appoint a replacement for the period of leave or for the remainder of the member or alternate's term, whichever is applicable.

The IRB chairperson will be appointed by the Dean of Basic Sciences. He or she will serve a three-year term with each year being a renewable contract between the individual and the Dean of Basic Sciences, and he or she may be reappointed for consecutive terms. Similarly, the IRB vice chairperson will be appointed by the Dean of Basic Sciences with input from the chairperson. He or she will serve a three-year term with each year being a renewable contract between the individual and the Dean of Basic Sciences, and he or she may be reappointed for consecutive terms. If either the IRB chairperson or vice chairperson takes a sabbatical, other leave of absence, or leaves the university, the Dean of Basic Sciences may appoint a replacement for the period of leave or for the remainder of the chairperson's or vice chairperson's term, or appoint a new chairperson or vice chairperson for a three-year term.

The current membership list is kept on file by the IRB administrator, and is open to inspection by any employee or student of UMHS. Additionally, a current membership list is posted on the UMHS website.

C.2 Responsibilities and Actions of the IRB Chairperson

The following actions are the responsibility of the chairperson of the IRB. He or she shall have the administrative and clerical assistance of the IRB administrator or an individual designated by the IRB administrator in carrying out these duties:

- Call each regular meeting of the IRB and provide copies of review materials and other items of business to each board member at least 5 working days before the meeting.

- Maintain records of all IRB proceedings, applications, and approved projects. Approved project files will be maintained for the period required by the funding agency, if applicable. In any case, records shall be maintained for at least three years from the date of termination of the project. Records will be maintained in a secure location with access limited to the IRB administrator and associated staff, the RCC and IRB members and alternates.
- Provide advice and counsel on behalf of the IRB to those requesting assistance with the preparation of applications; those requesting information about the protection of human research subjects; and to those inquiring about the policies, procedures, and actions of the IRB.
- Send each PI a letter informing him or her of the IRB's decision and actions after initial, continuation, modification, adverse event review, or upon any other action taken by the IRB.
- Oversee initial training and continuing instruction of IRB members, the IRB administrator, university administrators, and any other personnel for whom federal regulations and UMHS policy requires training regarding policies and procedures;
- Notify the RCC of IRB actions regarding applications (approved, disapproved, pending, and withdrawn). The notification will be provided each semester and in writing, with a copy to the IRB administrator. Notification will include: IRB action, application title, the IRB file number, the funding agency project or application number (if applicable), and the subject risk level (e.g., no more than minimal risk, more than minimal risk).
- Notify the IRB, IRB administrator, RCC and IERC of any unanticipated injuries or problems involving risks to subjects or others, any serious or continuing noncompliance with the regulations or requirements of the IRB, and any suspension or termination of IRB approval of research.
- Notify the IRB at its regularly scheduled meetings of all findings of expedited review procedures, and granting of exemptions.
- Monitor changes in U.S. federal guidelines and St. Kitts-Nevis laws (quarterly contact with St. Kitts-Nevis Attorney General), and alert the RCC if written policies and procedures need to be revised.
- Delegate to the vice chairperson or another IRB member or alternate any new applications, continuation requests, modification requests, or adverse event reports that are submitted by members of the chairperson's department or are projects in which the chairperson is involved.
- Delegate to the vice chairperson other duties and responsibilities as appropriate.
- When the chairperson is unavailable, the vice chairperson assumes the responsibilities of the chairperson.

C.3 Meetings and Quorums

A quorum is required to convene a meeting of the IRB. A quorum consists of at least a majority of members (or their alternates) present at the meeting, either in person or via a conference call. At least one member or alternate who is a nonscientist must be present at the meeting. When members or alternates are associated with a project being reviewed, they are ineligible to vote on the project, however, the IRB may ask them to provide information about the project or they make excuse themselves from the meeting during the review. Conflicts of interest should be noted in the IRB meeting minutes. Should the quorum fail during a meeting (e.g., loss of a majority through recusal of members with conflicting interests, early departures, absence of a nonscientist member or alternate), the IRB may not take further actions or votes until the quorum is restored. Alternate members of the board may be invited to each meeting and may participate in the discussion of agenda items, including reviews, although if they are not serving in a member's place, they are not be eligible to vote.

The chairperson will convene meetings of the board for review of new applications, modification requests, continuation requests, and suspension or termination of IRB approval. The meeting schedule shall be posted on the IRB website.

C.4 Functions and Operations of the IRB

- Conduct initial and continuing review of research with human subjects and report the findings and actions to the PI in writing;
- Determine which projects require more than an annual review and which projects require verification (from sources other than the investigators) that no material changes have occurred since the previous IRB review. Considerations used to make these determinations include the absolute risk to the subject, whether the risks outweigh the benefits, and prior conduct of the investigator(s) regarding the protection of human research subjects.
- Review proposed changes in research activities to insure that the protection of human research subjects is maintained.
- Investigate any actual or suspected adverse event or incident of noncompliance.
- Observe project activities at any point to ascertain whether human subject protections are implemented so as to reduce the likelihood of an adverse event or noncompliance.

C.5 Review of Research

In conducting the review of research, the IRB shall follow the regulations stated in 45 CFR 46.109 and outlined in Section F of UMHS Policies and Procedures for the Review of Research Involving Human Subjects.

C.6 Approval of Research

Requirements to be met for approval are listed in the Reviewer Checklist in Appendix 2. These requirements are described in 45 CFR 46.111. In order to approve research covered by stated regulations, the IRB shall determine that all of these requirements have been met.

C.7 Actions and Authority of the IRB

Action on any of the options listed below requires a majority vote of the quorum. Action to require revision of an application includes the option of empowering the chairperson, vice chairperson, or designated IRB member to accept revisions on behalf of the IRB or to require reconsideration of the application as revised at a subsequent meeting.

C.7.1 Actions Regarding Approval of Applications

The IRB may reach any of the following determinations with respect to any proposed project:

- Approve application as submitted.
- Approve pending changes. The IRB determines the changes that are required for approval and these are communicated in writing to the PI. The PI submits the changes to the IRB chairperson. The chairperson, vice chairperson, or designated IRB member may approve the application on

behalf of the IRB if the changes meet the requirements described in the written communication with the PI.

- Require modifications and resubmission to the IRB.
- Request consultant review. At any point, the IRB chairperson, vice chairperson, or the IRB may determine that someone not on the IRB with relevant expertise needs to be consulted to address research issues, as they relate to the protection of human research subjects. The consultant shall not be involved in the proposed project. In some cases, the identity of the consultant may need to remain confidential if there is any question that there could be problems should the PI know the identity of the consultant.
- Disapprove the application as submitted: When a project is disapproved, the PI may revise the proposal in accordance with IRB recommendations; discuss the project with the IRB chairperson or respond in writing; or withdraw the proposal application.

C.7.2 Additional Actions and Authority of the IRB

- Consult with the RCC concerning matters of development and implementation of policies and procedures regarding the protection of human subjects and the training of UMHS employees and students regarding the conduct of research involving human subjects.
- Suspend or terminate approval of research that is not being conducted in accordance with the requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a written statement of the reasons for the IRB's action and shall be reported promptly to the RCC and the funding agency (if applicable).

D. RESPONSIBILITIES AND ACTIONS OF THE RESEARCH COMMITTEE CHAIRPERSON

D.1 Administrative Responsibilities of the RCC

Administrative procedures and actions of the RCC include, but are not limited to the following:

- Designate one or more IRBs for which sufficient provision has been made for staff and space needs in order to support the IRB's functions;
- Appoint members and alternates to the IRB;
- Appoint the IRB chairperson and vice chairperson;
- Review research approved by the IRB in accordance with 45 CFR 46.112;
- Provide that research covered by the regulations will be reviewed, approved, and subjected to continuing review by the IRB;
- Ensure prompt reporting to the IRB, IRB administrator, appropriate university officials, and any sponsoring federal department or agency head of any unanticipated injuries or problems involving risks to subjects or others, any serious or continuing noncompliance with the regulations or requirements of the IRB, and any suspension or termination of IRB approval of research;
- Disseminate a statement of principles governing the institution in the discharging of its responsibilities in protection of the rights and welfare of human research subjects to the IERC;
- Provide of a list of IRB members to the Dean of Basic Sciences and IERC.

D.2 Actions of the RCC upon Receipt of Notice of IRB Action from the Chairperson

- For externally funded projects approved by the IRB, the RCC, if he or she also approves the project for submission, will complete any documentation required by the funding agency, and send the documentation to the proper agency.
- The RCC may review, approve, or disapprove research that has been reviewed and approved by the IRB. The RCC may not approve research covered by these regulations that has not been approved by the IRB (45 CFR 46.112).
- If the RCC does not also approve projects approved by IRB, he or she will notify the IRB and the PI in writing of his or her action and of necessary subsequent action by the PI.
- Records of these actions will become part of the project file maintained by the IRB.

D.3 Revisions of Policies and Procedures

- The RCC, in consultation with the IRB, may institute any changes of policy and procedure for the review of research involving human subjects as may be consistent with currently applicable regulations, institutional requirements, and IRB experience. As changes occur in 45 CFR 46 and applicable portions of 21 CFR 50 or to St. Kitts-Nevis research-related laws, they will be included in UMHS policy and procedures by reference, without requiring separate action by the RCC. When DHHS issues new or revised policies or procedures, the IRB chairperson will consult with the IRB and draft a recommendation to the RCC regarding adoption.
- Additionally, the RCC shall determine the appropriate method of dissemination of policy and procedural changes to the UMHS community.

E. RESPONSIBILITIES AND ACTIONS OF THE IRB ADMINISTRATOR

The IRB administrator will be designated by the RCC. The following actions are the responsibility of the IRB administrator:

- Retain copies of pertinent federal (U.S. & St. Kitts-Nevis) regulations, policies and guidelines related to the involvement of human subjects, as well as UMHS's policies and procedures;
- Serve as an ex-officio member, without vote, on the IRB;
- Arrange and oversee the training program for IRB members, IRB alternates, PIs, faculty, staff, and students on the ethical conduct of research involving human subjects;
- Disseminate changes to the IRB policy and procedures to members of the UMHS community;
- Report necessary updates of the IRB website to the UMHS Information Technology Department and ensure that these updates are made in a timely manner;
- Prepare and distribute meeting packets and agendas;
- Maintain records of IRB proceedings and decisions;
- Receive submissions from PIs and forward the submissions to the IRB chairperson, vice chairperson, or designated IRB member;
- Maintain filing system of submissions to the IRB;
- Maintain a log containing new applications, modification requests, adverse event reports, continuation requests, and completion reports;
- Send each PI Form E, as a reminder that a continuing request is needed, no less than 6 weeks before the expiration of IRB approval of the protocol;
- Ensure that IRB records are being maintained appropriately and that records are accessible upon request, to authorized federal officials;
- Ensure all cooperating research sites in federally supported research have appropriate government assurances and provide certification of IRB approval of proposed research to the appropriate federal department or agency;
- Report to the IRB, RCC, and appropriate institutional officials any unanticipated injuries or problems involving risks to subjects or others, any serious or continuing noncompliance with the regulations or requirements of the IRB, and any suspension or termination of IRB approval of research; and
- Maintain a current master copy of UMHS policy, will provide a copy of any changes in UMHS policy to all IRB members and alternates.

F. RESPONSIBILITIES AND RIGHTS OF THE PRINCIPAL INVESTIGATOR

F.1 Responsibilities

The PI has primary responsibility for all aspects of the protection of human subjects on a given project, including:

- Consult with IRB chairperson if unsure whether a study meets the definition of research with human subjects.
- Submit applications for review and approval prior to initiating research, and in accordance with Section F of UMHS policy.
- When a full review is required, attend the IRB meeting at which the application is reviewed, in accordance with Section F of UMHS policy.
- Conduct the study in accordance with the ethical standards described in the Belmont Report, federal regulations, UMHS policy, and the protocol as approved by the IRB.
- Begin research activities only after written approval by the IRB. If the research is administered to an individual in an emergency or other situation before the study begins, the individual may not be considered a subject in the research. If the project involves new drugs or devices, FDA requirements must be satisfied.
- If changes are needed in an approved protocol, submit the proper application to modify the protocol and wait to receive written approval before implementing any changes.
- Submit requests for continuing review in accordance with the timeframe established by the IRB at the time of approval of the protocol.
- Report any unanticipated risks, physical or psychological harm, or other problems to the IRB chairperson or vice chairperson immediately upon becoming aware of them, in accordance with Section G of UMHS Policy.
- Report to the IRB when the research project is completed (see Section F of UMHS Policy). Retain signed informed consent forms and research materials for at least three years after the completion of the research project. Some funding agencies may have different retention requirements, and the PI is responsible for understanding and complying with those policies.
- Make accessible all records for inspection and copying by a designated IRB member or the department or agency supporting the research.
- Keep certification for all investigators current regarding training to conduct research with human subjects, as required in Section N of UMHS's policy.

F.2 Rights

- Applications shall be reviewed by the IRB in accordance with the ethical principles described in the Belmont Report, federal regulations, and UMHS policy.
- When protocols are submitted, the IRB shall review the application in a timely manner as specified in the policy, barring any unforeseen and insurmountable problems.
- All decisions of the IRB shall be conveyed to the PI in writing.
- The PI may consult with the IRB chairperson or vice chairperson if he or she is unclear about the rationale for its decisions or if any questions arise at any time.

F.3 Responsibilities of the PI upon Leaving UMHS

When a PI plans to leave UMHS and continue the research activities at another institution, he or she must notify the IRB in writing. This will allow the IRB to close the active research file. The PI is responsible for obtaining IRB approval at the new institution. If the research project will continue at UMHS under another investigator, the PI must submit Form D, and the IRB will follow the review guidelines set forth in this policy.

G. PROCESS FOR IRB REVIEW AND APPROVAL OF RESEARCH

G.1 Levels of Review

This section describes the three possible levels of IRB review for studies that involve human research subjects.

G.1.1 Exemption Certification Review

G.1.1.1 New Application

Research activities in which the involvement of human subjects constitutes no more than minimal risk and falls within one or more of the exemption categories described in 45 CFR 46.101 (see Form B) may be eligible for exemption certification. The PI may request that the research application receive exemption certification by submitting Form B with his or her application. Only the IRB may certify that the proposed research meets the exemption criteria. Exempt review is conducted by the IRB chairperson or vice chairperson, or a designated IRB member who will verify level of review through the categories listed in form B (exempt research checklist) and consider the issues delineated in the reviewer checklist (Appendix 2), the informed consent information (Appendix 3), and local context issues. If the IRB chairperson is involved with the study or if the PI and IRB chairperson are from the same department or program, the IRB chairperson will designate the vice chairperson or another IRB member, who is not involved with the project or from the same department, to review the study for exemption certification. Similarly, if the IRB vice chairperson is unable to review the study because he or she is involved in the project or from the same department as the PI, the IRB chairperson or another IRB member will review the study for exemption certification. The PI may expect written notification of the status of the project (i.e., certified, additional information or modifications needed, or denial of exemption certification) within 10 working days of receipt of the research application by the IRB administrator.

The IRB chairperson, IRB vice chairperson, or designated IRB member may take one of the following actions:

- Certify the research project as exempt and requiring no further IRB review, unless modifications are proposed which are outside the exemption categories. The PI is sent an exemption certification letter.
- Require additional information or modification(s). The IRB chairperson, IRB vice chairperson, or designated IRB member will contact the PI in writing to request the required additional information or modification(s). If the IRB chairperson, IRB vice chairperson, or designated IRB member is satisfied that the protocol meets the exemption criteria, the research project is certified as exempt and an exemption certification letter is sent to the PI.
- Deny exemption certification. If the protocol does not fall within one or more of the exemption categories, as deemed by the IRB chairperson, IRB vice chairperson, or designated IRB member, the application is considered for expedited or full review.

G.1.1.2 Modification Request

If a study is certified as exempt, the PI must request approval for any proposed modifications (see Form D) to the research project's protocol or informed consent or assent forms that do not fall within the exemption categories. The modifications must be approved by the IRB prior to implementation.

G.1.1.3 Continuation Request

Once a study is certified as exempt, continuation reviews are not required.

G.1.2 Expedited Review

G.1.2.1 New application

Research activities in which the involvement of human subjects involves no more than minimal risk and falls within one or more of the expedited review categories (see Form C) may be eligible for expedited review. The PI may request that the research application receive expedited review by submitting Form C with his or her application. Only the IRB may decide whether the proposed research meets the expedited review criteria requirements. Expedited review is conducted by the IRB chairperson or vice chairperson, and a designated IRB member who will verify level of review through the categories listed in form C (expedited review research checklist) and consider the issues delineated in the reviewer checklist (Appendix 2), the informed consent information (Appendix 3), and local context issues. If there is a conflict of interest for both the chairperson and vice chairperson, two designated IRB members will conduct the review. Prior to sending the application for review by the second IRB member, the IRB chairperson, IRB vice chairperson, or designated IRB member may ask the PI to make revisions to the protocol or informed consent procedures. The PI should expect notification that revisions are required prior to the second review, the application has been sent to a second reviewer, or the application needs full review within 10 working days of receipt of the new application by the IRB. Once the revisions, if needed, are received, the revised application will be sent to the second reviewer, and the PI may expect notification of the status of his or her project within 10 working days. The reviewers may exercise all of the authorities of the IRB, except they may not disapprove the research application.

Under the expedited review process, the reviewers may take one of the following actions:

- Approve the research application and decide on the length of time the study is approved (one year or less). The PI is sent a letter of approval and the informed consent or assent form with the IRB approval validation stamp. (See Section J.1 for more information about the validation stamp.)
- Require additional information or modifications. The IRB chairperson, IRB vice chairperson, or a designated IRB member will contact the PI in writing to request the required additional information or modification(s). The reviewers may decide that one or both of them need to review the additional information or modifications. If the reviewers are satisfied that the protocol meets the IRB review criteria, the research project is approved for one year or less and a letter of approval is sent to the PI.
- Require a full review of the application. If the protocol does not fall within one or more of the expedited review categories, the reviewers have concerns about the rights and welfare of the subjects, or the additional information or modifications are extensive, the reviewers will forward the application for a full review. The PI will be notified in writing that a full review is required and will be informed of the reasons for this decision. Additionally, the PI may be asked to revise the application prior to distribution of the application to the full IRB committee.

G.1.2.2 Modification Request

The PI must request approval for any proposed modifications to the research project's protocol or informed consent or assent forms. The modifications must be approved by the IRB prior to implementation.

Modification requests to the protocol or informed consent or assent forms for research projects that were previously approved through the expedited review process may be reviewed under the expedited review process. The PI will submit Form D for review. For minor modifications that do not change the substance of the project, the level of risk to the subjects, or the level of review required, the IRB chairperson, vice chairperson, or a designated IRB member may conduct the review. For more than minor modifications, the review process is the same as for a new application. The timeline is the same as for a new application. The reviewers may take one of the following actions:

- Approve the requested modifications. The PI is sent a letter of approval of the requested modifications.
- Require additional information or modifications. The IRB chairperson, IRB vice chairperson, or designated IRB member will contact the PI in writing to request the required additional information or modification(s). The reviewers may decide that one or both of them need to review the additional information or modifications. If the reviewers are satisfied that the requested modifications meet the IRB review criteria, the modifications are approved and a letter of approval is sent to the PI.
- Require a full review of the modification request. If the modifications change the study protocol such that the study no longer falls within one or more of the expedited review categories, the reviewers have concerns about the rights and welfare of the subjects, or the additional information or modifications are extensive, the reviewers will forward the modification request for a full review. The PI will be notified in writing that a full review by the IRB is required and will be informed of the reasons for this decision. Additionally, the PI may be asked to revise the modification request prior to distribution of the modification request to the full IRB.

G.1.2.3 Continuation Request

Research projects, which are approved under the expedited review process, will require continuation review at a specified interval, which will not exceed one year.

A continuation request for a research project that was approved under expedited review procedures may be reviewed under the expedited review process. The PI will submit Form E. The IRB chairperson, IRB vice chairperson, or a designated IRB member will verify the appropriate level of review for the continuation request, and will inform the PI in writing or via e-mail if a full review is needed. For continuation requests without proposed modifications or with only minor modifications that do not change the substance of the project, the level of risk to subjects, or the level of review required, the IRB chairperson, IRB vice chairperson, or a designated IRB member may conduct the review. For continuation requests with more than minor modifications proposed, the expedited review process, timeline, and review actions are the same as for a new application.

If the PI fails to request a continuation or submit requested information, IRB approval will be terminated on the approval expiration date. All research activities, including data analysis, must cease, unless the IRB finds it is in the best interest of the individual subjects to continue participating in the research interventions or interactions. A notification letter will be sent by the IRB chairperson or vice chairperson to the PI and, if appropriate, the funding agency.

G.1.2.4 Completion of Research

For a completed research project that has undergone expedited review, the PI must submit Form G on or before the IRB approval expiration date. This will allow the IRB to close the active file. The IRB administrator will send Form G at least 6 weeks prior to expiration of IRB approval.

G.1.2.5 Informing IRB members of Expedited Reviews

At each regular IRB meeting, the IRB chairperson will provide the IRB with a list of new research applications, modification requests, and continuation requests that have been submitted or approved through the expedited review process.

G.1.3 Full Review

G.1.3.1 New application

Research activities in which the involvement of human subjects involves more than minimal risk does not fall within one or more of the exemption categories (Form B) or expedited review categories (see Form C), or involves certain vulnerable populations (e.g., children) must undergo a full IRB review. Prior to distribution to the IRB members, the IRB chairperson, IRB vice chairperson, or a designated IRB member will review the application and may ask the PI to make revisions to the protocol or informed consent procedures. Once revisions, if needed, are received, a full review will be scheduled for the next regular IRB meeting or a special meeting may be called. The application materials will be distributed to the IRB members at least 5 working days before the meeting. The PI must attend the meeting in which his or her application will be reviewed. If the PI is a student, the faculty sponsor must attend, and the IRB strongly recommends that the student attend, as well.

A schedule of the IRB meetings, along with submission deadlines for new applications, modification requests, and continuation requests requiring full review, is posted on the IRB website. The PI is responsible for submitting the required materials to the IRB administrator, care of OSP, by the deadline, typically 10 working days prior to a scheduled meeting. Submission of materials by the deadline does not guarantee the full review will be conducted at the next meeting. Reasons for delaying review until the next meeting may include an already full agenda or the protocol requires revisions prior to review. Therefore, the IRB recommends that the PI submit the materials as early as possible.

Under the full review process, the IRB will discuss issues delineated in the reviewer checklist (Appendix 2) and the informed consent form information (Appendix 3), as well as issues related to the local context. The IRB may take one of the following three actions:

- Approve the research application and decide on the length of time the study is approved (one year or less from the date of the convened meeting at which the IRB reviewed and approved the proposal). The PI is sent a letter of approval and the informed consent or assent form with the "IRB approval" validation stamp. See Section J.1 for more information about the validation stamp.
- Require additional information or modifications. During the IRB meeting, the IRB members may ask the PI for additional information. If the PI does not have the additional information available at the meeting, the PI will forward this information, in writing, to the IRB chairperson or IRB vice chairperson, as soon as possible. Additionally, the IRB may require that modifications be made. At the conclusion of the review, the IRB will decide whether:
    - The IRB chairperson, IRB vice chairperson, or designated member may review the additional information or modifications to ensure that they meet the IRB requirements

and approve the application, if appropriate. If the additional information or modifications are not sufficient, the IRB chairperson, IRB vice chairperson, or designated IRB member may continue to work individually with the PI until the IRB requirements are met. The IRB may require that the additional information or modifications be reviewed at the next IRB meeting. The PI would again need to be present at the meeting.

- Disapprove the research application. The PI is sent a letter describing the reasons the research application was not approved. The PI may revise the research application in accordance with IRB recommendations; discuss the reasons for disapproval with the IRB chairperson or a designated IRB member; or withdraw the research application.

G.1.3.2 Modification Request

The PI must request approval for any proposed modifications to the research project's protocol or informed consent or assent forms. The modifications must be approved by the IRB prior to implementation.

Modification requests to the protocol or informed consent or assent forms for research projects that were previously approved through the full review process may be reviewed under the expedited review process if the requested modifications are minor (see Modification Request under the discussion of Expedited Reviews, above), otherwise, a full review process will be used. The PI will submit Form D and the IRB chairperson, IRB vice chairperson, or a designated IRB member will decide the appropriate level of review for the modification request. The PI will be informed of the level of review required. For modification requests, which can be reviewed under the expedited review process, see the modification request section (Section F.1.2.1) under expedited review process (Section F.1.2). For modification requests that require a full review, prior to distribution to the IRB members the IRB chairperson or a designated IRB member will review the application and may ask the PI to make revisions to the protocol or informed consent procedures. Once revisions, if needed, are received, a full review will be scheduled for the next regular IRB meeting or a special meeting may be called. The modification request will be distributed to the IRB members at least 5 working days before the meeting. The PI must attend the meeting in which his or her modification request will be reviewed. If the PI is a student, the faculty sponsor must attend, and the IRB strongly recommends that the student attend, as well.

The IRB may take one of the following actions:

- Approve the requested modifications. The PI is sent a letter of approval of the requested modifications. If the modifications involve the informed consent or assent form, the revised informed consent or assent form will also be sent with the "IRB approval" validation stamp placed on the form.
- Require additional information or modifications. During the IRB meeting, the IRB members may ask the PI for additional information. If the PI does not have the additional information, the PI will forward this information, in writing, to the IRB chairperson or IRB vice chairperson. Additionally, the IRB may require that modifications be made. At the conclusion of the review, the IRB will decide whether:
    - The IRB chairperson, IRB vice chairperson, or designated IRB member may review the additional information or modifications to ensure they meet the IRB requirements and approve the application, if appropriate. If the additional information or modifications are not sufficient, the IRB chairperson, IRB vice chairperson, or designated IRB member

may continue to work individually with the PI until the IRB requirements are met or request that the IRB continue its review at the next meeting, or
    - The IRB should require that the additional information or modifications be reviewed at the next IRB meeting. The PI would again need to be present at the meeting.
- Disapprove the modification request. The PI is sent a letter describing the reasons the modification request was not approved. The PI may revise the modification request in accordance with IRB recommendations; discuss the reasons for disapproval with the IRB chairperson, IRB vice chairperson, or designated IRB member; or withdraw the modification request.

G.1.3.3 Continuation Request

Research projects that are approved under the full review process will require continuation review at a specified interval, which will not exceed one year.

A continuation request for a research project that was approved under the full review procedures may be reviewed under the expedited review process if the research project meets the requirements listed in Form C; otherwise a full review will be required. The PI will submit Form E and the IRB chairperson, IRB vice chairperson, or a designated IRB member will decide the appropriate level of review for the continuation request. The PI will be informed of the level of review required. For expedited reviews, see Continuation Review in Section F.1.2.2 under Expedited Review (Section F.1.2). For full reviews, the review process and review actions are the same as for a new application.

If the PI fails to request a continuation or submit requested information, IRB approval will be terminated on the approval expiration date. All research activities, including data analysis, must cease unless the IRB finds it is in the best interest of the individual research subjects to continue participating in the research interventions or interactions. A notification letter will be sent to the PI and, if appropriate, the funding agency.

G.2 Length of IRB Approval

Typically, the IRB approves a research study or continuation request for one year. However, approval may be granted for less than one year in some circumstances, which may include, but are not limited to, high-risk protocols, projects involving unusual types of risk to subjects, projects involving vulnerable subjects (e.g., children), and projects conducted by a PI who has previously failed to comply with IRB requirements.

G.3 Verification of Sources other than the PI

Some projects may require verification from sources other than the PIs that no material changes have occurred since previous IRB review. The criteria for determining which studies may need outside verification include, but are not limited to complex projects involving unusual levels or types of risk to subjects; projects conducted by PIs who previously failed to comply with 45 CFR 46 or the requirements or determinations of the IRB; and projects where concern about possible material changes occurring without IRB approval have been raised based on information provided in continuing review reports or from other sources.

G.4 Preparation of Public Use Data Files

Many funding agencies require or recommend that projects produce public use data files. If the PI knows that a public use data file will be created, he or she must indicate this on the initial application (Form A). Once the project is completed, the PI shall submit the proposed public use data file to the IRB for inspection. The funding agency may provide guidance in creation of public use files. The PI should provide this information to the IRB when submitting the protocol to prepare a public use data file. If the PI does not initially plan to develop a public use data file, once the determination to develop a public use data file is made, he or she will need to submit a modification request to the IRB.

For the IRB to classify the file as a public use data file, one of the two following situations must apply:

- The data were anonymous when originally collected or data were collected from unknown persons.
- The data were collected from identified persons, but the file has been stripped of individual identifiers and any other information that may risk disclosure of any subject's identity (e.g., date of birth).

When data have been collected from identified persons, the PI must consider the following elements in determining whether he or she has properly addressed the risk of disclosure of subjects' identity:

- All individual identifiers of each human research subject or any person named by any human research subject must be removed
- All variables that can be surrogates for individual identifiers (e.g., street address of subject) must be removed.
- To remove the possibility of identification when a human research subject is in a small subgroup within the sample, it may be necessary to collapse or combine categories of a variable. For example, detailed breakdowns of religious denomination in a survey question, ICD-9 codes, or medical procedure codes may need to be collapsed into fewer categories.
- Delete or mask, as described above, any variable that a secondary user may employ to identify any research subject. For example, the PI may need to assign a new subject ID to each individual if the original subject ID contained identifying information, such as letters from the last name or part of the date of birth.
- Use statistical methods to add random variation to variables that cannot otherwise be masked. For example, a data file may contain a combination of public and private information on a relatively small sample, perhaps demographic characteristics and salary of a public official, along with attitudinal information. The income variable may need to be altered so that it cannot be combined with the demographic characteristics to enable identifying the individual and thereby risking disclosure of private information. This option should be used only if other techniques do not work, because it may compromise the integrity of the data.

UMHS may post on the OSP website information regarding two types of public use data files: (1) a list of all data files created by UMHS investigators that have been certified for public use, and (2) a list of approved sources of publicly available data. The purpose of the first list is to allow investigators at other universities or organizations to be informed that the UMHS IRB has certified that a specific data file is a public use data file, even if it is available from another source (e.g., ICPSR). The primary purpose of the second list is to inform UMHS investigators that any data file obtained from these sources is certified as a public use data file and thus does not require IRB review.

H. PROBLEMS INVOLVING RISK, ADVERSE EFFECTS, AND NONCOMPLIANCE

H.1 Guidelines for Defining Problems to be Reported

Unanticipated problems involving risks to subjects or others and adverse effects need to be reported to the IRB and IERC. Adverse effects may be directly or indirectly related to the research and may be expected or unexpected.

The following examples illustrate what needs to be reported:

Unanticipated problem involving risk to subjects: The laptop computer which has identifying information about research subjects is stolen.

Unanticipated problem involving risk to others: The research assistant involved in the project is inadvertently exposed to a low level of radiation.

Expected adverse effect: Subject A becomes upset when asked about feelings regarding prior sexual abuse. The subject is referred for counseling.

Unexpected adverse effect: Subject B becomes agitated and angry when asked general non-invasive questions about the appropriateness of corporal punishment of children. The subject is referred for counseling.

The last two scenarios are examples of direct effects. An example of an indirect effect is if Subject A or B misses class or work due to the psychological conditions described.

In general, the PI must report the following events to the IRB chairperson or IRB vice chairperson:

- Situations related to the protection of study data, such that there is an inadvertent breach of confidentiality
- Negative outcomes from unintentional or intentional deviations from research protocol or informed consent process (e.g., loss of privacy, loss of rights, damage to reputation, legal problems, academic failure)
- Unforeseeable events that occur during or after a research intervention, even if it is unclear whether they were actually caused by the intervention
- Known side effects of an intervention
- Allergic reactions (or other adverse reactions to medications, devices, or procedures)
- Complications from procedures (e.g., infection, abnormal EEG, psychological change)
- Complications from research-related tests (medical and psychological)
- Increase in seriousness of a primary condition or situation

H.2 Guidelines for Defining Noncompliance

Noncompliance includes, but is not limited to:

- Misuse or nonuse of approved informed consent forms or procedures
- Failure to submit protocols in a timely manner
- Breaking confidentiality, unless required by law (e.g., child abuse)

- Unapproved subject recruitment activities
- Failure to secure confidential records in the required manner
- Failure to report problems involving physical or psychological injury to subjects or others
- Failure to report risks to subjects or others that exceed the protocol as approved
- Report from a subject of abuse by the PI or research staff
- Conducting research involving human subjects that has never been approved by the IRB
- Initiating changes to research protocols involving human subjects without prior IRB approval
- Continuing research activities beyond the IRB approval expiration date

Even though these types of events must be reported, the PI is encouraged to contact the IRB chairperson or IRB vice chairperson if anything occurs that causes concern regarding the protection of human subjects.

H.3 Reporting of Problems or Noncompliance by the PI

The PI must contact the IRB chairperson or vice chairperson via phone or e-mail immediately following an incident of injury, increase in risk, unanticipated risk, other adverse effects experienced by subjects or others involved in research, or incident(s) of noncompliance. Additionally, the PI must submit Form F to the IRB administrator as soon as possible thereafter, but no later than 5 working days after first awareness of the problem. The report will be reviewed by the IRB chairperson, IRB vice chairperson, designated IRB member(s), or the full IRB. If the incident is severe or increases the risk to subjects or others, the PI may be asked to suspend research activities pending further review by the IRB or RCC.

H.4 Investigations of Problems and Noncompliance

If any member of the IRB receives information about injuries to subjects, unanticipated problems involving risk to subjects or others, or serious noncompliance, through a source other than the PI or co-PI, he or she will immediately inform the IRB chairperson or vice chairperson. The IRB chairperson or vice chairperson may temporarily suspend IRB approval for a study, pending investigation, after learning of the problem, adverse effect, or noncompliance.

The IRB chairperson or vice chairperson may conduct an informal inquiry into allegations of problems or noncompliance to make the determination whether an investigative subcommittee should be formed. If, based upon the level of risk to the research participants and the seriousness of the allegation, the decision is made that no formal investigation is necessary, the IRB chairperson or vice chairperson will provide a report to be filed with the confidential project records which details the allegation of problems, noncompliance, and any corrective actions. If, however, the determination is made that a formal investigation should be conducted, a subcommittee of the IRB consisting of the IRB chairperson or vice chairperson, an IRB member or alternate who is the community representative, and another IRB member, who holds tenure and is outside the PI's department, will investigate the allegation of a problem involving risk to subjects or others, an adverse effect, or noncompliance. The IRB chairperson or vice chairperson will request an interview with the individual(s) alleging the problem, adverse effect, or noncompliance, unless the allegation was received in writing. The IRB chairperson or vice chairperson will share the results of this interview or written correspondence with the other members of the ad hoc committee, and they will decide how to proceed. The IRB chairperson or vice chairperson will notify the PI in writing within 5 working days that an allegation of problem, adverse effect, or noncompliance was received. Following the interview or upon receipt of a written allegation, the IRB chairperson or vice chairperson will request an interview with the PI and any other researchers involved,

in order to assess the situation, require changes in the protocol, if necessary, and resolve the issues without further official action. The ad hoc committee members will decide if both need to be present at the interview with the PI and other researchers involved. If the ad hoc committee members are not satisfied with the results of the initial interview with the PI, they may expand the investigation. The ad hoc committee members may interview the research staff and any other persons who have relevant information, including research subjects. The ad hoc committee will produce written summaries to the interviewed parties for comments, and written comments received will be included in the record of the investigation.

The ad hoc committee will prepare a report which includes a description of the investigative activities, how and from whom information was obtained about the problem(s), a list of those interviewed, a summary of records obtained, finding, basis of findings, and actions taken. Before the report is shared with the IRB and RCC, identifying information which may put the individual making the allegation at risk may be removed. The final report, which contains all identifying information, will be filled with confidential project records.

Appropriate institutional officials, funding agency officials (if applicable) and IERC will be notified if problems are confirmed by the ad hoc committee.

H.5 Suspension or Termination of Approval of Research Activities

The IRB chairperson or vice chairperson may suspend a study at any point after receiving information regarding unacceptable and uncorrectable levels of risk or harm to the subjects or others or serious disregard on the part of the researcher to the policies and directives of the IRB. The chairperson or vice chairperson will promptly notify the PI(s), as well as the IRB administrator and RCC, in writing of this decision and the reason(s) for suspension of approval. The RCC will notify IERC and funding agencies (if applicable) of the suspension or termination of approval.

Furthermore, the IRB chairperson or vice chairperson will call a meeting of the IRB to discuss the suspension of IRB approval and the IRB will decide whether (1) IRB approval should be reinstated with or without modifications, (2) suspension of IRB approval should be continued, or (3) IRB approval should be terminated. The PI will be informed, in writing, of the outcome of the IRB meeting.

H.6 Reporting by UMHS/IUON of Problems or Noncompliance

The IRB chairperson or vice chairperson will keep the RCC informed of reports by PIs or others of unanticipated problems involving risk to subjects or others, adverse effects, serious or continuing noncompliance, and suspension or termination of IRB approval. The RCC will notify appropriate institutional officials, IERC and the Department or Agency head of the funding agency (if the study is funded) of unanticipated problems involving risk to subjects or others, unanticipated adverse effects, serious adverse effects that may have been expected, serious or continuing noncompliance, and the IRB suspension or termination of approval for research activities.

I. CONFLICTING INTERESTS

Several types of conflicting interests may arise in conducting research. Project personnel must report all such real or potential conflicts to the PI. The PI is responsible for making certain that no project personnel perform research tasks if there is likely to be a conflicting interest.

Conflicting interests apply to both funded and non-funded research. 45 CFR 46 does not directly address conflicts of interest, but the IRB is required to determine that information provided to potential and actual subjects regarding the research is objective regarding the risks and benefits. It is also required to determine whether risks of the research have been properly addressed in the protocol. If conflicting interests exist, then such objectivity and handling of risks can be compromised.

Such potential conflicting interests include, but are not necessarily limited to those discussed below.

I.1 Financial Conflict of Interest

Disclosure of any such conflicts must be made in writing. U.S. Federal policy covers Financial Conflicts of Interest in Research that is funded by DHHS, FDA, and NSF, among others.

The RCC has final responsibility to assure compliance with university policy and state and federal law regarding financial conflicts of interest.

I.2 Intellectual Property

All investigators must adhere to UMHS's policy regarding intellectual property claims (see the *University Handbook*).

I.3 Conflicts of Commitment

Conflicts of commitment arise when an investigator's time or other commitments to a project cannot be honored because of existing commitments to the university. All investigators must avoid such conflicts that may arise due to the conduct of a research project.

I.4 Dual Relationships

Dual relationships exist whenever one role of the investigator calls into question his or her ability to be objective about fulfillment of another role. While such dual relationships may involve financial conflicts of interest, many do not.

At UMHS, the most common situations are likely to be those in which faculty recruit students for research projects. Faculty must not recruit students from their classes, unless the IRB grants approval for doing so. See Section O of this policy for a more detailed discussion of students as research subjects.

J. COOPERATIVE RESEARCH

Cooperative research projects are those projects that involve more than one institution. The official relationship between the two institutions is not relevant. Each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with federal and institutional policies. See 45 CFR 46.114 for more information.

PI(s) at UMHS who are conducting research at another institution are required to abide by UMHS requirements, as well as the requirements of the other institution. The PI will need to request a letter of approval from other institution stating that the research may be conducted at the site and that those at the site agree to comply with UMHS's IRB requirement for the protection of human subjects. If the other institution has an IRB, the PI may be required to seek its approval as well, or file a request to designate one of the institutions' IRB to review the research (e.g., IRB authorization agreement). For studies funded by DHHS the PI is responsible for ensuring all data collection sites within the cooperative research protocol have an approved DHHS assurance (e.g., federal wide assurance), and each will review the research separately or designate one of the institutions' IRB to review the research (e.g., IRB authorization agreement).

When UMHS is considered to be "engaged in research" (see OHRP guidance document "Engagement of Institutions in Research," January 26, 1999) but the PI is not associated with UMHS, the PI must submit the following for review by the IRB: an application (Form A, and Forms B or C, if applicable), a letter of support from a faculty member or EAP staff member at UMHS who will sponsor the project, and a letter of approval from IRB of the institution where the individual is at, unless the individual's institution does not have an IRB. The IRB will then complete the appropriate review process, based on the nature of the research project. UMHS may choose to rely on the review of the PI's IRB, in which case both institutions would need to complete the IRB authorization agreement. When UMHS is not "engaged in the research," the unaffiliated PI needs to obtain IRB approval at his or her institution and secure permission from an UMHS official (e.g., department chairperson, dean, supervisor) to conduct the study at UMHS.

K. INFORMED CONSENT

K.1 Informed Consent Requirements

Informed consent is an ongoing process, not just a form that is signed. Informed consent assures that potential subjects understand the nature of the research project and their participation and can make an informed, voluntary decision about participating or not participating in a research study. The language used to present the information needs to be appropriate for the targeted subject population. Researchers should keep in mind that individuals have the right to participate or not participate in a study and those who decide to participate may withdraw their consent from the study at any time for any reason, without incurring negative consequences.

The process of obtaining informed consent must comply with the requirements of 45 CFR 46.116. Documentation of informed consent must comply with 45 CFR 46.117 and IERC requirements. Unless changes to the informed consent process are approved by the IRB, the PI is responsible for ensuring that informed consent is obtained in writing from the subject or the subject's legally authorized representative (e.g., parent), is understandable to the subject (or representative), is obtained in circumstances that are not coercive and that offer the subject (or representative) sufficient opportunity to decide whether he or she will participate. If any subjects are members of certain vulnerable populations, 45 CFR 46 Subpart B, Subpart C, and Subpart D describe additional informed consent requirements.

The informed consent form checklist in Appendix 3 delineates the basic elements that must be included in an informed consent form. The checklist also provides additional elements that may need to be included in the informed consent form, depending on the nature of the research study. The informed consent process and documents in research studies that involve health information may need to include statements that meet the requirements of Privacy Rule of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Section K.4 and Appendix 4). Informed consent forms should be written in second person (e.g., "You are invited to participate…"), with the exception of the signature section, which may be written in first person. Use of first person in the body of the informed consent may be interpreted as suggestive or coercive. The informed consent form may not include exculpatory language in which the subject or representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the PI, sponsor, or institution (or its agents) from liability for negligence. The person who signs the informed consent form must be given a copy as a reference.

Informed consent procedures must be delineated in the research description portion of the application to the IRB (Form A). Any waivers to the procedure or documentation must be requested, as well. For studies in which the documentation of informed consent is waived, a letter of invitation to participate, which includes the elements of informed consent, may be appropriate. Additionally, informed consent forms and assent forms, if applicable, must be submitted to the IRB for review. Once approved, the IRB will place an "IRB approval" validation stamp on the approved informed consent or assent form. The "IRB approval" validation stamp will contain the IRB number, the approval date and the expiration date. The IRB number and approval and expiration dates must appear on the informed consent document. The PI may use the copy with the IRB approval validation stamp for distribution to potential subjects or the PI may type the information (i.e., "IRB#…, Approval date…, Expiration date…*)* at the end of the informed consent form.

K.2 Alterations to the Informed Consent Procedure

U.S. Federal regulations on informed consent do allow for modifications in the consent procedures and, under certain circumstances, informed consent may be waived entirely if the research meets certain conditions [see 45 CFR 46.116(c)(d)]. Note that such modifications and waivers are not allowed under FDA regulations. See 45 CFR 46.116(c)(d) and Appendix 3 for more information.

K.3 Alterations in the Documentation of Informed Consent

Typically, informed consent must be documented through the use of a written informed consent form that has been approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy should be given to the individual signing the form. However, documentation of informed consent may be waived in some circumstances. See 45 CFR 46.117(c) and Appendix 3 for more information.

K.4 Research Involving Children

Research projects involving children as subjects typically require the written permission of one or both parents [see 45 CFR 46.408(b)] or guardian in accordance with the informed consent procedures delineated in the informed consent requirements (Section J.1). In addition to parental or guardian permission for a child to participate in a research study, the assent of the child may be solicited, assuming the child is capable of providing assent. To make this judgment, the IRB will consider the age, maturity, and psychological state of the targeted child population. Even if the children are capable of providing assent, the IRB may waive the assent requirement when consent requirements are waived (see CFR 46.116).

Typically, parental or guardian permission must be documented. However, a PI may request a waiver of the documentation of informed consent based on 45 CFR 46.117(c) (see Appendix 3 for information). Additionally, the IRB may determine that parental or guardian permission is not a reasonable requirement to protect subjects (e.g., neglected or abused children) and it may waive the consent requirements, provided that an appropriate mechanism for protecting the children who participate as subjects in the research is substituted and the waiver is not inconsistent with U.S. or St. Kitts-Nevis federal law [45 CFR 46.408(c)].

L. PROTECTION OF CONFIDENTIAL INFORMATION

The PI is responsible for ensuring the privacy and confidentiality of all personally identifiable information from research subjects, except as required by law (e.g., child abuse) or allowed with written permission of the research subject. This information may be contained in either electronic or hard copy formats. When appropriate, the informed consent document should outline those conditions under which data are not considered confidential (e.g., child abuse). Data collection and storage, and safeguards to ensure confidentiality must be delineated by the PI in the research description portion of the application to the IRB.

In the case that child abuse is found while conducting research, St. Kitts-Nevis' Probation & Child Welfare & Board Act (2013) under the Ministry of Social & Community Development requires that incidents are reported to Child Protection Services at (869) 467-1309 or (869) 467-1311 (M-F). After hours or weekend incidents should be reported to (869) 662-6833.

L.1 Storage and Retention of Confidential Records

The PI must store confidential hard copy information gathered from or about any research subject in a secure (locked) facility to which only the PI and authorized project staff have access. Electronic data shall be password-protected at the workstation or file level. If this level of protection is not feasible, electronic data should be stored on removable media.

Confidential information must not be stored at the study site (e.g., hospital, prison, school) unless the PI is assured in writing that no one outside of the study at the research site has access.

L.2 Access to Confidential Records

The university has the right of access to the supporting records for all research at the university or supported by university-sponsored funds, provided such access to the records shall be for reasonable cause, at reasonable times, and after reasonable notice. The university's right of access to the data shall continue regardless of the location of the responsible investigator. Information or data that would violate the confidentiality of sources or subjects involved in the research should not be disclosed. Extramural sponsors providing support for research at UMHS may also have the right to review the data and records resulting from that extramural support. Co-investigators and trainees who are an integral part of a research project have the right to review all records and data which are part of that project.

L.3 Other Regulations related to Privacy, Confidentiality, and Consent

In addition to 45 CFR 46 and FDA regulations (21 CFR 50), other federal regulations (U.S. and St. Kitts-Nevis) may apply to research involving human subjects.

L.3.1 Privacy Rule under the Health Insurance Portability and Accountability Act of 1996 (HIPAA)

The Privacy Rule, a U.S. Federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996, regulates the way covered entities handle individually identifiable health information known as protected health information (PHI). The Privacy Rule itself applies only to

covered entities, not to research itself; however, the Privacy Rule may affect researchers because it establishes the conditions under which covered entities can use or disclose PHI for research. UMHS is a hybrid entity, which means that some units are covered under HIPAA, while other units are not. The Privacy Rule does not directly regulate researchers who are engaged in research within units that are not part of the covered entities, even though they may gather, generate, access, and share personal health information. The Privacy Rule is in 45 CFR Part 160 and Subparts A and E of Part 164. Appendix 4 contains more detailed information related to the Privacy Rule. PIs planning to engage in physical or medical health related research that is covered under the Privacy Rule are advised to begin consultation with the covered entity early in the research design process.

L.3.2 Family Education Rights and Privacy Act

The Family Education Rights and Privacy Act (FERPA) is a U.S. federal law (20 U.S.C. § 1232g; 34 CFR Part 99) that applies to educational agencies and institutions that receive federal funds under any program administered by the Secretary of Education. FERPA gives parents certain rights with respect to their children's education records. These rights transfer to the student when he or she reaches age 18 or attends a postsecondary school. Students to whom the rights have been transferred are "eligible students." Generally, schools must have written permission from the parent or eligible student before releasing any identifiable information from a student's education record. The consent must specify the records that may be disclosed, state the purpose of the disclosure, and identify the party to whom the disclosure may be made. FERPA does, however, allow schools to disclose records to organization(s) conducting studies for, or on behalf of the school, in order to develop, validate, or administer predictive tests; administer student aid programs; or improve instruction. Additionally, schools may disclose, without consent, "directory" information, unless specifically directed by parents or eligible students not to disclose directory information about them. PIs are encouraged to consult with U.S. school early in the research design process regarding the need to obtain consent for educational records.

L.3.3 Protection of Pupil Rights Amendment

The Protection of Pupil Rights Amendment (PPRA) is a U.S. federal regulation (20 U.S.C. § 1232g; 34 CFR Part 99) that was amended by Congress in 2001 by the No Child Left Behind Act regulates survey research in schools. Schools and contractors must obtain prior written parental consent before minor students are required to participate in any U.S. Department of Education funded survey, analysis, or evaluation that reveals information concerning the following: political affiliations or beliefs of the student or the student's parent; mental and psychological problems of the student or the student's family; sex behavior or attitudes; illegal, anti-social, self-incriminating, or demeaning behavior; critical appraisals of other individuals with whom respondents have close family relationships; legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers; religious practices, affiliations, or beliefs of the student or student's parent; or income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program). Additionally, U.S. local educational agencies or institutions that receive funds under any program administered by the U.S. Department of Education are required to develop and adopt policies concerning parents' rights to inspect, upon request, any survey created by a third party before the survey is administered or distributed by a school to students and provide parents the opportunity to ask that their child not participate. PIs are encouraged to consult with the U.S. school early in the research design process regarding how PPRA may impact the research protocol.

M. INTERNET RESEARCH

Research using the Internet has unique characteristics that are not directly addressed by the Federal regulations. Currently, the Internet is used primarily for two research activities – recruitment of subjects and survey administration. Most human subjects protection issues that arise in conducting research activities on the Internet concern privacy and consent. For a thorough discussion of the pertinent issues, refer to "Ethical and Legal Aspects of Human Subjects Research on the Internet," prepared for DHHS by The American Association for the Advancement of Science (http://www.aaas.org/spp/dspp/sfrl/projects/intres/main.htm)

The ability to consent is difficult to ascertain over the Internet. Generally, this ability is related to age, but may be relevant to other vulnerable populations (e.g., decisionally impaired, incarcerated). Also, email-based activities are far less secure than website-based activities. Software exists to enhance the privacy of both types of activities. UMHS strongly recommends that researchers work with a vendor that specializes in Internet-based research to minimize risks in these areas.

Internet-based studies may not include minors as subjects unless the IRB waives written parental permission and informed consent.

Whether the purpose is recruitment, survey administration, or some other purpose, Internet-based materials must include the following items, to the extent applicable. These items are to be included in addition to all information that is normally required for informed consent:

1. email addresses of the investigator and IRB
2. no claim about the superiority, safety, or effectiveness of procedures, interventions, devices, or any other materials used in research;
3. a description of the process for completing the on-line research activity
4. information on subsequent contacts that will be made if the individual agrees to participate
5. no promise of anonymity
6. information regarding procedures for protection of information that the subject provides over the Internet
7. a statement that there will be no future email contacts or an opt-out message that permits individuals to have their names removed from any future mailings. If future contacts are planned, the information must state the number and frequency of such contacts.
8. instructions to delete the email message that originated the contact

After reading information about the study, the individual must be required click a button either to indicate his or her wish to continue or to leave the site and opt out of participation. After clicking the button, the subject will be taken via a link to the study task. If the individual opts out, clicking the button will exit the site.

Generally, Internet-based surveys do not require written documentation of consent. If the IRB does require such documentation, the following additional procedures must be used:

1. The "agree to participate" button must contain a message, or there must be a separate statement right above the button, that indicates that clicking the button means the subject has read the statement, printed a copy for his or her files, and agrees to participate in the study or be considered for recruitment for the study and accepts that personal information will be

electronically supplied to the researcher to document his or her participation (such as name, e-mail name, and date).
2. There must be a mechanism by which information is returned to the researcher that identifies the person who is participating. This documentation must be kept by the researcher for at least three years beyond the end of the study.

The following apply to all types of study materials:

1. Individuals must be able to easily print a readable copy of information about the study and the informed consent documentation (if required) for their own records.
2. The printed version of all information must carry the approval date and the date approval expires for the study as determined by the IRB. The researcher should replicate the text of the stamps on the electronic version of the study materials.
3. The IRB must be able to access the document on-line before approval will be given.

N. HUMAN SUBJECTS PROTECTION IN FIELD RESEARCH

Field research typically involves observation of and interaction with individuals and groups in their own environment, often over long periods of time. It also includes other types of generally qualitative activities that fall under the definition of research, such as interview conducted for historical or biographical research and archival research on identifiable living individuals. Interviews by journalists conducted solely for the purpose of writing an article in a newspaper, magazine, or other media outlet are not considered research and do not require IRB review.

It may not be possible to specify in an informed consent statement the detailed description of the research protocol, as the research itself may involve interactions between the researcher and subjects that evolve over time. Likewise, differences in language, culture, or the nature of the subjects or topic may preclude the use of a written informed consent document. If appropriate justification is given, the IRB may waive the requirement for some or all of the informed consent requirements or the requirement to obtain signed informed consent in certain situations; 45 CFR 46.116(c) and (d) describes the circumstances in which waiver is possible (also see Appendix 3 of this policy for more information). The investigator should request such a waiver if he or she determines that it is appropriate. The IRB will make the final determination.

Investigators conducting field research should consider guidelines developed by a relevant professional association, such as the American Anthropological Association, Association of Social Anthropologists of the UK and Commonwealth, the American Historical Association, or the American Sociological Association, when designing their protocols.

O. OTHER STUDIES INVOLVING HUMAN SUBJECTS

This section sets out policy for conducting other types of studies that include human subjects, but do not meet the US or St. Kitts-Nevis Federal definition of research.

O.1 Student Projects

Generally student research involving human subjects is either in the form of class projects or independent directed research projects. The type of review required is determined by whether the research projects are intended to contribute to generalizable knowledge. Student projects involving human subjects that fall into the following categories always require IRB review and approval or exemption certification, as described in previous sections of this policy.

- Projects undertaken with the intent of presenting findings at a conference (including UMHS or other university-affiliated research presentation venues)
- Projects undertaken with the intent of publication, including publication on the Internet.

Many courses include projects that are designed to train students in research methods such as anonymous surveys, oral histories, field work in cultural anthropology, clinical interns practicing diagnosis, and program evaluations conducted in connection with a student internship. Many independent directed research projects may have these same goals. While these projects do not normally require IRB review, they are subject to faculty oversight.

Class projects and independent directed research projects not designed to contribute to generalizable knowledge do not require IRB review unless the proposed research places the subjects at more than minimal risk, usually evidenced by one or more of the following:

- Subjects are members of a vulnerable population (as defined in UMHS policy).
- The study asks identifiable subjects about illegal activities (e.g., underage drinking), which may place the data at risk of subpoena.
- The study places identifiable subjects at risk of a breach of confidentiality that may lead to criminal or civil liability, or damage the subject's financial standing, employability, or reputation [45 CFR 46.109(b)(3)].
- The study places subjects at more than minimal risk due to psychologically sensitive subject matter (e.g., interviews covering traumatic events).

O.1.2 Sponsor Responsibilities in Student Projects

All student projects must have an UMHS faculty or EAP staff sponsor. For class projects, this is usually the instructor. The instructor should supervise the student researcher sufficiently to assure the protection of human research subjects in accordance with ethical standards of the relevant discipline.

All faculty members or EAP staffs who supervise any type of student project using human subjects must be trained in accordance with UMHS policy.

The instructor is responsible for determining whether the proposed study is designed to contribute to generalizable knowledge and is subject to IRB review. If so, the instructor (i.e., faculty sponsor) must assist the student in preparing the application for review.

Even though IRB review may not be required for most student projects, these projects must communicate applicable elements of informed consent (e.g., institutional affiliation of researcher, risk, benefit, voluntary participation, permission to withdraw, etc.) and include appropriate anonymity and confidentiality protections.

Before conducting research, students must be taught about the ethics of conducting research with human subjects. Instruction should, at a minimum, include information on the purpose of the IRB, the informed consent process, and the principles set forth in the *Belmont Report*. The instructor may require the student to complete the training program described in Section N. The IRB advocates that departments use this training program in research methods courses as the mechanism to insure that students have been properly instructed in the protection of human research subjects.

The instructor must investigate any problem reported by the student. If any harm to a subject has occurred, the instructor must report in writing to the IRB immediately and have the student cease research activities until a decision is made regarding continuation of the project.

O.1.3 Student Researcher Responsibilities

Students must conduct only the activities approved by the instructor. Activities must be conducted in accordance with the principles set forth in the *Belmont Report* and UMHS Policy.

Students must report to the instructor any problems that arise regarding human subjects.

O.2 Institutional Research

Data collected or studies conducted for purposes of providing information to the university, any unit within the university, or any other organization (e.g., accrediting agency), with the purpose of addressing issues deemed important to university operations is considered to be institutional research. Studies of this nature do not require IRB review. If information collected is intended for further dissemination, publication (including Internet), or involves more than minimal risk, it requires IRB review.

When IRB review is not required, institutional research projects or other activities must still communicate applicable elements of informed consent (e.g., purpose, risk, benefit, voluntary participation, permission to withdraw) and include appropriate anonymity and confidentiality protections.

O.3 Other Projects

The primary types of projects included in this category are program evaluation, policy analysis, or quality assurance studies conducted for the purpose of providing information only to the organization studied. Such studies do not require IRB review if they involve no more than minimal risk as defined in U.S. Federal regulations and UMHS policy and do not involve vulnerable populations.

Any such project conducted with the intent of further dissemination of results meets the definition of research according to federal and UMHS policy and requires IRB review.

When IRB review is not required, such projects must still communicate applicable elements of informed consent and include appropriate anonymity or confidentiality protections.

O.4 Publicly Available Data

Many private organizations and public agencies make individual level data available to the public. Such files fall outside the U.S. and St. Kitts federal regulations for the protection of human subjects, once they have been classified as public use data files. Not all publicly available data, however, has been classified as public use.

To classify files as public use, producers and suppliers of such files are responsible for having the data reviewed by the appropriate IRB before making them available to the public. Information to this effect should be indicated on the documentation supplied with the file.

PIs do not need to obtain IRB approval to use public use data files nor do they need to seek IRB review of the exemption status of the data. Where applicable, such information has already been reviewed for the protection of human subjects and the files produced have been certified not to violate confidentiality.

If an UMHS PI plans to obtain individually identifiable data (from the sponsor of the public use data file or any other source) and merge with the public use data file, the UMHS investigator must seek IRB approval.

If the public use status cannot be ascertained from the documentation supplied with the file, the UMHS PI must contact the supplier to ascertain the public use status of the data. If this status cannot be ascertained and provided to the PI in writing or if the data are not classifiable as "public use," then the UMHS PI must submit an application for IRB review. For example, this situation may occur when an investigator receives permission from a PI at another university to use data produced from a research project that is ongoing.

In addition to data files, any published hard copy or electronic documents (including web pages) available to the public that contain individual data (whether identifiable or not identifiable) fall outside U.S. and St. Kitts-Nevis federal regulations for the protection of human subjects. PIs do not need to obtain IRB approval to use such information nor do they need to seek IRB review of the exemption status of the data.

P. TRAINING

P.1 Who Must Be Trained?

UMHS requires certification for all IRB members and alternates, PIs, and co-PIs who conduct research involving human subjects. UMHS also requires renewal certification every three years on research with human subjects.

The training requirements discussed herein cover all funded and non-funded projects that include human subjects. This policy covers all proposed and ongoing projects submitted to the IRB for approval, regardless of the level of review required (i.e., full, expedited, exempt).

If any new investigator is added after the submission of the initial application or a continuation request, the PI must submit these names to the IRB administrator. These investigators must be trained before working with human research subjects. The IRB strongly recommends that the PI and co-PI provide the opportunity for all staff working on the research project to successfully complete the training.

P.2 When Training Must Occur

Training of all PIs and co-PIs must be completed before the project or renewal is approved.
In addition, funding agencies may require completion of training before funds are approved or released, and may have training requirements that exceed UMHS's. The PI is responsible for adhering to both UMHS's and the funding agency's training policies.

Initial certification is valid for three years. All investigators trained must renew certification every three years while working with human subjects. All IRB members and alternates must complete the certification when first appointed to the IRB; furthermore, they must participate in continuing education through IRB meeting activities.

No less than 30 days before the expiration of certification, the IRB administrator will inform individuals currently certified of the requirements for re-certification. Recertification of all investigators must occur before the IRB can renew approval of a project.

P.3 Training Procedures and Certification

Follow the training procedures described in Appendix 5.

Q. STUDENTS AS RESEARCH SUBJECTS

Students are often used as subjects in research studies, both by UMHS student, faculty, and staff researchers as well as researchers from other universities and organizations. Because of their unique position, UMHS policy addresses several issues pertaining to the use of students in research projects.

Q.1 Types of Activities Covered by this Section

Some course work involves research-type activities that serve an entirely pedagogical purpose. For example, professors may have students administer surveys or psychological instruments to each other in class so that they can practice interviewing techniques. These activities are not considered research, as defined by U.S. and St. Kitts-Nevis Federal regulations or this policy, do not require IRB review, and are not covered by this section. Projects in which students include other students in studies that are not designed for use beyond a course are not considered research as defined by U.S. and St. Kitts-Nevis federal regulations or this policy (e.g., administering a brief survey to students in the dining hall regarding food service). Although they are not covered in this section, these studies require review as set forth in Section M of this policy.

Research involving normal educational practices typically falls under an exempt review category (see Form B) under 45 CFR 46.101(b)(1) and must be submitted to the IRB for exemption certification. Informed consent procedures must be followed, though. In many such cases, students cannot opt out of participation in the intervention, because the intervention may be the pedagogical techniques routinely used in the class. In such studies, the instructor should provide information on the research at the beginning of the course. This information should offer the student the option to refuse to have his or her information (e.g., grades) included in the study. If the study is conducted at another school (e.g., student teaching assignment), informed consent must be obtained in accordance with the rules of that school, as well. In these studies, the informed consent must include a contact person to address questions regarding the study who it not the instructor or graduate assistant assigned to the course.

Research that is exempt under 45 CFR 46.101(b)(2) and (3) and all non-exempt research must follow the recruitment and protection policies set forth in this section.

Q.2 Recruitment of Students for Research Studies

This section discusses three distinct groups of students – a PI's current students, other UMHS students, and students at other schools who are participants in UMHS studies.

UMHS policy regarding protection of human subjects must be followed with all students, whether they are UMHS students or students at another school. Additional protections are required when the potential research subjects are a PI's current students. A PI's current students include those at UMHS or at any other location(s) where the person teaches under the auspices of UMHS (e.g., student teaching, prison-based courses).

UMHS does not normally allow students to participate in a research study conducted by a PI from whom they are currently taking classes except under the exemption categories [45 CFR 46.101(b)(1)]. If the nature of the study or other circumstances makes it impossible to conduct the study without using one's own students, the IRB may consider exceptions on an individual basis.

The preferred method is to have data collected by an independent third party (e.g., colleague in own or other department), in such a way that the instructor does not know the identity of the participants and does not have access to identifiable data until final course grades have been assigned and entered. If data are collected in the classroom, the instructor shall not be present. The third party cannot be a teaching assistant assigned to the course. This method should be used wherever feasible, even if the information from the students is anonymous (e.g., anonymous self-administered survey).

If a third party is not available, data from an instructor's current students may be used only if written consent is obtained from the student after final course grades are assigned and entered. This written consent must include language that indicates that participation is voluntary.

UMHS discourages situations that allow a student to enter the faculty researcher's class while that student is participating in the faculty member's research project. While this may not be avoidable (e.g., due to scheduling of courses in a student's major), special care must be taken to follow the rules discussed above.

Q.3 Awarding Credit for Participation in Research Studies

Researchers may award course credit or extra credit for participation in research if and only if another opportunity to earn the same amount of credit is available to students who decline to participate. The amount of work required to receive the credit must be similar to that required for participation in the study. For example, if the study consists of completion of an approximately 30-minute survey, then the extra credit for non-participants should require a task that takes about the same length of time.

The informed consent process must explicitly state how much extra credit is to be awarded and at what point. Informed consent must indicate how or whether extra credit will be awarded if the student withdraws from the study before completion. UMHS generally favors awarding extra credit if a student withdraws, unless the withdrawal is immediate (e.g., before the intervention or experiment begins) or unless there is ample evidence of bad faith on the part of the student. If the student disputes awarding of credit in an approved study, he or she may appeal to the department chairperson, whose decision is final. If the department has a different policy regarding handling of disputes over the awarding of credit for research project participation, then the department's policy takes precedence.

APPENDICES

Appendix 1 — Instructions for Submissions and Forms

Instructions for Submitting Materials for Review by the University Institutional Review Board
Form A—Initial Application to the Institutional Review Board for Review of Research Involving Human Subjects
Form B—Exempt Research Checklist
Form C—Expedited Review Research Categories
Form D—Proposed Modifications to Study Protocol or Informed Consent/Assent Form(s) after IRB Approval
Form E—Continuation Request
Form F—Adverse Incident Report
Form G—Completion of Research Activities

Instructions
for Submitting Materials for Review by the
Institutional Review Board

New Application—Checklist of materials required for review

Submit 1 hard copy and 1 electronic copy of the following to the IRB administrator:

____ Form A, including answers to all research description items
• If you are submitting your proposal for funding or your project has been funded, submit a copy of your grant proposal

_____ Questionnaires, surveys, tests, or other materials that will be administered to subjects

_____ Form B or C, if applicable

_____ Written permission from other institutions or agencies involved in the research (e.g., school board, hospital, agency, prison)

_____ Informed consent form or written request for waiver of an informed consent form

_____ HIPAA Authorization or waiver of Authorization if your proposed study involves protected health information

_____ Advertisements, letters, or flyers that will be used, if any

Reminder: All PIs, co-PIs, and sponsors must complete training prior to IRB approval. See Appendix 4

Modification Request—Checklist of materials required for review

Submit 1 copy of the following:

_____ Form D and documentation requested on the form

Continuation Request—Checklist of materials required for review

Submit 1 copy of the following:

_____ Form E and required documentation requested on the form

_____ Protocol summary, including approved modifications since last review and/or proposed changes

_____ Informed consent forms, permission forms, and assent forms, if applicable

Adverse Incident Report

Call or e-mail the IRB Chairperson immediately and complete and submit Form F and documentation requested on the form to IRB and RCC within 5 working days

Submit 1 copy of the following:

_____ Form F

Completion of Research Activities—Checklist of materials required

Submit 1 copy of the following:

_____ Form G

UNIVERSITY OF MEDICINE AND HEALTH SCIENCES

For IRB use only

IRB File No:_____
Date received:_____
Approval expires:_____

Application for Review of Research Involving Human Subjects

Form A

U.S. Federal regulations and UMHS's IRB policy require that all research involving humans as subjects be reviewed and approved by the University's Institutional Review Board (IRB) prior to the commencement of recruitment and the data collection. Any person (UMHS faculty member, student, staff member, or other person) wanting to engage in human subject research at or through UMHS must receive written approval from the IRB before conducting the research. Approval of this project by the IRB only signifies that the procedures adequately protect the rights and welfare of the subjects.

1. Title of Project: **For all form fields, please expand the cell to fit text.**

2. Principal Investigator:

Status: ☐ Faculty ☐ Student* ☐ Other—specify:
*Students engaging in research are required to have a faculty sponsor or executive, or administrative, sponsor. List sponsor in section 3.

Phone: Email:

Has PI completed IRB training? ☐ Yes ☐ No
(IRB approval cannot be granted until training is successfully completed by all PIs, co-PIs, and

Which track was or will be completed? ☐ Biomedical ☐ Social & Behavioral

3. Co-Investigator or Sponsor:

Additional co-investigators:

Status: ☐ Faculty ☐ Student ☐ Other—specify:

Phone: Email:

Has co-investigator or sponsor completed IRB training? ☐ Yes ☐ No

4. Level of Review Sought: ☐ Exempt (submit Form B in addition to this form)
☐ Expedited (submit form C in addition to this form)
☐ Full

5. Is this research being conducted to meet requirements of a course or to complete an academic degree?
☐ Yes (do NOT submit your dissertation or thesis proposal). If applicable, submit evidence of committee approval.
☐ No

6. Estimated starting date: Estimated Completion Date:

7. Extramural or Internal Funding sought or attained: ☐ Yes ☐ No (skip to #8)
Grant award date: OR Grant due date:
Principal Investigator of Contract or Grant:
Funding Source:
Contract or Grant Title:
Contract or Grant Number:

8. Indicate the categories of subjects and controls to be included in the study: Check ALL that apply:

☐ Abortuses/Fetuses
☐ Decisionally Impaired
☐ Decisionally Impaired (Institutionalized)
☐ Minors (17 years or less – Give age range:
☐ Normal Volunteers
☐ Patients
☐ Prisoners
☐ Pregnant Women
☐ Students

9. Approximate number of human subjects:

10. Indicate which of the categories listed below accurately describes this protocol:

☐ Not greater than minimal risk
☐ Greater than minimal risk, but presenting the prospect of direct benefit to individual subjects
☐ Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a

11. Does this research involve past, present, or future physical or mental health or condition of the subjects; provision of health care to subjects; or the past, present, or future payment for the provision of health care to subjects?

☐ Yes (see HIPAA section of the UMHS Policy for more information)
☐ No

12. Does this research involve identifiable information from students' educational records?

☐ Yes (See FERPA section in the UMHS Policy for more information)
☐ No

13. Does this research involve minor students in which any of the following information will be ascertained: political affiliations or beliefs of the student or student's parent; mental and psychological problems of the student or the student's family; sex behavior or attitudes; illegal, anti-social, self-incriminating, or demeaning behavior; critical appraisal of others with whom respondents have close family relationships; legally recognized privileged or analogous relationships (e.g., lawyer, physician, minister); religious practices, affiliations, or beliefs of the student or student's parent; or income?

☐ Yes (see PPRA section in the UMHS Policy for more information)
☐ No

14. Will a public use data file be created? ☐ Yes ☐ No

RESEARCH DESCRIPTION

Provide responses to the following items and submit your responses along with Form A. Each response should be numbered or labeled to correspond to the following items. If an item does not apply to your research project, simply indicate "Not applicable." The research description (answers to all of the items below) should not exceed 5 type-written pages. Use a font size of 11 or larger. A proposal, thesis, or dissertation will not be accepted in lieu of responses.

PROJECT DESCRIPTION

1. Provide a brief description using layperson's terms of the proposed research. Include the purpose, research questions or hypothesis, and supporting literature to demonstrate the value of this project.

Project Description

METHODOLOGY

2. PARTICIPANT CHARACTERISTICS – Describe the characteristics (e.g., age, gender, ethnicity, health status) of the subject population whom you re targeting and the approximate number of participants. Provide exclusion and inclusion criteria. Will there be any special populations (see 45 CFR 46, subparts B, C, and D), such as children, individuals who are mentally incapacitated, prisoners, or others whose ability to give voluntary informed consent may be in question included? – If yes, explain the rationale for their inclusion.

Participant Characteristics

3. SAMPLE SIZE – State your sample size and justify reasons for this sample size (e.g., statistical power calculation determined appropriate sample size)

Sample Size and Rationale

4. RECRUITMENT—Describe how you will identify and recruit prospective subjects. Attach a draft or final copy of any planned advertisements, flyers, and letters to potential subjects.

Recruitment

5. LOCATION OF STUDY—Identify specific sites or agencies to be used. For research conducted at a facility other than one owned and operated by UMHS, additional information is required.

Location

Notes:

(a) If the research project will not be conducted at a facility owned by and operated by UMHS, a letter from the appropriate administrator of each facility should be submitted on the facility's letterhead stationary and should contain the following: agreement for the study to be conducted; identification of someone at the site who will provide information about appropriateness for its population; assurance of adequate capabilities to perform the research as approved by the IRB; and, if applicable, assurance that facility personnel involved in data collection have appropriate expertise and will follow IRB approved procedures. If the approval letters are not available at the time of IRB review, IRB approval will be contingent upon receipt of the letters.

(b) U.S. Federally funded research—If the research project receives U.S. federal funds from an agency such as the National Institutes of Health (NIH) and the study will be conducted at a site other than one owned and operated by UMHS, each study site must have a Federal Wide Assurance (FWA) with the Office for Human Research Protections (OHRP). FWAs are a requirement of OHRP or NIH and not UMHS's IRB. If the study is a collaborative project and another organization in addition to UMHS is engaged in human subjects research (as defined by DHHS), then the PI must obtain information on the other organization's FWA and provide it in this section of the UMHS application. Guidance may be found at OHRP's web site, http://ohrp.osophs.dhhs.gov/irbasur.htm

6. INSTRUMENTS, RESEARCH MATERIALS, RECORDS—Identify the sources of research material (e.g., specimens, records, data) to be obtained from subjects. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data. If applicable, attach a copy of all questionnaires, tests, surveys, or other materials to be administered to the subjects; describe the setting and mode of administration (e.g., group, telephone, individual); describe the duration of administration, intervals of administration (if multiple administrations), and overall length of participation.

Instruments, Reaserch Materials, Records

7. PROCEDURES—Describe the study design and research procedures that will be followed. Identify all procedures that will be carried out with each group of subjects. If applicable, differentiate between procedures that involve standard or routine procedures for care or treatment from those which will be performed specifically for the conduct of this research project.

Procedures

8. DATA COLLECTION, STORAGE, AND CONFIDENTIALITY

(a) Describe how data will be collected and recorded. If subjects are identifiable by name or other means, explain special steps that will be taken to ensure confidentiality. Describe how data will be stored during the study and how it will be secured. Delineate who will have access to the data or to subject identifiers. Describe what will happen with data from subjects who formally withdraw from the study. Describe what will happen to the data when the research has been completed. [Note: Records (e.g., signed informed consent forms, data) relating to the research project must be retained for at least three years after completion of the research. See 45 CFR 46.115(b)]

Data Collection, Storage & Confidentiality

(a) If all or some of the subject(s) of the proposed research will be audio or videotaped, justify why the use of audio or videotaping is necessary to the study. Who will have access to the tapes and for what purposes? Where will the tapes be stored and what security measures will be taken to prevent unauthorized persons from accessing the tapes? What are your plans for the ultimate use and disposal of the tapes?

☐ Not Applicable

Audio or Videotape

9. INFORMED CONSENT—Describe the informed consent procedures to be followed, including circumstances under which consent will be sought and obtained, who will seek it, and the method for documenting consent. If minors will be included, refer to 45 CFR 46.408 for information regarding parental consent and minor's assent. Include applicable informed consent and assent forms for review purposes. If written consent or a signed informed consent is not to be obtained, specifically point this out and provide a rationale [see 45 CFR 46.116(d) and 45 CFR 46.117(c)]. Refer to Appendix 3, Informed Consent Checklist, for required elements of informed consent, information on conditions for waiver of some or all informed consent requirements, and for waiver of the requirement to obtain signed informed consent.

Informed Consent

RISKS/BENEFITS

10. RISKS – Describe the short-term and long-term potential risks (physical, psychological, social, legal or other) to subjects and assess their likelihood and seriousness. Where appropriate, describe alternative treatments or procedures that might be advantageous to the subjects. If risks are not greater than minimal risk, (i.e., 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) state this.

Risks

11. SAFETY PRECAUTIONS—Describe the procedures for protecting against or minimizing any potential risks, including risks to confidentiality. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subject(s) and attach a referral list. Also, where appropriate, describe the provisions for monitoring the data collected to ensure the safety of subjects.

Safety Precautions

12. BENEFITS—Describe the potential direct benefits subjects may receive as a result of participating in this research. Describe the potential benefits to society that may be expected from this research.

Benefits

13. BENEFITS VS. RISKS—Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.

Benefit vs. Risks

14. INCENTIVES AND RESEARCH RELATED COSTS—Describe the incentives, if any, being offered for participation in the research study. If monetary compensation is offered, indicate how much subjects (or other entity) will be paid and describe terms of payment. Describe what will be done if subjects withdraw before completion of the research (e.g., will monetary payments be prorated or paid in full?). Also, if applicable, describe any costs which will be accrued by the subjects as a consequence of participating in the research.

☐ Not Applicable

Incentives & Reserach Related Costs

QUALIFICATIONS OF INVESTIGATORS

15. Briefly describe the qualifications of the investigators(s) conducting this research project.

Investigator(s) Qualifications

16. Briefly describe the training that will be provided for research assistants working on this research project.

☐ Not Applicable

RA Training

OTHER

17. DATA SAFETY AND MONITORING FOR NIH SPONSORED RESEARCH—The National Institutes of Health policy requires that grantees have in place procedures for data safety monitoring of clinical trials. The IRB is required to review and approve the data safety monitoring plans. For NIH funded clinical trials, include a description of the Data Safety Monitoring Plan.

☐ Not applicable

Data Safety & Monitoring for NIH Research

18. Describe any requirements imposed by funding agencies that are not already covered in this application.

☐ Not applicable

Funding Agency Requirements

Investigator Assurance
I certify that the information provided for this project is correct and that no other procedures will be used in this protocol. I agree to conduct this research as described in the attached supporting documents. I will request approval from the IRB for changes to the study's protocol and/or consent forms and will not implement the changes until I receive IRB approval for these changes. I will comply with the IRB policy for the conduct of ethical research. I will promptly report significant or adverse effects or noncompliance to the IRB via phone or e-mail immediately, and then in writing (Form F) within 5 days of occurrence. I will be responsible for ensuring that the work of colleagues involved with this project complies with this protocol. I will complete, on request by the IRB, the Continuation Request or Completion of Research Activities Forms.

_____ _____
Principal Investigator's Signature Date

Faculty or EAP Staff Sponsor Assurance (required when a student is the PI)
This is to certify that I have reviewed this research protocol and that I attest to the scientific merit of this study and the competency of the investigator(s) to conduct the project. I assure that the investigator(s) is knowledgeable about the regulations and policies governing research with human subjects. I agree to meet with the investigator on a regular basis to monitor study progress and compliance with IRB policy for the conduct of ethical research.

_____ _____
Faculty Signature Date

Administrator (Dean of Basic Sciences) Assurance
This is to certify that I have reviewed this research protocol and that I attest to the scientific merit of this study and the competency of the investigator(s) to conduct the project.

_____ _____
Administrator's Signature Date

_____ _____
Administrator's Printed Name Date

SUBMIT ALL MATERIALS TO THE IRB CHAIRPERSON

UNIVERSITY OF MEDICINE AND HEALTH SCIENCES

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IRB File No:_____
Date received:_____
Approval expires:_____

Form B

Exempt Review Research Categories (45 CFR 46.101B)

Research activities in which ONLY the involvement of human subjects will be in one or more of the categories specified below are eligible for exemption certification. If the research study involves a vulnerable population, such as children, prisoners, pregnant women, refer to 46 CFR subparts B, C, and D for protections afforded these groups.

CHECK THE APPROPRIATE CATEGORIES THAT APPLY TO YOUR RESEARCH PROJECT:

☐ 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 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. *Note: According to 45 CFR 46.401, if the subjects are children, this exemption applies only to research involving educational tests or observations of public behavior when the investigator(s) does not participate in the activities being observed.*

☐ 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 #2 (above) 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 as 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 St. Kitts-Nevis Food & Safety Department of the Ministry of Health.

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IRB File No:_____
Date received:_____
Approval expires:_____

Form C — Expedited Review Research Categories

Principal Investigator:
Title of Project: **For all form fields, please expand the cell to fit text.**

APPLICABILITY

A. Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures in one or more of the following categories, 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.

B. The categories in this list apply regardless of the age of the subjects, except as noted.

C. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risk related to invasion of privacy and breach of confidentiality are no greater than minimal.

D. The expedited review procedure may not be used for classified research involving human subjects.

E. The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review—expedited or convened—utilized by the IRB.

F. Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

RESEARCH CATEGORIES

Research projects may receive expedited review when the involvement of human subjects falls within one or more of the categories below.

Check the appropriate categories that apply to your research project.

☐ 1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

☐ (a) Research on drugs for which an investigational new drug application (21CFR Part 312) is not required (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review).

☐ (b) Research on medical devices for which (i) an investigational device exemption application (21CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

☐ 2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

☐ (a) From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 –week period and collection may not occur more frequently than 2 times per week; OR

☐ (b) From other adults and children[1], considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

☐ 3. Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulation by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time or rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washing; (j) sputum collected after saline mist nebulization.

☐ 4. 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 subjects' 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.

☐ 5. 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.)

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

[1] Children are defined in the U.S. Department of Health and Human Services regulations as "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." 45 CFR 46.402(a).

☐ 7.	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) (4). This listing refers only to research that is not exempt.)
☐ 8.	Continuing review of research previously approved by the convened IRB as follows: ☐ (a) 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 ☐ (b) where no subjects have been enrolled and no additional risks have been identified; OR ☐ (c) where the remaining research activities are limited to data analysis.
☐ 9.	Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

SUBMIT ALL MATERIALS TO THE IRB CHAIRPERSON

UNIVERSITY OF MEDICINE AND HEALTH SCIENCES

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IRB File No:_____
Date received:_____
Approval expires:_____

Form D

Proposed Modifications to Protocol or Informed Consent/Assent Form(s) After IRB Approval

1. Title of Project: **For all form fields, please expand the cell to fit text.**

IRB File Number:

2. Principal Investigator:

Status: ☐ Faculty ☐ Student* ☐ Other—specify:
*Students engaging in research are required to have a faculty sponsor or executive, or administrative, sponsor. List sponsor in section 3.

Phone: Email:

3. Co-Investigator or Sponsor:

Additional co-investigators:

Status: ☐ Faculty ☐ Student ☐ Other—specify:

Phone: Email:

PROVIDE RESPONSES TO THE FOLLOWING ITEMS

4. PROTOCOL CHANGES—Are there any proposed changes in the protocol requested? ☐ Yes ☐ No
If yes, describe proposed changes to the protocol.

Protocol Changes

5. INFORMED CONSENT/ASSENT FORM CHANGES—Are there any proposed changes to the informed consent/assent form(s)? ☐ Yes ☐ No
If yes, describe the changes. Attach two sets of the revised consent/assent form(s). On one set highlight the proposed changes.

Informed Consent/Assent Form Changes

6. SITE CHANGES—Are there any additions or changes in sites where data are being collected?

☐ Yes ☐ No

If yes, identify specific sites or agencies to be used or changed. If a new site is added that is not owned or operated by UMHS, additional information is required. (See #4 Location of Study, in the research description of the New Application packet – Form A.) List sites.

Site Changes

7. KEY PERSONNEL CHANGES—Are there changes in key personnel assisting in the research project?

☐ Yes ☐ No

If yes, list changes (i.e., who is being added, who has left the project.) For new personnel, include name, rank/degree, affiliation, responsibility in project, the human subjects training certification, and the date human subjects training was completed.

Key Personnel Changes

8. ADDITIONAL CHANGES— Describe any other proposed changes not listed above.

Additional Changes

Investigator Assurance

I certify that the information provided for this project is correct and that no other procedures will be used in this protocol. I agree to conduct this research as described in the attached supporting documents. I will request approval from the IRB for changes to the study's protocol and/or consent forms and will not implement the changes until I receive IRB approval for these changes. I will comply with the IRB policy for the conduct of ethical research. I will promptly report significant or adverse effects or noncompliance to the IRB via phone or e-mail immediately, and then in writing (Form F) within 5 days of occurrence. I will be responsible for ensuring that the work of colleagues involved with this project complies with this protocol. I will complete, on request by the IRB, the Continuation Request or Completion of Research Activities Forms.

_____ _____

Principal Investigator's Signature Date

Faculty or EAP Staff Sponsor Assurance (required when a student is the PI)

This is to certify that I have reviewed this research protocol and that I attest to the scientific merit of this study and the competency of the investigator(s) to conduct the project. I assure that the investigator(s) is knowledgeable about the regulations and policies governing research with human subjects. I agree to meet with the investigator on a regular basis to monitor study progress and compliance with IRB policy for the conduct of ethical research.

_____ _____

Faculty Signature Date

Administrator (Dean of Basic Sciences) Assurance

This is to certify that I have reviewed this research protocol and that I attest to the scientific merit of this study and the competency of the investigator(s) to conduct the project.

_____ _____

Administrator's Signature Date

_____ _____

Administrator's Printed Name Date

SUBMIT ALL MATERIALS TO THE IRB CHAIRPERSON

UNIVERSITY OF MEDICINE AND HEALTH SCIENCES

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IRB File No:_____
Date received:_____
Approval expires:_____

Form E

Continuation Request

U.S. Federal guidelines (45 CRF 46.109e) require that Institutional Review Boards (IRB) "conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year." In conducting the continuation review, the IRB will review, at a minimum, a protocol summary and informed consent/assent forms, as well as a status report on the progress of the research.

1. Title of Project: **For all form fields, please expand the cell to fit text.**

IRB File Number:

2. Principal Investigator:

Status: ☐ Faculty ☐Student* ☐ Other—specify:
*Students engaging in research are required to have a faculty sponsor or executive, or administrative, sponsor. List sponsor in section 3.

Phone: Email:

3. Co-Investigator or Sponsor:

Additional co-investigators:

Status: ☐ Faculty ☐Student ☐ Other—specify:

Phone: Email:

PROVIDE RESPONSES TO THE FOLLOWING ITEMS

4. Project begin date: Anticipated end date:

5. Approximate total number of subjects who will be enrolled: ☐

a. Number of subjects actually enrolled as of this date: ☐

b. Number of subjects who have dropped out: ☐

c. Number of subjects who have formally withdrawn: ☐

If subjects have withdrawn, please summarize reason(s) for withdrawal

6. Since the last IRB review, have any injuries or adverse events occurred?

☐ Yes ☐ No

If yes, summarize injuries or events.

Injuries or Events

7. Since the last IRB review, have any unanticipated problems involving risks to subjects or others occurred?

☐ Yes ☐ No

If yes, summarize problems.

Risk to Subjects of Others

8. Since the last IRB review, have any complaints about the research been received?

☐ Yes ☐ No

If yes, summarize complaints.

Complaints

9. Are there any changes to the protocol requested?

☐ Yes ☐ No

If yes, describe proposed changes to the protocol and attach a protocol summary. Include amendments or modifications to the research since the last review. If no, attach a protocol summary. Include amendments or modifications to the research since the last reviews.

Protocol Changes

10. Are there any changes to the informed consent/assent form(s)?

☐ Yes ☐ No

If yes, describe changes and attach new consent/assent form(s) with changes highlighted. If no, attach informed consent/assent forms.

Informed Consent/Assent Changes

11. Are there any additions or changes in sites where data are being collected?

☐ Yes ☐ No

If yes, list additional sites or changes. Attach approval letters (See #4 – Location of Study in research description of the New Application packet – Form A).

Site Changes

12. Are there changes in key personnel assisting in the research project?

☐ Yes ☐ No

If yes, list changes (i.e., who is being added, who has left project). Include for new personnel, name, rank/degree, affiliation, responsibility in project, human subjects training track, and the date human subjects training was completed.

Personnel Changes

13. Summarize any relevant recent literature and interim findings.

Recent Literature and Interim Findings

14. If this is a multi-center trial, summarize any relevant trial reports.

Trial Reports

15. Summarize any other relevant information, especially information about risks associated with the research, not requested above.

Other Relevant Information

Investigator Assurance

I certify that the information provided for this project is correct and that no other procedures will be used in this protocol. I agree to conduct this research as described in the attached supporting documents. I will request approval from the IRB for changes to the study's protocol and/or consent forms and will not implement the changes until I receive IRB approval for these changes. I will comply with the IRB policy for the conduct of ethical research. I will promptly report significant or adverse effects or noncompliance to the IRB via phone or e-mail immediately, and then in writing (Form F) within 5 days of occurrence. I will be responsible for ensuring that the work of colleagues involved with this project complies with this protocol. I will complete, on request by the IRB, the Continuation Request or Completion of Research Activities Forms.

_____ _____

Principal Investigator's Signature Date

Faculty or EAP Staff Sponsor Assurance (required when a student is the PI)

This is to certify that I have reviewed this research protocol and that I attest to the scientific merit of this study and the competency of the investigator(s) to conduct the project. I assure that the investigator(s) is knowledgeable about the regulations and policies governing research with human subjects. I agree to meet with the investigator on a regular basis to monitor study progress and compliance with IRB policy for the conduct of ethical research.

_____ _____

Faculty Signature Date

Administrator (Dean of Basic Sciences) Assurance

This is to certify that I have reviewed this research protocol and that I attest to the scientific merit of this study and the competency of the investigator(s) to conduct the project.

_____ _____

Administrator's Signature Date

_____ _____

Administrator's Printed Name Date

SUBMIT ALL MATERIALS TO THE IRB CHAIRPERSON

UNIVERSITY OF MEDICINE AND HEALTH SCIENCES

For IRB use only
IRB File No:_____
Date received:_____
Approval expires:_____

Form F

PI Report of Problems Involving Risks, Adverse Effects, or Noncomplianc

All problems involving risk to subjects or others, injury or other adverse effects experienced by subjects in research and incidents of noncompliance must be reported to the IRB via phone or e-mail immediately. This report should be submitted as soon as possible, but NO LATER THAN 5 WORKING DAYS after first awareness of the problem.

1. Date of Report:

1. Title of Project: **For all form fields, please expand the cell to fit text.**

IRB File Number:

2. Principal Investigator:

Status: ☐ Faculty ☐ Student* ☐ Other—specify:
*Students engaging in research are required to have a faculty sponsor or executive, or administrative, sponsor. List sponsor in section 3.

Phone: Email:

3. Co-Investigator or Sponsor:

Additional co-investigators:

Status: ☐ Faculty ☐ Student ☐ Other—specify:

Phone: Email:

4. DESCRIPTION OF PROBLEM INVOLVING RISK TO SUBJECTS OR OTHERS, ADVERSE EFFECT, OR NONCOMPLIANCE

a. Date: ☐

b. The problem, adverse effect or noncompliance was: ☐ mild ☐ moderate ☐ severe ☐ fatal

c. Was the event related to the research procedure? ☐ Yes ☐ No ☐ Maybe ☐ Unknown

d. Provide a brief description of the problem, adverse effect, or noncompliance

Problem, Adverse Effect, or Noncompliance

TREATMENT PROVIDED TO THE SUBJECT OR OTHER

5. Was treatment provided to the subject or other?

☐ Yes

a. Date of treatment:

b. Description of treatment

Description of Treatment

☐ No – Explain why treatment was not provided

Explanation For Why Treatment was not Provided

CHANGES NECESSITATED BY ADVERSE EVENT

6(a) Change in Protocol: In your judgment is a change in your protocol necessary to reduce or eliminate risk?

☐ Yes – Provide revised protocol with changes highlighted. Note that data should not be collected until the revised protocol is approved by the IRB.

☐ No – Provide a brief rationale.

Brief Rationale

6(b) Changes in Informed Consent/Assent Document(s): Are any changes required in the informed consent/assent document(s) to better inform and protect the rights and welfare of the subjects?

☐ Yes – Attach the revised consent/assent form with changes highlighted. Note: No new subjects may be enrolled in the study until the revised consent/assent form(s) is approved by the IRB.

☐ No - Provide a brief rationale.

Brief Rationale

6(c) Enrolled Subjects: Is it necessary to inform presently enrolled subjects/legal representatives of the adverse event?

☐ Yes – Describe how subjects/legal representatives will be informed and if necessary, attach a revised consent/assent form.

Inform Subjects or Legal Representative

7. Additional Comments:

Additional Comments

Investigator Assurance
I certify that the information provided for this project is correct and that no other procedures will be used in this protocol. I agree that I will not implement changes proposed until I receive IRB approval.

_____ _____
Principal Investigator's Signature Date

Faculty or EAP Staff Sponsor Assurance (required when a student is the PI)
This is to certify that I have reviewed this research protocol and I have discussed it with the PI.

_____ _____
Faculty Signature Date

Administrator (Dean of Basic Sciences) Assurance
This is to certify that I have reviewed this report.

_____ _____
Administrator's Signature Date

_____ _____
Administrator's Printed Name Date

SUBMIT ALL MATERIALS TO THE IRB CHAIRPERSON

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IRB File No:_____
Date received:_____
Approval expires:_____

Form G — Completion of Research Activities

1. Title of Project: **For all form fields, please expand the cell to fit text.**

IRB File Number:

2. Principal Investigator:

Status: ☐ Faculty ☐ Student* ☐ Other—specify:
*Students engaging in research are required to have a faculty sponsor or executive, or administrative, sponsor. List sponsor in section 3.

Phone: Email:

3. Co-Investigator or Sponsor:

Additional co-investigators:

Status: ☐ Faculty ☐ Student ☐ Other—specify:

Phone: Email:

4. Project begin date: Project end date:

5. Subject Recruitment
   a. Total number of subjects enrolled in study:
   b. Number of subjects who formally voluntarily withdrew from study at their own request:
   c. Number of subjects who dropped out or did not finish the study:

PROVIDE RESPONSES TO THE FOLLOWING ITEMS

6. a. Please identify any problems that participants may have encountered during the research study:

Participant Problems

b. How were the problems handled?

Methods for Handling Problems

7. Provide a summary of the completed research (An abstract is sufficient).

Site Changes

Investigator Assurance
I certify that the information provided for this project is correct.

_____ _____
Principal Investigator's Signature Date

Faculty or EAP Staff Sponsor Assurance (required when a student is the PI)
This is to certify that I have reviewed this completion of research activities report.

_____ _____
Faculty Signature Date

Administrator (Dean of Basic Sciences) Assurance
This is to certify that I have reviewed this completion of research activities report.

_____ _____
Administrator's Signature Date

_____ _____
Administrator's Printed Name Date

SUBMIT ALL MATERIALS TO THE IRB CHAIRPERSON

Appendix 2 — Reviewer Checklist

University of Medicine and Health Sciences Institutional Review Board
for Review of Research Involving Human Subjects
REVIEWER CHECKLIST

The following are minimal regulatory requirements for IRB review, discussion, and documentation in the meeting minutes from IRB Protocol Review Guidelines (http://ohsr.od.nih.gov/info/checklist_IRB_protocol.html).

☐ 1. The proposed research design is scientifically sound & will not unnecessarily expose subjects to risk.

- ☐ (a) The hypothesis is clear and clearly stated.
- ☐ (b) The study design is appropriate to test the hypothesis.
- ☐ (c) The research will contribute to generalizable knowledge and it is worth exposing subjects to risk.

☐ 2. The risks to subjects are **reasonable** in relation to anticipated benefits, if any, to subjects, **and** the importance of knowledge that may reasonably be expected to result.

A. RISK

Regulatory definition of minimal risk: 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 (45 CFR 46.102(h)(i)).

What does the **IRB** consider the level of risk to be?

Check appropriate risk categories:

- ☐ (a) The research involves no more than minimal risk to subjects.
- ☐ (b) The research involves more than minimal risk to subjects.
  - ☐ (i) The risk(s) represents a minor increase over minimal risk, **or**
  - ☐ (ii) The risk(s) represents more than a minor increase over minimal risk.

What does the **PI** consider the level of risk/discomfort/inconvenience to be?

Check appropriate risk categories:

- ☐ (a) The research involves no more than minimal risk to subjects.
- ☐ (b) The research involves more than minimal risk to subjects.
  - ☐ (i) The risk(s) represents a minor increase over minimal risk, **or**
  - ☐ (ii) The risk(s) represents more than a minor increase over minimal risk.

B. BENEFIT

A research benefit is considered to be something of health-related, psychosocial, or other value to an individual research subject, or something that will contribute to the acquisition of generalizable knowledge. Money or other compensation for participation in research is not considered to be a benefit, but rather compensation for research-related inconveniences.

Check appropriate benefit category:

- ☐ (a) The research involves no prospect of direct benefit to individual subjects, but is likely to yield generalizable knowledge about the subject's disorder or condition.
- ☐ (b) The research involves the prospect of direct benefit to individual subjects.

☐ 3. The subject selection is equitable.

- ☐ (a) The rational for inclusion/exclusion is addressed when considering who is enrolled (Men? Women? Ethnic minorities? Children? Seriously-ill persons? Healthy volunteers?)
- ☐ (b) The subjects are appropriate for the protocol.

☐ 4. Additional safeguards are in place for subjects likely to be vulnerable to coercion or undue influence.

- ☐ (a) Appropriate protections are in place for vulnerable subjects (e.g., pregnant women, fetuses, socially- or economically-disadvantaged, decisionally-impaired)

☐ 5. Informed consent is obtained from research subjects or their legally authorized representative(s).

- ☐ (a) The informed consent document includes the eight required elements.
- ☐ (b) The consent document is understandable to subjects.
- ☐ (c) Concern has been given to who will obtain the informed consent (PI, nurse, other) and in what setting.
- ☐ (d) If appropriate, there is a children's assent.
- ☐ (e) If the IRB is requested to waive or alter any consent requirement, this is appropriate.

☐ 6. Subject safety is maximized.

- ☐ (a) The research design minimizes risks to subjects.
- ☐ (b) If appropriate, consideration has been given to determining if the use of a data & safety monitoring board or other research oversight process would enhance subject safety.

☐ 7. Subject privacy & confidentiality are maximized.

- ☐ (a) Personally-identifiable research data will be protected to the extent possible from access or use.
- ☐ (b) Special privacy & confidentiality issues are addressed properly (e.g., use of genetic information).

Additional Considerations

1. In the case of ionizing radiation, is the use of ionizing radiation in this protocol medically indicated or for research use only?
2. Is this domestic/international collaborative research? If so, are SPAs or other assurances required for the sites involved?
3. Is an investigational new drug (IND) or investigational device exemption (IDE) involved in this protocol?

Appendix 3 — Informed Consent

Informed Consent Form Checklist
Conditions of waiver of some or all informed consent requirements
Conditions for waiver of requirement to obtain signed informed consent

University of Medicine and Health Sciences
for Review of Research Involving Human Subjects
Informed Consent Form Checklist

Informed consent/assent forms should be written in second person (e.g., You are being asked to participate…).

Basic elements to include

	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, an estimate of their likelihood, and a description of what steps will be taken to prevent or minimize them
	A description of any benefits to the subject or to others which may reasonably be expected from the research. Monetary compensation is not a benefit. If compensation is to be provided to research subjects or healthy volunteers, the amount should be stated in the consent document
	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. Include a description of whom may have access to research records
	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
	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

	An explanation as to why subject is eligible to participate
	The approximate number of subjects involved in the study
	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
	Payment for participation—give amount and if/how it will be prorated if subject does not complete study
	A statement that the collection of data will be audiotaped or videotaped
	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
	When appropriate, a statement concerning an investigator's potential financial or other conflict of interest in the conduct of the study
	If the subject is or may become pregnant, a statement that the particular treatment may involve risks, which are currently unforeseeable, to the subject or to the embryo or fetus

Conditions for Waiver of Some or All Informed Consent Requirements

The IRB may approve a waiver of some or all of the informed consent requirements provided that:

- the research involves no more than minimal risk to the subjects;
- the waiver or alteration will not adversely affect the rights and welfare of the subjects;
- the research could not practically be carried out without the waiver or alteration; and
- whenever appropriate, the subjects will be provided with additional pertinent information after participation. [see 45 CFR 46.116 (d)]

Additionally, for research studies that are designed to evaluate or demonstrate possible changes in (or alternatives to) provision of benefits or services provided under federal, state, or local programs, an IRB may approve alteration or waiver of informed consent requirements providing the research could not be practically carried out without such waiver or alteration. [See 45 CFR 46.116 (c)]

Conditions for Waiver of Requirement to Obtain Signed Informed Consent

Federal regulations [45 CFR 46.117 (c)] allow the IRB to waive the requirement to obtain a signed informed consent for some or all of the subjects providing that the IRB finds either of the following:

- 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; or
- 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.

Additionally, the IRB may decide to waive written documentation of informed consent (i.e., signature of subjects) for research that falls within one or more exemption categories (see Form B). For example, a PI who is using a survey may include the elements of informed consent in a letter of invitation to participate and by completing the survey subjects are consenting to participate in the research study.

Appendix 4 — HIPAA Information

4.a Definitions used in the Privacy Rule
4.b Authorizations
    4.b.1 Authorization document
    4.b.2 Waiver of alteration of authorization
4.c Exceptions
    4.c.1 Limited data set
4.d Disclosure of PHI
4.e. Existing protocols
4.f HIPAA defined personal identifiers

4.a Definitions used in the Privacy Rule

(1) *Covered Entity* - A health plan, a health care clearinghouse, or a health care provider who transmits health information in electronic form in connection with a transaction for which HHS has adopted a standard.

(2) *Health Care Provider* - A provider of services (as defined in section 1861(u) of the Act, 42 U.S.C. 1395x(u)), a provider of medical or health services (as defined in section 1861(s) of the Act, 42 U.S.C. 1395x(s)), and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business.

(3) *Health Care* - Care, services, or supplies related to the health of an individual, including (1) preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status, of an individual that affects the structure or function of the body; and (2) sale or dispensing of a drug, device, equipment, or other item in accordance with a prescription.

(4) *Protected Health Information* - PHI is individually identifiable health information transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium. PHI excludes education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. 1232g, records described at 20 U.S.C. 1232g(a)(4)(B)(iv), and employment records held by a covered entity in its role as employer.

(5) *Research (as defined under the Privacy Rule)* - A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. This includes the development of research repositories and databases for research.

(5) *Authorization* - An individual's written permission to allow a covered entity to use or disclose specified PHI for a particular purpose. Except as otherwise permitted by the Rule, a covered entity may not use or disclose PHI for research purposes without a valid Authorization.

(6) *Data Use Agreement*- An agreement into which the covered entity enters with the intended recipient of a limited data set that establishes the ways in which the information in the limited data set may be used and how it will be protected.

(7) *Health Information* - Any information, whether oral or recorded in any form or medium, that (1) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

(8) *Individually Identifiable Health Information* - Information that is a subset of health information, including demographic information collected from an individual, and (1) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision

of health care to an individual; and (a) that identifies the individual; or (b) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

(9) *Limited Data Set* - Refers to PHI that excludes 16 categories of direct identifiers and may be used or disclosed, for purposes of research, public health, or health care operations, without obtaining either an individual's Authorization or a waiver or an alteration of Authorization for its use and disclosure, with a data use agreement.

(10) *Waiver or Alteration of Authorization* - The documentation that the covered entity obtains from a researcher or an IRB or a Privacy Board that states that the IRB or Privacy Board has waived or altered the Privacy Rule's requirement that an individual must authorize a covered entity to use or disclose the individual's PHI for research purposes.

4.b Authorizations

The Privacy Rule allows covered entities to use and disclose PHI for research if explicitly authorized to do so by the subject in accordance with the Privacy Rule. The Authorization for use of PHI for research may be combined with informed consent for participation or the Authorization may be a stand alone HIPAA authorization document. The Authorization and informed consent form must be kept for 6 years after the conclusion of the study.

4.b.1 Authorization Document

The HIPAA authorization document (either a stand-alone document or part of an informed consent form) must contain the following specific core elements and required statements:

Authorization Core Elements:

- A description of the PHI to be used or disclosed, identifying the information in a specific and meaningful manner.
- The names or other specific identification of the person or persons (or class of persons) authorized to make the requested use or disclosure.
- The names or other specific identification of the person or persons (or class of persons) to whom the covered entity may make the requested use or disclosure.
- A description of each purpose of the requested use or disclosure.
- Authorization expiration date or expiration event that relates to the individual or to the purpose of the use or disclosure ("end of the research study" or "none" are permissible for research, including for the creation and maintenance of a research database or repository).
- Signature of the individual and date. If the individual's legally authorized representative signs the Authorization, a description of the representative's authority to act for the individual must also be provided.

Authorization Required Statements:

- A statement of the individual's right to revoke his/her Authorization and how to do so, and, if applicable, the exceptions to the right to revoke his/her Authorization or reference to the corresponding section of the covered entity's notice of privacy practices.
- Whether treatment, payment, enrollment, or eligibility of benefits can be conditioned on Authorization, including research-related treatment and consequences of refusing to sign the Authorization, if applicable.
- A statement of the potential risk that PHI will be re-disclosed by the recipient. This may be a general statement that the Privacy Rule may no longer protect health information disclosed to the recipient.

4.b.2 Waiver or Alteration of Authorization

Waiver or Alteration of Authorization, in whole or in part, needs to satisfy the following criteria:

1. The use or disclosure of the PHI involves no more than minimal risk to the privacy of individuals based on, at least, the presence of the following elements:
   a. An adequate plan to protect health information identifiers from improper use and disclosure.
   b. An adequate plan to destroy identifiers at the earliest opportunity consistent with conduct of the research (absent a health or research justification for retaining them or a legal requirement to do so).
   c. Adequate written assurances that the PHI will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.
2. The research could not practicably be conducted without the waiver or alteration.
3. The research could not practicably be conducted without access to and use of the PHI.

4.c Exceptions

The Privacy Rule also allows covered entities to use and disclose PHI without Authorization for certain types of research activities, including de-identified PHI; when the covered entity and researcher enter into a data use agreement for sharing a limited data set; and documentation that an IRB or Privacy Board has waived the requirement for Authorization or allowed an alteration of Authorization. Refer to Appendix 4 for more information on identifiers, data use agreement, and Authorization waivers or alteration.

Additionally, covered entities may use or disclose PHI to a researcher without an individual's Authorization, a waiver or alteration of authorization, or a data use agreement, when the researcher's request is solely to review PHI necessary to prepare a research protocol, the PHI will not be removed from the covered entity in the course of review, and the PHI is necessary for the research.

The covered entity may also use or disclose PHI of the deceased for research purposes without obtaining Authorizations from personal representatives or next of kin, a waiver or an alteration of Authorization, or a data use agreement. The covered entity, however, must obtain the following from the researcher who is seeking access to decedents' PHI: (1) oral or written representations that the use and disclosure is sought for research on the PHI decedents, (2) oral or written representations that the PHI for which use or disclosure is sought is necessary for research purposes, and 3) documentation, at the request of the covered entity, of the death of the individuals whose PHI is sought by the researchers.

4.c.1 Limited Data Set

The following identifiers must be removed from health information if the data are to qualify as a limited data set:

1. Names.
2. Postal address information, other than town or city, state, and ZIP Code.
3. Telephone numbers.
4. Fax numbers.
5. Electronic mail addresses.
6. Social security numbers.
7. Medical record numbers.
8. Health plan beneficiary numbers.
9. Account numbers.
10. Certificate/license numbers
11. Vehicle identifiers and serial numbers, including license plate numbers.
12. Device identifiers and serial numbers.
13. Web universal resource locators (URLs).
14. Internet protocol (IP) address numbers.
15. Biometric identifiers, including fingerprints and voiceprints.
16. Full-face photographic images and any comparable images.

A data use agreement is the means by which covered entities obtain satisfactory assurances that the recipient of the limited data set will use or disclose the PHI in the data set only for specified purposes. Even if the person requesting a limited data set from a covered entity is an employee or otherwise a member of the covered entity's workforce, a written data use agreement meeting the Privacy Rule's requirements must be in place between the covered entity and the limited data set recipient.

The Privacy Rule requires a data use agreement to contain the following provisions:

- Specific permitted uses and disclosures of the limited data set by the recipient consistent with the purpose for which it was disclosed (a data use agreement cannot authorize the recipient to use or further disclose the information in a way that, if done by the covered entity, would violate the Privacy Rule).
- Identify who is permitted to use or receive the limited data set.
- Stipulations that the recipient will
    - Not use or disclose the information other than permitted by the agreement or otherwise required by law.
    - Use appropriate safeguards to prevent the use or disclosure of the information, except as provided for in the agreement, and require the recipient to report to the covered entity any uses or disclosures in violation of the agreement of which the recipient becomes aware.
    - Hold any agent of the recipient (including subcontractors) to the standards, restrictions, and conditions stated in the data use agreement with respect to the information.
    - Not identify the information or contact the individuals.

4.d Disclosure of PHI

Upon receiving a subject's request, a covered entity must account for disclosures of that individual's PHI made on or after the covered entity's compliance date, unless a particular disclosure or type of disclosure (e.g., under Authorization for the disclosure, part of a limited data set under a data use agreement, prior to the compliance date) is excluded from this accounting requirement in 45 CFR 164.528(a). The accounting of disclosures starts with the covered entity's compliance date and goes back 6 years from the date of the request, not including periods prior to the compliance date. Therefore, a covered entity must keep records of disclosures for 6 years. The Privacy Rule allows for three methods for accounting for research-related disclosures that are made without the individual's Authorization or other a limited data set: (1) standard approach, (2) a multiple-disclosures approach, and (3) an alternative for disclosures involving 50 or more individuals. See 45 CFR 164.528 for more information.

4.e Existing Protocols

For research studies that began before the compliance date (April 14, 2003), a covered entity may use or disclose PHI that was created or received for research either before or after the compliance date, if the covered entity obtained any of the following prior to the compliance date: 1) an Authorization or other express legal permission from an individual to use or disclose PHI for research, 2) the informed consent of the individual to participate in the research, or 3) a waiver of informed consent by the IRB. If a waiver of informed consent was granted initially, but an informed consent is sought from the research subject after the compliance date, the covered entity must obtain the individual's Authorization as required by the Privacy Rule unless use or disclose is permitted without Authorization. Also, if informed consent was obtained after the compliance date, the covered entity must obtain the individual's Authorization to use or disclose PHI.

4.f HIPAA Defined Personal Identifiers

1. Names.
2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP Code, and their equivalent geographical codes, except for the initial three digits of a ZIP Code if, according to the current publicly available data from the Bureau of the Census:
   a. The geographic unit formed by combining all ZIP Codes with the same three initial digits contains more than 20,000 people.
   b. The initial three digits of a ZIP Code for all such geographic units containing 20,000 or fewer people are changed to 000.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
4. Telephone numbers.
5. Facsimile numbers.
6. Electronic mail addresses.
7. Social security numbers.
8. Medical record numbers.
9. Health plan beneficiary numbers.
10. Account numbers.
11. Certificate/license numbers.
12. Vehicle identifiers and serial numbers, including license plate numbers.
13. Device identifiers and serial numbers.
14. Web universal resource locators (URLs).
15. Internet protocol (IP) address numbers.
16. Biometric identifiers, including fingerprints and voiceprints.
17. Full-face photographic images and any comparable images.
18. Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification.

Appendix 5 — Training Procedures for Human Subjects Protection

University of Medicine and Health Sciences
Institutional Review Board
TRAINING PROCEDURES FOR HUMAN SUBJECTS PROTECTION

On-line Program Required

Unless otherwise approved by the IRB administrator, all training and recertification must be completed using the online system described below. If an investigator has received training elsewhere, the PI must submit the investigator's certification to the IRB administrator for assessment of that training.

Initial certification and recertification are valid for three years.

Overview of Course

NIH Office of Extramural Research's "Protecting Human Research Participants" online training consists of seven modules; each addressing the principles used to define ethical research using humans and the regulations, policies, and guidance that describe the implementation of those principles.

A quiz will be given at the end of four of the modules. If you score less than the required number of correct answers for a quiz, you must reread the module. After you reread the module, you may retake the quiz. This may be repeated until a satisfactory score has been attained.

The entire course will take approximately 2-3 hours to complete.

Initial Certification & Recertification

To successfully complete this course and receive a certificate, you must view the content in all 7 modules and pass all 4 of the quizzes. Once the course is successfully completed, a link will become available on the main menu for you to print your personalized certificate. This certificate will always be available by logging into the course and must be provided to the IRB Administrator upon completion.

Based on the substantive content of the project, IRB chairperson, designated member or IRB administrator will determine whether any additional training is required.

Go to http://phrp.nihtraining.com to access the online training modules:

- Click on "Registration" for the New to PHRP Course.
- Complete the User Registration form fields.
- Click "Create Account."
- Click "Click here to begin."
- Begin by clicking on "Introduction."

Appendix 6 — Request for No Human Subject Research Determination

UMHS
UNIVERSITY OF MEDICINE AND HEALTH SCIENCES

Request for No Human Subject Research Determination

This form is intended to assist UMHS researchers to determine if their proposed activities constitute human subject research and will therefore require Institutional Review Board (IRB) review and approval. Please complete this form and return it to the UMHS No Human Subject Research Determination Appointee, Dr. David Herrick (dherrick@umhs-sk.net). NOTE: A determination of "IRB Review Not Required" does not absolve individuals conducting the activity of any other ethical or legal responsibilities and obligations that may apply.

SECTION 1: CONTACT INFORMATION
Principal Investigator (PI):
Project Title:
Phone:
Email:

SECTION 2: DETERMINATION OF "RESEARCH"

Federal Definition of Research (45 CFR 46.102(d)):

***Research* - a *systematic investigation*, including research development, testing and evaluation, *designed* to *develop or contribute to generalizable knowledge*.**

- If all response below are YES the activities meet the definition of "Research"
- If ANY checked NO, the activity may not meet the definition of "Research".

1. Do the proposed activities constitute an *investigation*: a searching inquiry for ascertaining facts, detailed or careful examination?

   ☐ Yes ☐ No

   If No, please explain why not:

2. Do the proposed activities involve a *systematic approach*? "Systematic" means having or involving a system, method or plan

   ☐ Yes ☐ No

   If No please explain why not:

3. Are the proposed activities *designed* to *develop* or *contribute* to *knowledge*? (*Designed*: done with purpose and intent. *Develop*: to elaborate or expand in detail. *Contribute*: to be an important factor in; help to cause. *Knowledge*: truth, facts, information)

   ☐ Yes ☐ No

   If No please explain why not:

4. Is the information obtained *generalizable* (*scholarly*)? This includes activities designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations beyond the specific study population), inform policy, or generalize findings.

☐ Yes ☐ No

If No please explain why not:

SECTION 3: DETERMINATION OF "HUMAN SUBJECT"

Federal Definition of Human Subject (45 CFR 46.102(f)):

Human subject - 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 researcher 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 information). Private information must be individually identifiable. Individually identifiable includes where the identity of the subject is or may be ascertained by the researcher or associated with the information.

• ***About (whom)*** includes questions about the living individual. These would not include questions about processes. For example an anonymous survey asking questions about how a training program is organized would not meet this definition.

Use the definitions above to answer the following questions.

1. Do the activities include obtaining information about (whom) living individuals?

☐ Yes ☐ No

1a. If "Yes" to #1, do the activities involve intervention or interaction with the individuals (i.e., prospective collection of human data/specimens)? For example, physical procedures or manipulations of those individuals or their environment. (*Intervention*); Communication or interpersonal contact with the individuals (*Interaction*)

☐ Yes ☐ No

If YES, the activities involve human subjects.

If NO, please attach a copy of the proposed questions that are considered to not meet the definition of "about whom" or describe why the research is not on living individuals or does not meet the definition of "interaction" or "intervention":

2. Do the activities involve obtaining individually identifiable and private information about living individuals?

☐ Yes ☐ No

If YES, the activities involve human subjects.

If NO, please explain the type of information that will be obtained and the reasons why it is not considered individually identifiable private information.

3. Do the activities involve analysis of existing human *data/specimens* (i.e., data/specimens have already been collected and are available for analysis, i.e. there will be no ongoing collection of specimens)?

☐ Yes ☐ No

3a. If yes to #3, will the human data/specimens be coded such that a link exists that could allow the source of the data/specimens to be re-identified (i.e., key available to decipher the code)?

☐ Yes ☐ No

3b. If "Yes" to #3a, Then one of the following must be true in order to not meet the definition of human subjects:

i. ☐ Yes ☐ No: The provider of the human data/specimens will remove the code before sending the data/specimens to the researcher

ii. ☐ Yes ☐ No: The holder of the key and investigator enter into an agreement prohibiting the release of the key to the investigator under any circumstances, until the individuals are deceased. Provide a copy of this agreement (informal email exchange is sufficient, provide a copy in this document submission);

iii. ☐ Yes ☐ No: The investigator has documentation of written policies and operating procedures from a repository or data management center that prohibits the release of the key to the investigators under any circumstances, until the individuals are deceased (provide this documentation).

iv. ☐ Yes ☐ No: There are other legal requirements prohibiting the release of the key to the investigator, until the individuals are deceased. (Provide copy of these legal requirements.)

4. Human subjects a defined by FDA regulations: "an individual who is or becomes a participant in research, either as a recipient of the test article or as a control")

Does the activity involve human subjects as defined by FDA regulation? The activity involves human subjects if EITHER of the following is checked YES.

☐ Yes ☐ No: An individual will be a recipient of any test article (i.e. drug, medical device) or as a control

☐ Yes ☐ No: An individual on whose specimen a medical device will be used

SECTION 4: IS YOUR PROTOCOL HUMAN SUBJECTS RESEARCH?
 The activities constitute human subjects research if all responses in section 2 are yes and per your responses in Section 3 the activities involve human subjects. Please complete and submit an IRB Application with the appropriate protocol narrative. DO NOT submit this form. All forms are available on the IRB forms website Otherwise complete sections 5-7 below and submit this form to dherrick@umhs-sk.net for a formal determination as to whether IRB oversight is required. In the event that Dr. Herrick determines that the activities do not meet either the definition of "research" or the definition of "human subject" then IRB review and approval are not required and you will be provided with a letter of exemption.

SECTION 5: STUDY INFORMATION
1. Purpose, specific aims, and/or objectives:
2. Procedures used to gather information (e.g., communication or interpersonal contact with individuals, manipulation of individuals, manipulation of individual's environment, or physical procedures). Indicate if these procedures would be conducted as part of standard of care, regardless of research.
3. Description of human data/samples gathered about individuals without using interaction or intervention including names of datasets, URLs, etc. a. What data will be collected, and describe how and by whom the data will be analyzed

b. How were the data/samples originally gathered from individuals (e.g., obtained as part of another IRB approved protocol at this institution/another institution or as part of routine clinical practice or Performance Improvement projects)?

Can the collected information be directly or indirectly associated/linked with individual identities?

c. Can others directly or indirectly associate/link the collected information with individual identities?

d. List and attach with submission a copy of any applicable agreements (e.g., Data Use Agreement-DUA, an attestation from the data provider) that indicate that under no circumstances will you have access to the identities (or links to identities) of individuals from whom the data was collected.

SECTION 6: PRINCIPAL INVESTIGATOR
Principal Investigator's Signature:
Date:

SECTION 7: DETERMINATION OF HUMAN SUBJECTS RESEARCH
☐ The activities as described **DO NOT** constitute Human Subjects Research. IRB Application is not required. ☐ The activities as described **DO** constitute Human Subjects Research. An IRB Application **IS REQUIRED**. IRB Approval must be obtained before the research can begin.
_____ _____ Dr. David Herrick Date *No Human Subject Research Determination Appointee*

Appendix 7 — Charts

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

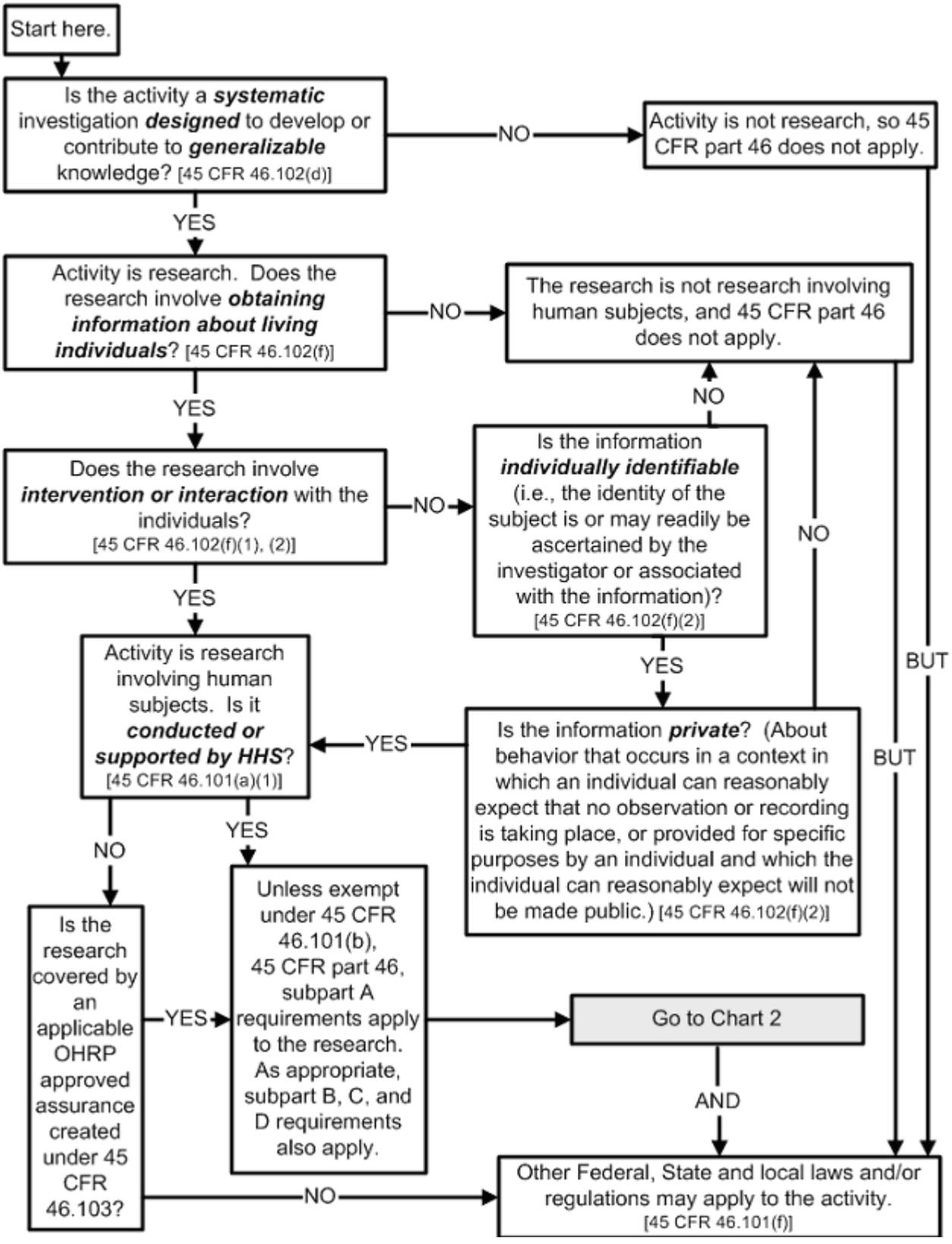


Chart 2 Is the Research Involving Human Subjects Eligible for Exemption?

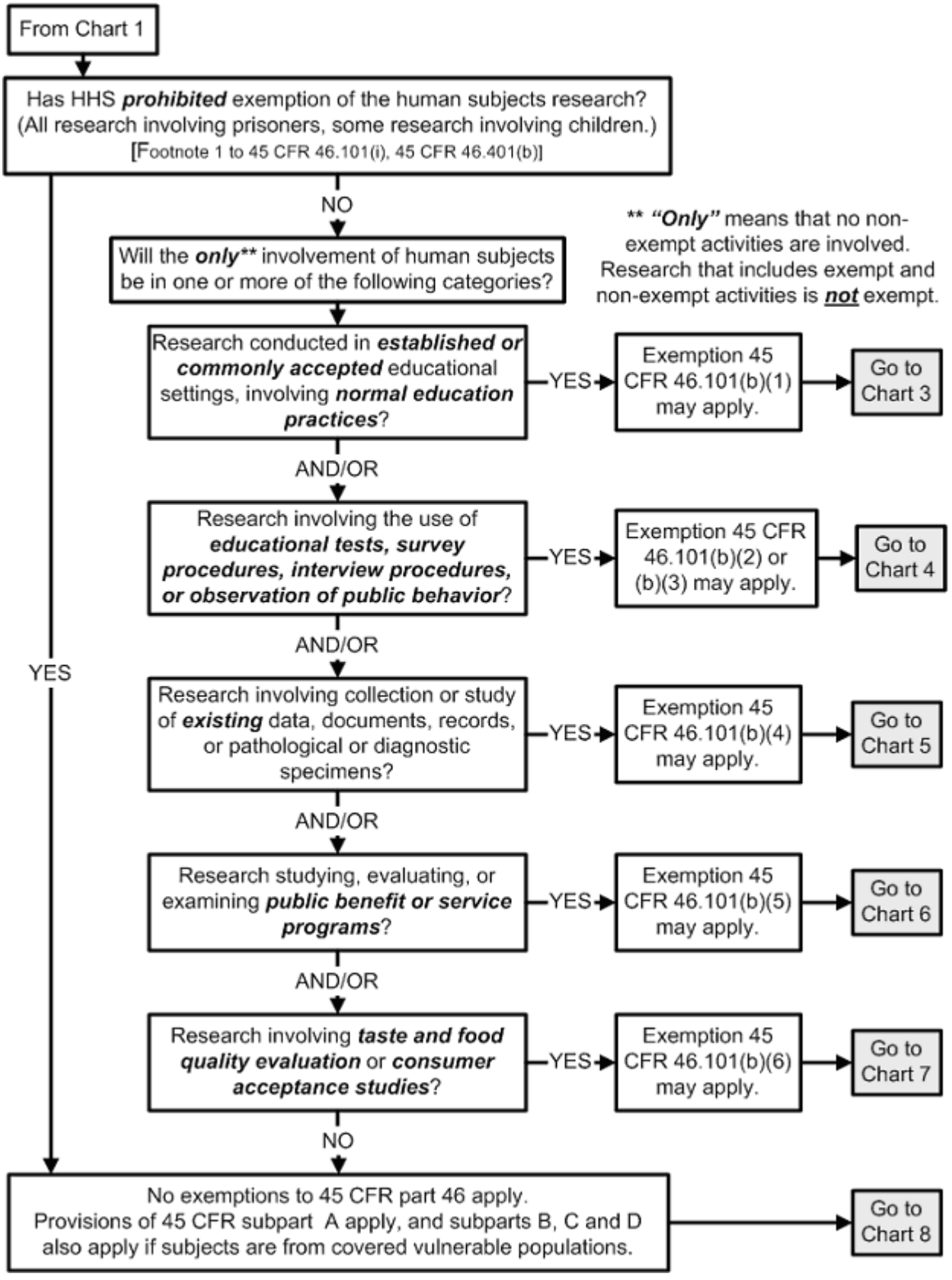


Chart 3 Does Exemption for Educational Settings Apply?

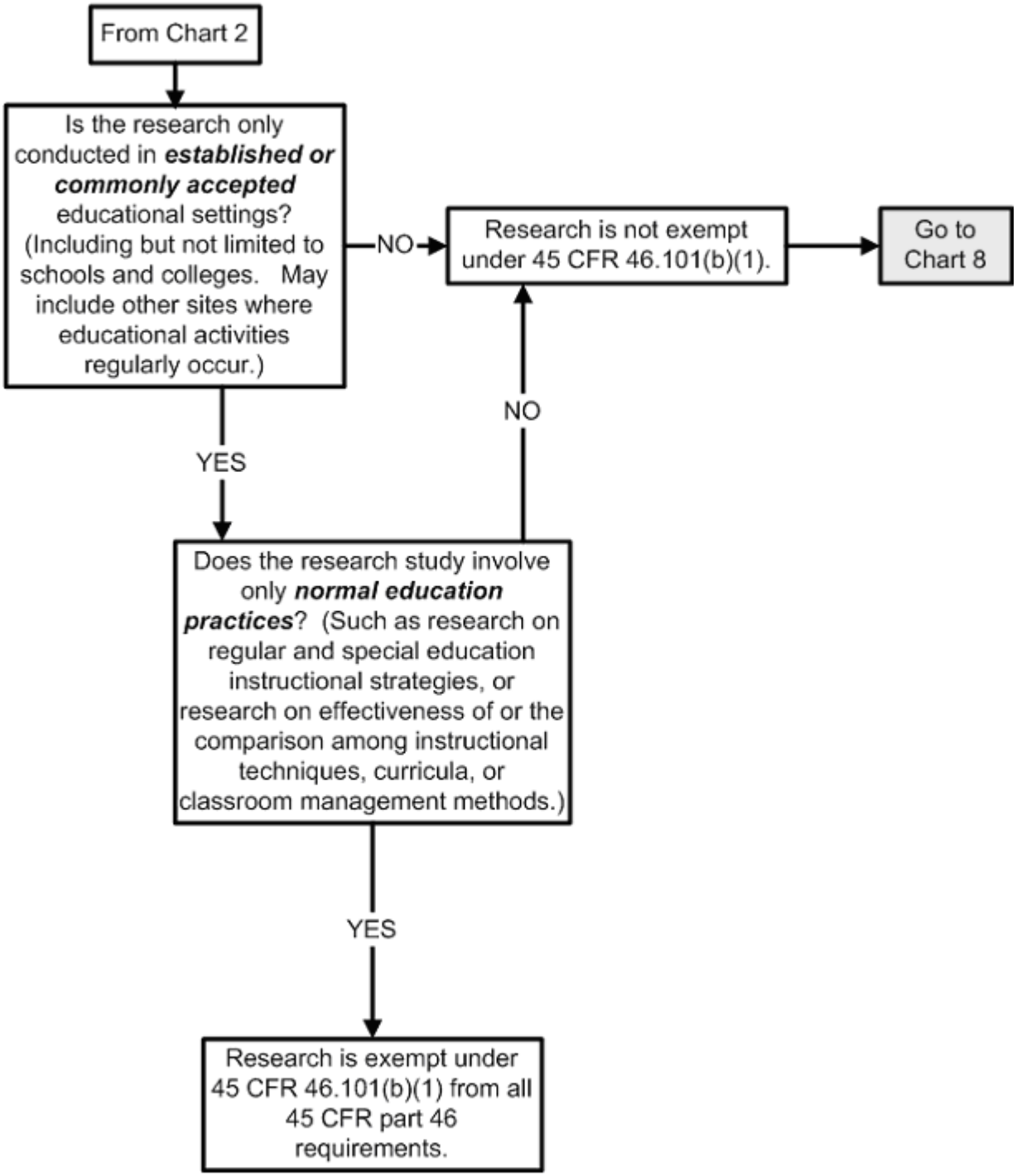


Chart 4 Does Exemption for Tests, Surveys, Interviews or Public Behavior Observation Apply?

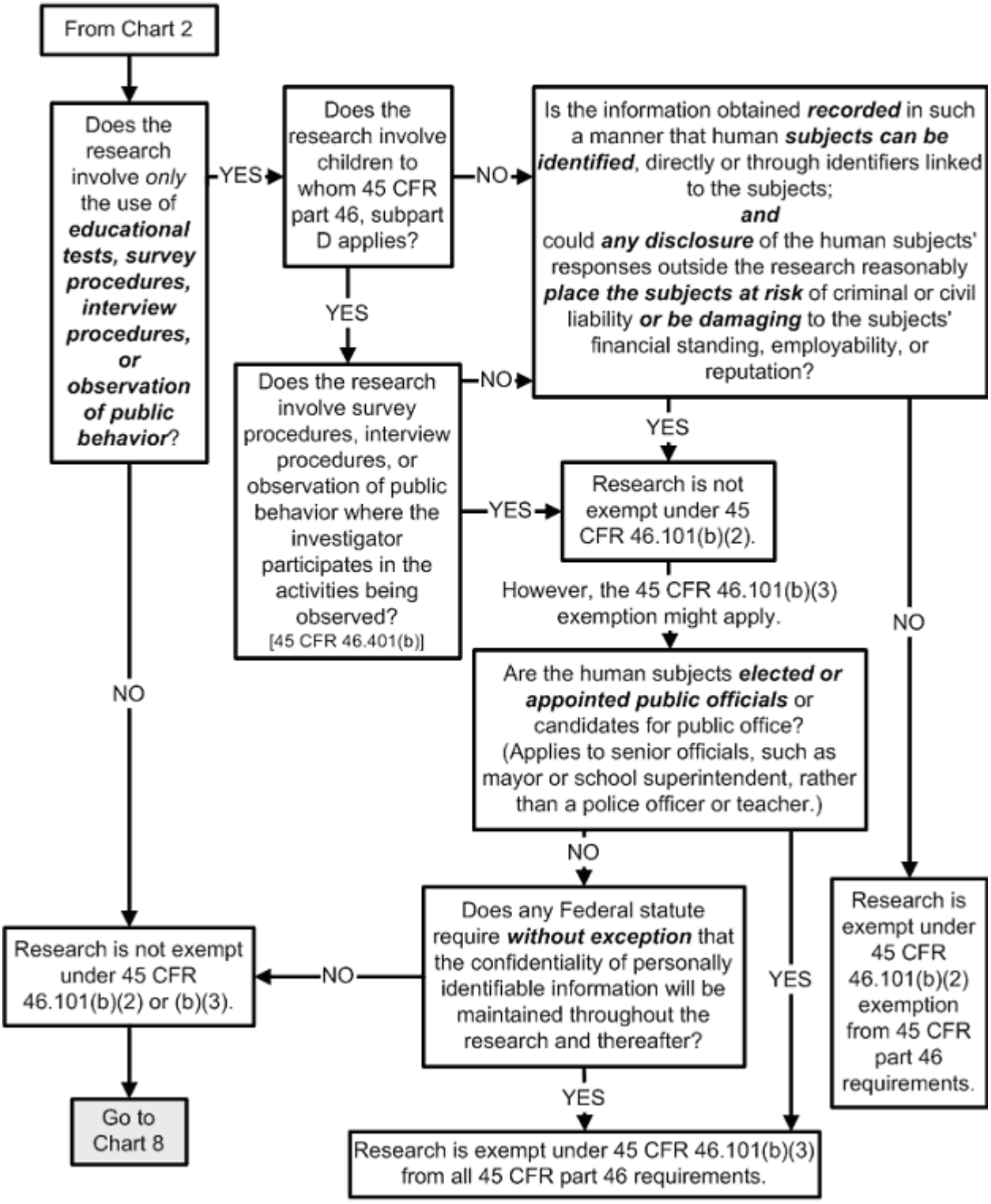
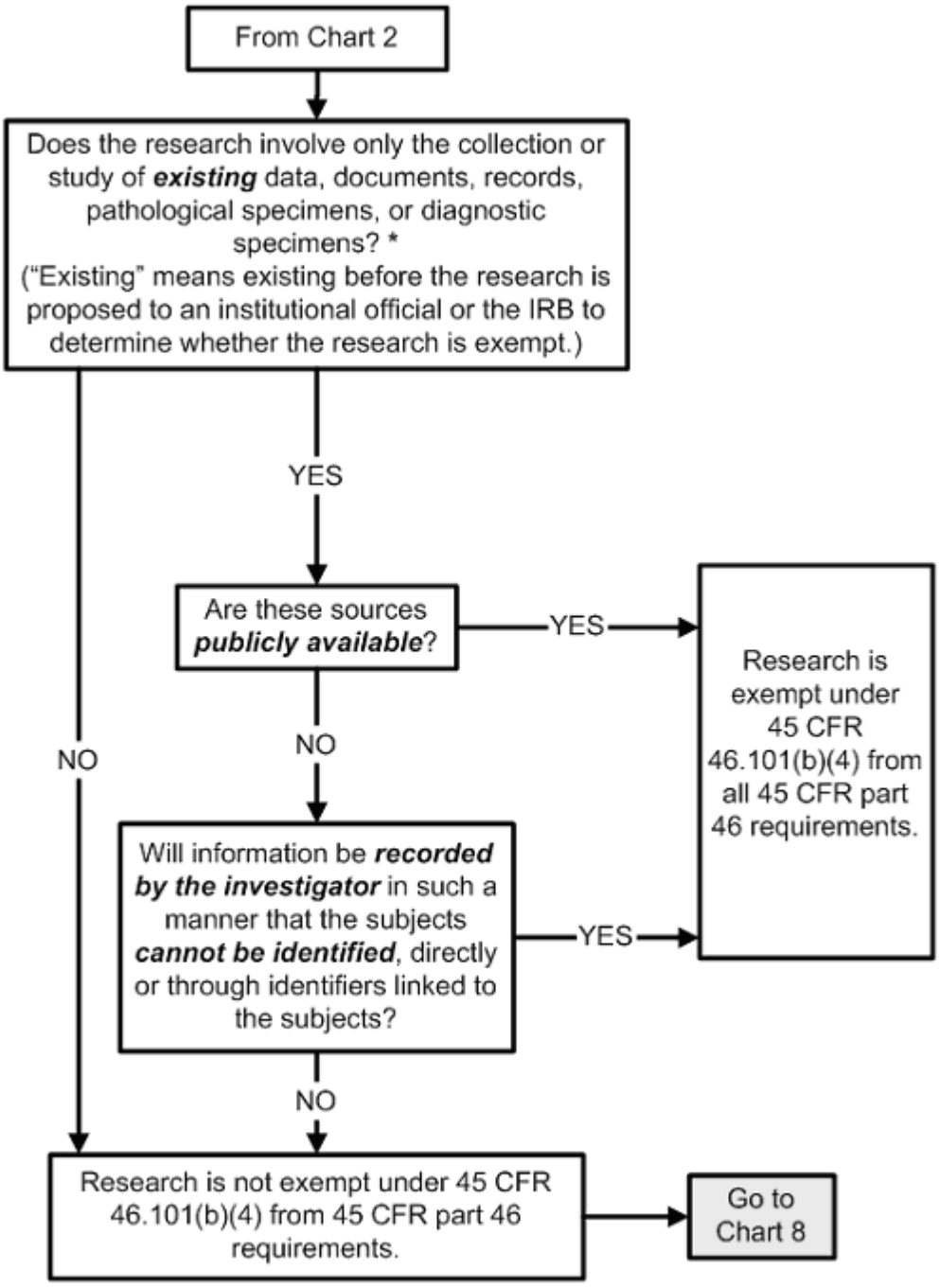
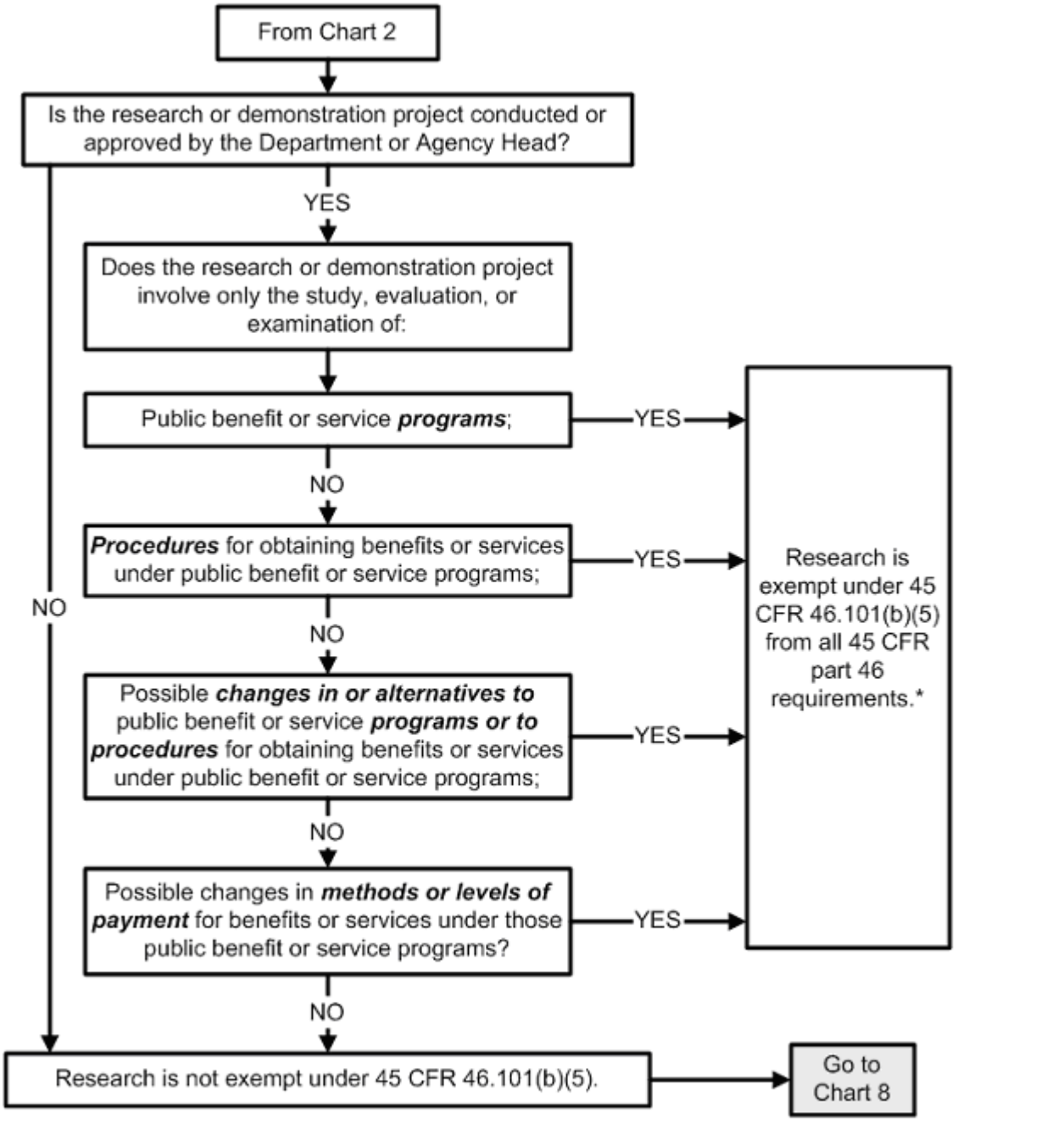


Chart 5 Does Exemption for Existing Data Documents and Specimens Apply?



* 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.

Chart 6 Does Exemption 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.

Chart 7 Does Exemption for Food Taste and Acceptance Studies Apply?

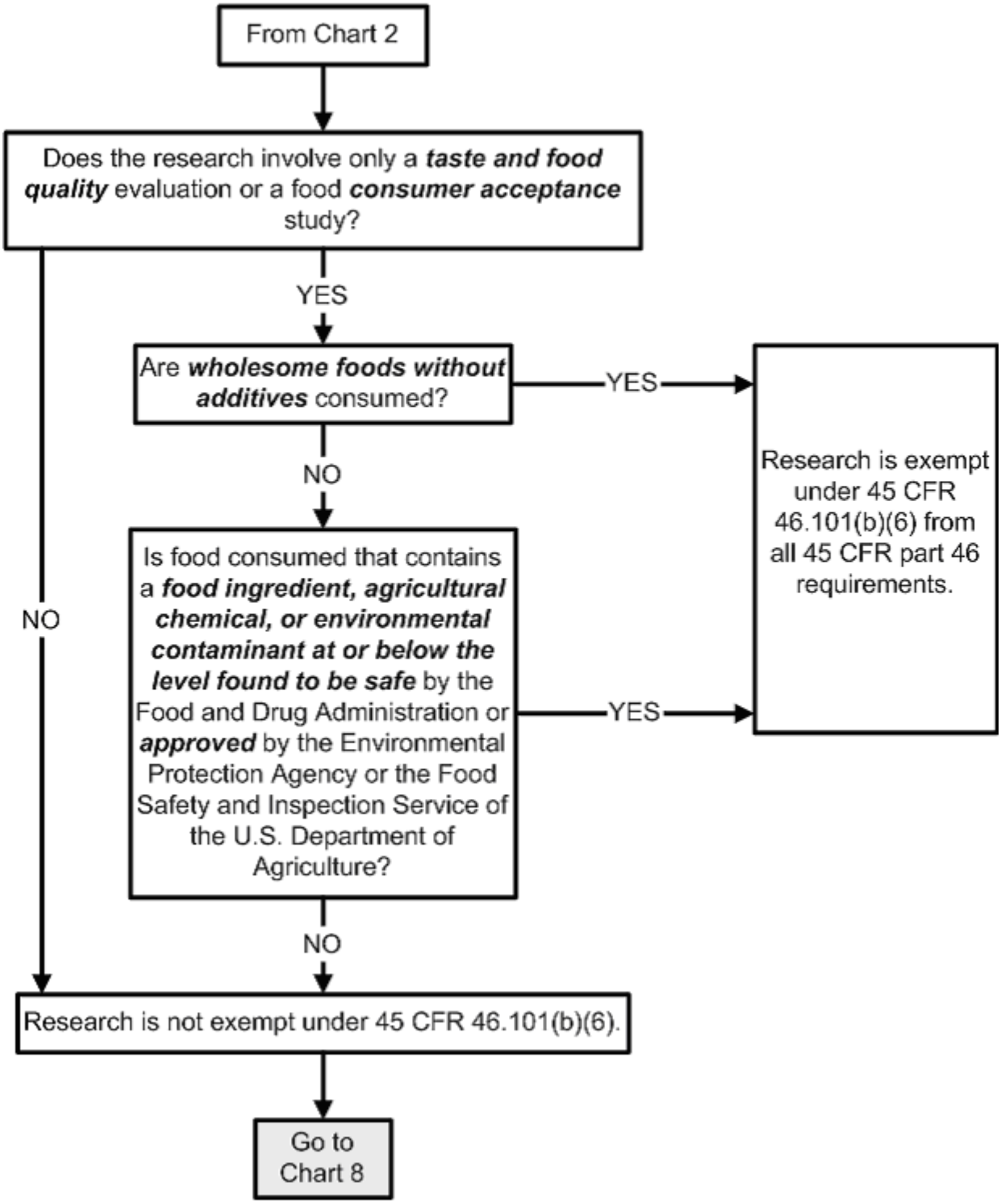


Chart 8 May the IRB Review be Done by Expedited Process?

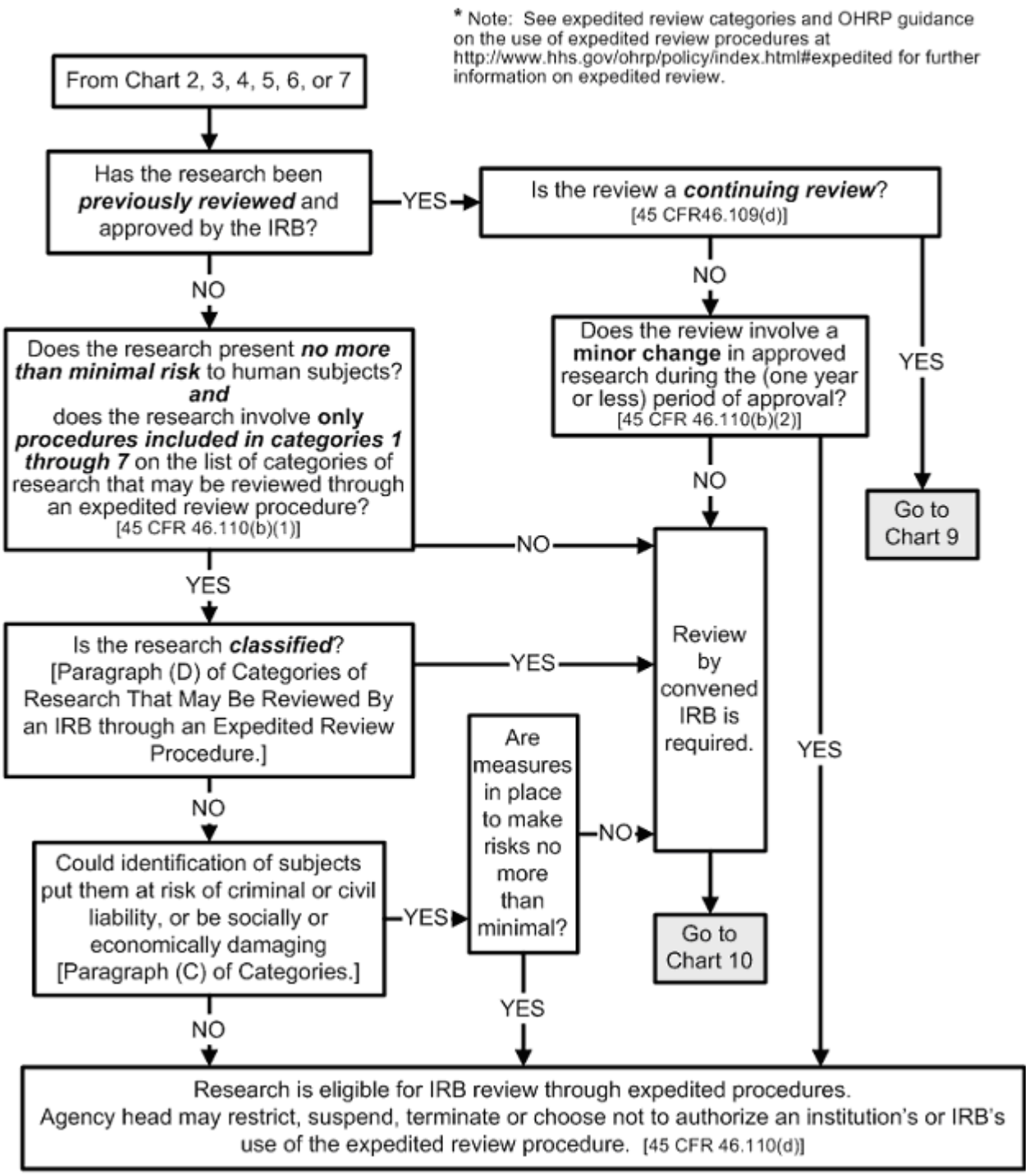


Chart 9 Can Continuing Review be Done by Expedited Procedures?

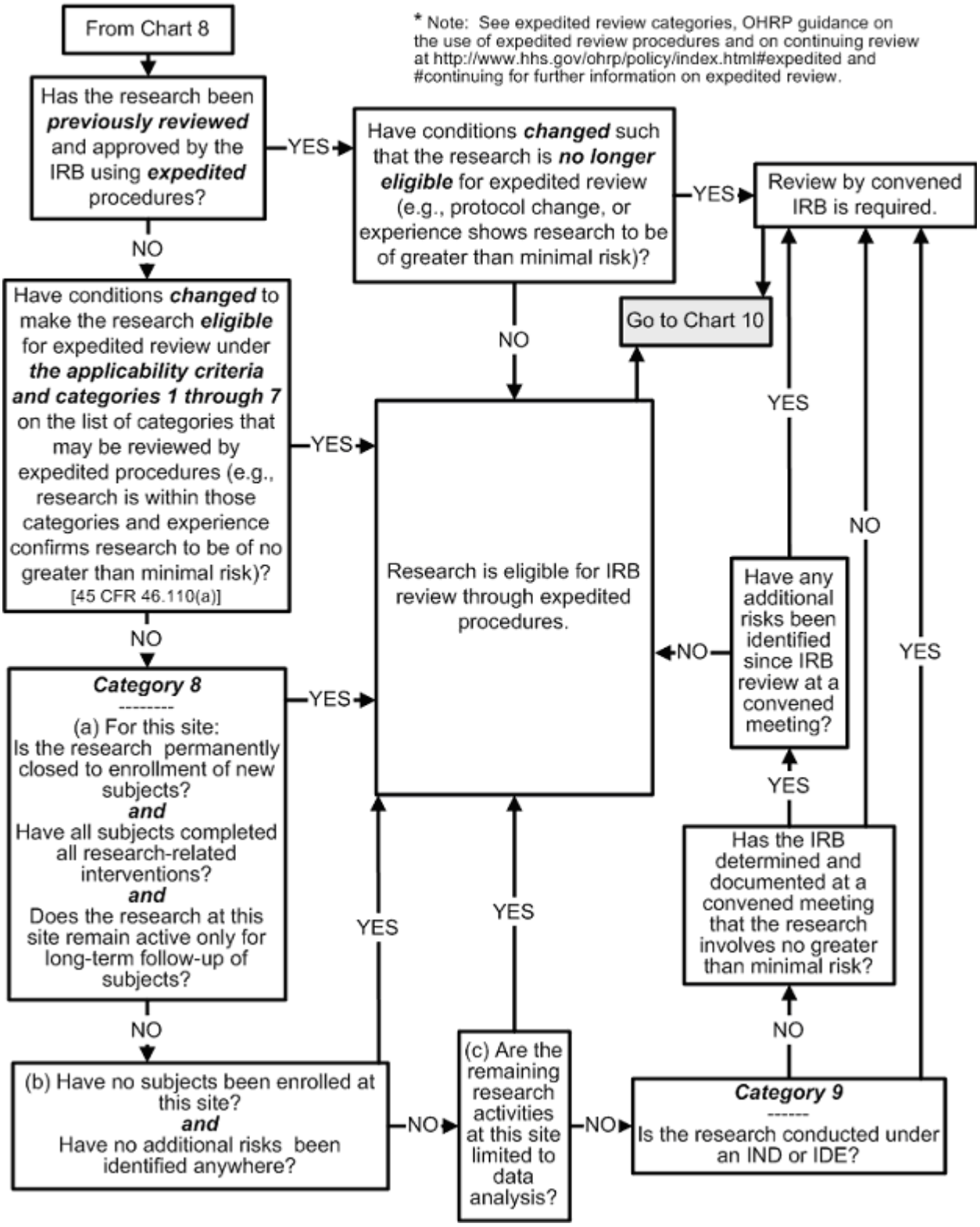
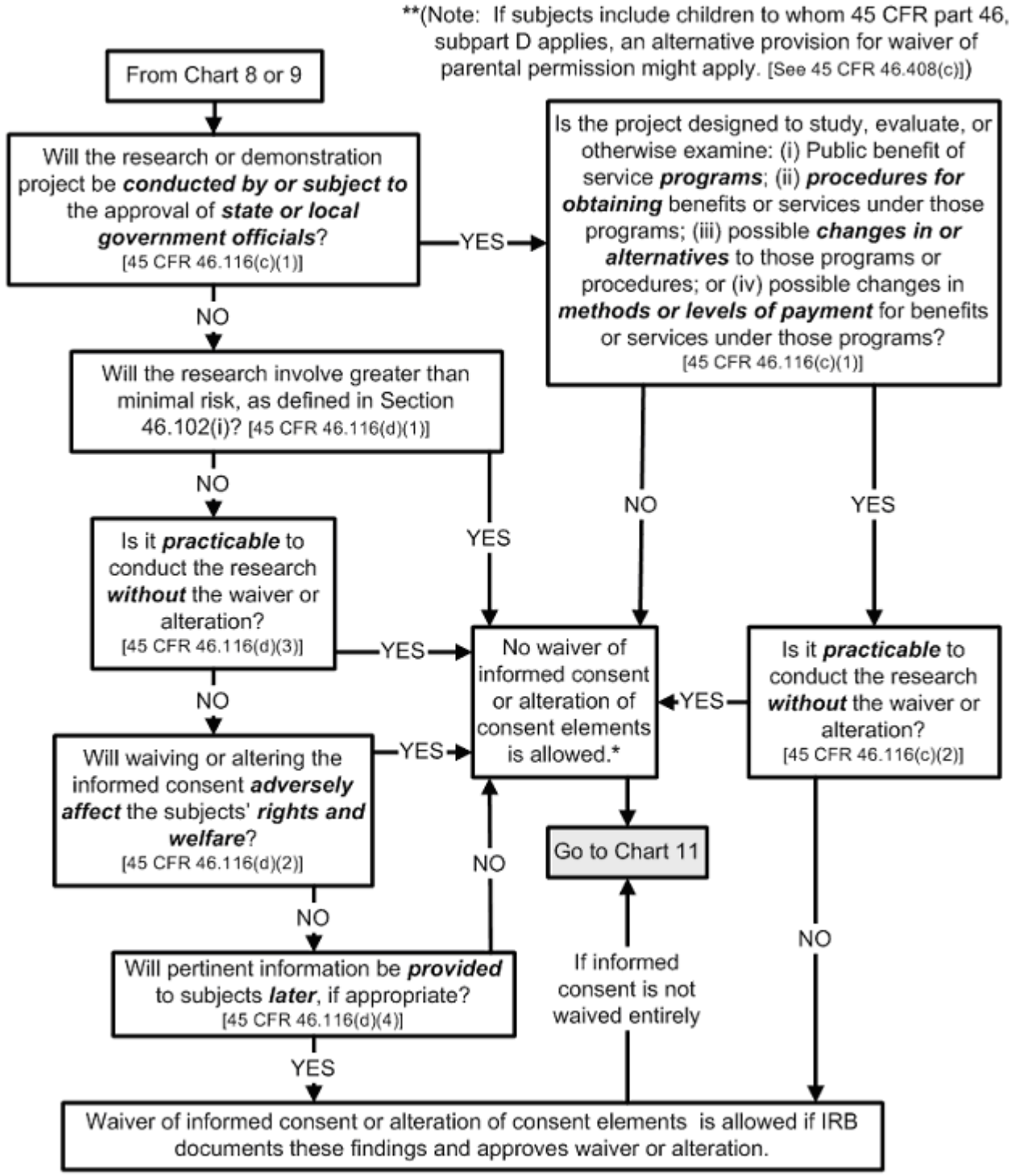


Chart 10 Can Informed Consent be Waived or Consent be Altered?



* 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.

Chart 11 Can Documentation of Informed Consent Be Waived?