NATIONAL UNIVERSITY

PROCEDURES GOVERNING HUMAN SUBJECTS RESEARCH

National University Institutional Review Board

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NATIONAL UNIVERSITY GUIDELINES
For Human Subjects Research

This document has been authored to assist members of the University community in fulfilling the requirements of Human Subjects Research Policy of National University. It is understood that due to the complex nature of the work in the National University Institutional Review Board (NU-IRB), these procedures cannot address all possible contingencies or issues. It is expected that when issues arise that are not covered in these procedures, they will be resolved through discussion.

The Procedures will be reviewed at least annually for accuracy and completeness. Any NU-IRB member can question procedures and/or suggest changes at any time. Other changes may be prompted by external sources, e.g., in response new Federal guidance. The proposed changes are reviewed by the NU-IRB and administration, and revised when warranted. Each revised procedure will supersede all previously approved versions, and will be effective on the most recent revision date.

This document is written with the intent that each section may be read individually, and therefore duplication of information may occur when related to more than one section. Also, for clarification of terminology, please refer to the appendices.

I. The Institutional Authority under which the NU-IRB is Established and Empowered

National University supports research as an integral element of its mission to advance and disseminate knowledge. The University's practices and policies in support of research will firmly uphold the highest standards of ethics and integrity and comply with all Federal regulations and guidelines. National University is committed to the principle of protecting the rights of human subjects participating in research and related activities.

A. The National University Board of Trustees has approved a Human Subjects Research Policy (2010), which complies with governmental regulations applicable to human research subjects and establishes the NU-IRB. This Policy is in accordance with:
   1. Code of Federal Regulations (CFR), Title 45 Department of Health and Human Services (DHHS) - Part 46 (45 CFR part 46);
   2. CFR, Title 45 DHHS - Part 21 CFR 50 and 56, and 34 and CFR Part 99;
   3. Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy rules (CFR 50 and 56)
   4. Family Educational Rights and Privacy Acts Regulations (FERPA) privacy rules (34 CFR Part 99)

B. National University acknowledges that it bears full responsibility for the performance of all research involving human subjects including complying with Federal, state or local laws as they may relate to such research.

C. The University Provost and Administration are charged with the implementation of the Human Subjects Research Policy and the NU-IRB Procedures (2011). To this end, they have the responsibility to:
   1. Assure that human subjects PIs are familiar with and comply with all rules and regulations and procedures governing Human Subjects Research;
   2. Establish an Institutional Review Board in accordance with Federal regulations to ensure the rights and welfare of human subjects in any research activity, whether financially supported or not, and irrespective of the source of any supporting funds;
   3. Authorize the NU-IRB review of projects involving research with human subjects/participants that are proposed by researchers;
   4. Determine which research projects submitted to them for authorization should also be submitted to the NU-IRB for review.

D. The NU-IRB will implement these procedures in accordance with the Human Subjects Research Policy, all relevant laws, and regulations and in a manner that conforms to the NU-IRB's understanding of the law. To do so, the NU-IRB will create procedures, forms and other instruments, as it deems necessary. This document outlines the required procedures of Human Subjects Research as specified in the Human Subjects Research Policy.

E. The NU-IRB has authority to approve, require modifications in, or disapprove research activities if they fall in any of the following categories:
   1. The project is supported, in whole or in part, by funds or equipment provided by the Federal government, a State government, or any Federal or State governmental agency;
   2. The project encompasses research over which a Federal Department or Agency has specific responsibility for regulating as a research activity;
   3. The project involves human subjects taking part in biomedical or clinical research, or in behavioral research where the research activities reasonably could be expected to place participants at risk of physical or psychological harm. The determination of risk is determined by the NU-IRB;
   4. The project includes members of vulnerable populations who are relatively or absolutely incapable of protecting their interests. These populations may include, but are not limited to: children under the age of 18; individuals with cognitive or decisional impairment; prisoners; fetuses and pregnant women; the terminally ill; students and employees of NU; and comatose patients.
   5. The project targets (not simply includes) a particular religious, racial, ethnic, or sexual-orientation population. This criterion is included to ensure the equitable distribution of the benefits and burdens of research according to the justice principle of the Belmont Report (1979);
   6. The project is a type that the responsible University unit has specified to require NU-IRB review and approval;
   7. The external funding source for the project has required that it be submitted for NU-IRB review and approval;
   8. The project is significantly beyond minimal risk to the subjects and requires NU-IRB review in consultation with appropriate experts.

II. The Purpose of the NU-IRB and the Protection of Human Subjects in Research
The primary purpose of the NU-IRB is to protect human subjects used in research conducted under the auspices of National University and to ensure that all research involving human subjects is conducted in conformance with ethical principles relating to the health, welfare, safety and rights of the participants, and in accordance with policies and regulations established by the United States Department of Health and Human Services.

A. The NU-IRB ensures that the research it reviews will strictly adhere to the three principles of the Belmont Report: respect for persons, beneficence, and justice. The NU-IRB will review, approve, require modifications or disapprove all research activities that fall within its jurisdiction as specified by both the Federal regulations and NU policy. Research that has been reviewed and approved by NU-IRB may be subject to review and disapproval by appropriate officials of the institution. However, those officials may not approve research if it has been disapproved by the NU-IRB.

B. Before a research project involving human subjects is initiated, it must first be reviewed and approved by the NU-IRB, and then conducted according to the procedures as set forth by the NU-IRB. It is the responsibility of the NU-IRB to determine whether proposed research exposes subjects to unreasonable or unnecessary risk, to review informed consent forms and process, and to monitor the progress of research. The NU-IRB safeguards the rights and welfare of human subjects involved in all research projects conducted under University auspices (research conducted by any University employee, student, or agent either in the course of his or her University responsibilities or when using the University's name, symbols, property, or services in connection with the research).

C. Any Human Subjects Research conducted under University auspices and for which National University is responsible, regardless of the source of the funding or whether the research is funded must adhere to the Human Subjects Research Policy and Procedures. This applies to any research conducted by National University faculty, staff, or students that involves human subjects or any research that utilizes National University faculty, staff, or students as subjects. Any research that utilizes National University faculty, staff, or students as subjects must be approved by the NU-IRB before the research can be undertaken.

D. Research that is based solely on scholarly literature, written by others about human subjects, or research that is purely theoretical or is exclusively limited to non-human subjects, does not fall under the *Human Subjects Research Policy*. Activities conducted only as part of class assignments or as tools for learning about research, and are not disseminated beyond that class do not meet the defined criteria of research and, therefore, do not fall under this policy. However, class research projects that result in a published thesis (e.g. a bound volume in the NU library, or a journal article) are considered research under the generalizable knowledge criteria and do fall under this policy.

E. The NU-IRB will review proposed research activities to ensure that:
   1. All risks to human subjects and investigators shall be minimized;

2. Risks to Human Subjects participants shall be reasonable in relation to the anticipated benefits of the human participants, if any, and the knowledge expected to be acquired from the research;
3. Investigators shall select the subjects equitably and impartially;
4. Investigators protect the rights of participants who may be subject to exploitation, coercion or undue influence. In addition to participants identified as members of "vulnerable populations," this may include, but is not limited to: minority groups and/or non-English speakers; individuals over the age of 65; individuals from the Department of Veterans Affairs (VA); and economically or educationally disadvantaged persons. Where members of these populations are included in the participants, the research proposal must include additional safeguards to protect the rights and welfare of these participants, satisfying the legal and government requirements;
5. Information given to subjects as part of the informed consent process conforms with legal and governmental requirements and that the informed consent shall be obtained from each participant, or from the participant's legally authorized representative, to the extent required;
6. Informed consent will be appropriately documented in writing, signed by each participant, or the participant's legally authorized representative, in conformance with and to the extent required;
7. The research proposal provides for monitoring the data collection process to safeguard the participants from adverse events;
8. The research proposal adequately provides, where appropriate, for protection of the privacy of participants and the confidentiality of data.

III. The Principles that Govern the NU-IRB

National University fosters a research environment that promotes respect for the rights and welfare of individuals recruited for, or participating in, research conducted by or under the auspices of the University. National University is committed to safeguarding the rights and welfare of human subjects involved in all research projects conducted under University auspices; providing timely and high quality review and monitoring of human research projects; and facilitating excellence in Human Subjects research. The responsibility of Principal Investigator will be guided by the University's mission statement and by accepted ethical principles for Human Subjects Research. As protecting human participants is the responsibility of everyone within the University, these policies and associated procedures serve as the basis for an effective system.

A. **Federal Regulations:** In the review and conduct of research, actions by the University will be guided by the principles (i.e., respect for persons, beneficence, and justice) set forth in the Belmont Report (1979). The University has established policies and these procedures to comply with and strive to exceed the Federal regulations applicable to human research subjects as set forth in the Code of Federal Regulations, 45 CFR Part 46, 21 CFR 50 and 56, and 34 CFR Part 99. National University's Federalwide Assurance (#14390) with the DHHS Office of Human Research Protections (OHRP) mandates that the institution follows these regulations for all funded and non-funded research.

B. **Local, State and International Laws:** These procedures do not affect any local, state or international laws or regulations which may otherwise be applicable and which provide additional protections to human subjects or research.

C. **Professional Organization Guidelines:** These procedures are not intended to supplant ethical guidelines for research established by professional organizations that represent the various disciplines within the academic and professional communities. As a result, researchers shall maintain a working knowledge of, and be guided by the policies of the professional societies and organizations that represent their professional disciplines. For example, researchers in the University's Psychology Department shall adhere to the ethical principles of psychologists as promulgated by the American Psychological Association.

D. **Ethical Standards:** Researchers at the University strive to maintain the highest ethical standards and shall utilize the guidelines described in this policy as minimum standards in the effort to protect the welfare and rights of their subjects and to contribute knowledge to their disciplines. If a researcher has questions regarding the ethical, legal, or regulatory effects or issues beyond the researcher's expertise, the NU-IRB administration, under the direction of the Provost's office may obtain advice from outside professionals, including legal counsel, to respond to such issues.

IV. The Authority of the NU-IRB

The NU-IRB is granted authority through the terms of National University's Federal Wide Assurance (#14390) with the Department of Health and Human Services Office of Human Research Protections.

A. **The Scope of Authority:** The NU-IRB is granted authority through the terms of the Federalwide Assurance (FWA) (per 45 CFR 46.103), by way of the NU Institutional Official to OHRP, to review and act upon Human Subjects Research, in which NU is engaged, that is conducted or supported by any Federal department or agency. NU indicates in its FWA that it applies 45 CFR 46 in its entirety to all Human Subjects Research regardless of source of funding, unless the research is covered under a separate Assurance. The NU-IRB review applies to Human Subjects Research conducted by NU faculty, students, staff, or others, either on NU premises or elsewhere. NU indicates in its FWA that it applies 45 CFR 46 in its entirety to all Human Subjects Research regardless of source of funding, unless the research is covered under a separate Assurance. The NU-IRB review applies to Human Subjects Research conducted by NU faculty, students, staff, or others, either on NU premises or elsewhere.

   This responsibility extends to all Human Subjects Research including pilot studies and feasibility studies, even if such studies include only one subject; and it includes all research involving human subjects performed under the auspices of NU regardless of whether the studies are extramurally funded, funded by University sources or non-funded.

B. **Authority To Disapprove, Modify or Approve Studies Based upon Consideration of Human Subjects Protection Aspects:** The NU-IRB has the responsibility and authority to

review all research projects involving human subjects before the data collection may begin and to approve, defer and/or require modifications to secure approval, table, or disapprove all Human Subjects Research overseen and conducted by NU and covered by the University's FWA to ensure the rights, welfare and protection of all human subjects.

The NU-IRB can require from investigators revisions to research protocols and informed consent documents as a condition for initial or continuing approval; approve new research projects and the continuation of previously approved projects; and disapprove the initiation of new research projects. In addition, the NU-IRB has the responsibility and authority to review and take appropriate actions regarding conflict of interest.

The NU-IRB may consider recommendations from other institutional or extramural review committees, but the NU-IRB has the responsibility and sole authority to carry out its review responsibilities in accordance with these policies and procedures.

The NU-IRB shall define whether proposed research is acceptable based on regulations and policies, applicable law, validity of study design as it relates to risks and benefits, sensitivity to community standards and attitudes, as well as standards of professional conduct and practice. University official can disapprove a research project that has received NU-IRB approval. However, University officials may not approve a study that has not received NU-IRB approval [45 CFR 46.112; 21 CFR 56.112].

C. **Authority to Require Progress Reports from the Principal Investigators and Oversee the Conduct of the Study:** The NU-IRB has the responsibility and the authority to observe, or have a third party observe, the consent and the research. This may include, but is not limited to, the research progress of studies or the monitoring of activities in approved projects including: (a) regularly scheduled continuing review at least annually, (b) requiring verification of compliance with approved research protocols; and (c) informed consent procedures through means such as audit, observation or third party review.

   The authority to review progress of studies includes the authority to develop mechanisms for prompt reporting to the NU-IRB of any planned changes in approved projects prior to the implementation of those changes and the authority to develop mechanisms for prompt reporting to the NU-IRB of any unanticipated problems occurring in, or related to, approved protocols.

D. **Authority to Suspend or Terminate Approval of Research:** The NU-IRB and/or certain members of the University administration and/or the NU-IRB chair/designee have the responsibility and the authority to suspend or terminate approval of any study that it has originally reviewed and approved that has (a) unanticipated problems involving risks to human subjects, (b) serious or continuing noncompliance with any Federal regulation, or (c) serious or continuing noncompliance with the requirements or determinations of the NU-IRB. The NU-IRB shall consider the rights and welfare of current research subjects when suspending or terminating approval of active studies.

E. **Authority to Place Restrictions on Research:** The NU-IRB has the responsibility and the authority to restrict any study that it has originally reviewed and approved if it determines such action is warranted. Under this policy, "restrict" is defined as suspending or terminating a portion of a study found in non-compliance either permanently or until it is brought into compliance. One example of this may be if an aspect of a study fails to comply with Federal regulations or NU-IRB requirements or determinations. In this circumstance, the NU-IRB may suspend or terminate approval of the entire study pursuant to the policy on suspending or terminating approval of research (see above) or the NU-IRB may place restrictions on one or more portions of the study. The NU-IRB may also request that a study audit be conducted.

F. **Authority to Observe, or have a Third Party Observe, the Consent Process [45 CFR 46.109(e); 21 CFR 56.109(e)]:** If the NU-IRB approves a study, that NU-IRB has sole authority for oversight of the study including the consent process. To carry out this responsibility, the NU-IRB may observe or have a third party observe the consent process and/or it may seek information on this process from the Principal Investigator or others.

G. **Authority to Observe, or have a Third Party Observe, the Conduct of the Research [45 CFR 46.109(e); 21 CFR 56.109(e):** If the NU-IRB approves a study, it has sole authority for oversight of the study including the conduct of the research under the approved protocol.

H. **Authority to Investigate Accusations of Violations**: The NU-IRB will investigate allegations and findings of non-compliance and to report potential serious or continuing non-compliance with applicable regulations or NU policies to the Institutional Official. For further information please refer Section XVI.

V. The NU-IRB's Relationship with other Groups

Collectively, the University community seeks to create both a culture of research that provides a supportive environment, and one which produces quality research while properly protecting human subjects. The NU-IRB works with others in this community to accomplish this common goal. It is through effective relationships that researchers are guided and supported to successful completion of their research activities.

A. **The Executive Administration of the Institution:** The University Provost (Institutional Official) and administration are charged with the implementation of the *Human Subjects Research Policy* and the NU-IRB Research Procedures. They have the responsibility to appoint members to the NU-IRB and provide support for NU-IRB activities. The NU-IRB is accountable to the administration and will provide appropriate reports.

B. **School Deans, Department Chairs, and Research Committees:** The NU-IRB is accountable to the School Deans, Department Chairs, and Research Committees for providing educational tools, Collaborative Institutional Training Initiative (CITI) access, timely review of proposals and researcher questions, and on-going support for researchers and Faculty Sponsors. Likewise, School Deans, Department Chairs, and Research Committees are expected to model appropriate Human Subjects Research methods within their respective schools and committees.

C. **The Principal Investigators (researchers):** The NU-IRB is accountable to the Principal Investigators for providing educational tools, CITI training, timely review of proposals and researcher questions, and on-going support for researchers. Likewise Principal Investigators are expected to comply with Federal regulations and NU policies and procedures, including completion of all proposal documents and submitting to IRBNet (web-based proposal review system, for more information please refer to the Appendices), following decisions of the NU-IRB, and applying appropriate Human Subjects Research methods.

D. **Faculty Sponsors:** The NU-IRB is accountable to the Faculty Sponsors for providing educational tools, CITI training, timely review of proposals and Faculty Sponsor questions, and on-going support for researchers. Likewise, Faculty Sponsors must complete the CITI training and NU-IRB orientation prior to teaching graduate research courses. They are expected to model appropriate Human Subjects Research methods, and ensure that student research conducted under their direction must conform to the requirements of Federal law and regulations on research regarding human subjects, the *Human Subjects Research Policy*, and the NU-IRB Research Procedures. Faculty Sponsors must review all documents, verify document completion, electronically sign and submit proposal packages, and monitor proposal progress.

E. **External Entities:** The NU-IRB supports inter-institutional research and researchers from external organizations. For research that involves more than one entity, each entity is responsible for safeguarding the rights and welfare of human subjects and for complying with Federal regulations, NU policies and NU procedures. With the approval of the IRB or agency head, the researcher may enter into a joint review arrangement, which can include (a) NU-IRB continuing review, (b) reliance upon the review of another qualified IRB, or (c) make similar arrangements for avoiding duplication of effort.

F. **Regulatory Agencies:** In accordance with the requirements of the DHHS Protection of Human Subjects regulations, 45 CFR part 46.103(a), the NU-IRB is registered with the Office for Human Research Protections (OHRP). NU's FWA with the DHHS OHRP mandates that NU follows the regulations for all funded and non-funded research. OHRP's Division of Compliance Oversight (DCO) reviews institutional compliance with the Federal regulations governing the protection of human subjects in research.

1. The NU-IRB functions in accordance with these governmental regulations:
   - CFR, Title 45 DHHS - Part 46 (45 CFR part 46);
   - CFR, Title 45 DHHS Part 21 CFR 50 and 56, and 34 and CFR Part 99;
   - HIPAA privacy rules (CFR 50 and 56);
   - FERPA privacy rules (34 CFR Part 99);

2. The NU-IRB also functions in accordance with all local, state or international laws and regulations which are applicable, and which provide additional protections to human subjects or research.

VI. Functions of the NU-IRB

According to the Human Subjects Research Policy of NU, the primary function of the NU-IRB is to protect human subjects used in research conducted at this institution. The functional mandates of the NU-IRB as approved in the Human Subjects Research Policy are as follows:

A. Provide educational tools for CITI certification and monitor completion of required training.
B. Conduct initial and continuing review of Human Subjects Research;
C. Report findings and actions of the NU-IRB to the Principal Investigator, Faculty Sponsor, and the institution;
D. Determine which projects meet Exemption criteria, or require Expedited or Full Board review.
E. Monitor Expedited and Full Board review projects and determine whether approved projects require continuing review more often than annually;
F. Determine which projects need verification from sources other than the investigators to ensure that no substantive changes have occurred since previous NU-IRB review;
G. Ensure that changes to in approved research are not initiated without NU-IRB review and approval except where necessary to eliminate apparent immediate hazards. The NU-IRB may determine that the change does not constitute a serious deviation in the research activity, or may determine that additional steps must be taken to ensure compliance;
H. Ensure prompt reporting to the NU-IRB, appropriate institutional officials, and appropriate Federal agencies of: changes in research activities, unanticipated problems involving risks to subjects or others, serious or continuing noncompliance with 21 CFR parts 50 and 56 or the requirements of the NU-IRB, suspension or termination of NU-IRB approval;
I. Determine which device studies pose significant or non-significant risk.

VII. Management of the NU-IRB

The NU-IRB is charged in accordance with federal regulations to ensure the rights and welfare of human subjects in any research activity. The management of the NU-IRB is established to meet this charge as delineated in the *NU Human Subjects Research Policy*.

A. **Chairpersons:**
   1. *Selection:* The Chair or Co-chairs are appointed by the Provost. In addition to possessing the professional competence necessary to review specific research activities, the Chair/Co-chair must be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable laws, and standards of professional conduct and practice.
   2. *Length of term/service:* The length of service is two years and may be renewed.
   3. *Duties:* In collaboration with the Administrator (see below), the Co-chairs set the agenda for meetings, conduct the meetings, and reviews potential exempt applications. In collaboration with the Administrator, the Co-chairs and responsible for updating the procedures. In the absence of both Chairs, the Provost will appoint a temporary Chair from the members to conduct the meeting.
   4. *Review responsibilities:* The Co-chairs are responsible for reviewing all Full Board reviews and those Expedited reviews that may be assigned. The Co-chairs are responsible for all potential exempt reviews.

5. *Continuing education:* The Co-chairs should attend at least one workshop provided by OHRP annually to keep abreast of changes that may need to be made in policy or procedures.
6. *Dismissal:* The Co-chairs may be removed, by the Provost, for failure to perform the duties and responsibilities.

B. **Administrator:**
1. *Service on the NU-IRB*: The Director of Instructional Services and Research Compliance serves as the Administrator, ex officio and non-voting member, and is appointed by the Provost.
2. *Responsibilities*: The Administrator is responsible for:
   a. coordinating functions of the NU-IRB;
   b. serving as the liaison to the NU-IRB;
   c. interpreting institutional and Federal policies, procedures and regulations to ensure compliance with Federal, State and University regulations governing Human Subjects Research;
   d. educating and advising Principal Investigators and Faculty Sponsors on the regulatory and ethical issues involved in conducting Human Subjects Research;
   e. supervise administrative assistants in their responsibilities.
3. *Vacancy:* In the event the Administrator of the NU-IRB becomes vacant or is unable to serve, the Provost will appoint a substitute until a new Administrator is appointed or the Administrator resumes the NU-IRB duties.

C. **IRB Members:**
1. *Selection:* Following the guidelines in 45 CFR 46.107, the NU-IRB will consist of a minimum of seven voting members, including at least one faculty member from each of the University's academic schools, at least one member who is not otherwise affiliated with the University or part of the immediate family of a person who is affiliated with the University, and one administrator as an ex officio and non-voting member. At all times, the NU-IRB shall have:
   a. at least one member from a scientific area;
   b. at least one member from a non-scientific area;
   c. at least one member from the community.
2. *Diversity:* The members will have varying backgrounds to promote a complete and adequate review of research activities commonly conducted by the University. The NU-IRB will be sufficiently qualified through the experience and expertise of its members, including consideration of race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.
3. *Certification:* Prior to appointment to the NU-IRB, the Co-chairs and members must complete the CITI modules required by National University for instruction in the protection of human subjects in research.
4. *Alternate members:* It is highly recommended that all members have an alternate member with similar expertise who can complete reviews and participate in meetings in his or her absence.

5. *Appointment:* Faculty members will be appointed by Provost and can be appointed at anytime during the year. All appointed members may be reappointed to serve additional terms indefinitely.
6. *Length of term/service:* Members are appointed for three years of active service. The terms will be staggered to assure some degree of consistency over the life of the IRB. Members may be reappointed.
7. *Vacancy:* When a vacancy occurs, the Administrator will immediately notify the Provost and the NU-IRB Chair, and request the appointment of a new member to fill the vacancy from the same College/School or representative category as the departed member.
8. *Duties:* Members act as surrogates and advocates for potential subjects in research. Members must prepare for and actively participate in all meetings to discuss regulatory and ethical considerations surrounding proposed research. Members must complete assigned reviews as required.
9. *Review responsibility:* In addition to Full Board reviews, members will be assigned as a panel of two reviewers for Expedited proposals. A completed review requires: reviewing all proposal documents, completing and attaching the reviewer worksheets for the application and any supplements, completing the remainder of the review if modifications are requested, and notifying the Administrator when the review is complete. All reviews must be completed within 5 working days from the day sent to the reviewer. (see Appendix F for Reviewer User Guide).
10. *Warning and Dismissal:* Members may be removed, by the Provost, for failure to perform the duties and responsibilities.
    a. a warning will be issued from the Administrator and copied to Department Chair or appropriate School Dean and NU-IRB Co-chairs for:
        - unexcused absence for two Full Board review and/or quarterly meetings within an academic year
        - not fully completing two (2) consecutive assigned proposals within the established five (5) working days.
    b. after the third infraction, a recommendation of dismissal will be sent to the Provost.

D. **Training of NU-IRB Chairs and Members:**

1. *Training:* Instruction in human subjects protection is required by Federal Assurance with the DHHS for all Principal Investigators and research personnel regardless of the source of funding. The NU-IRB Chair, Co-chair and NU-IRB members must complete the CITI modules required by National University for instruction in human subject's protection. As changes occur in guidelines for protection of human subjects, NU-IRB members may be required to update their CITI training or take additional modules.
2. *Orientation:* New members are expected to review the Human Subjects Research Policy and NU-IRB orientation course available on eCollege. In their initial inclusion to the NU-IRB, new members may request a faculty mentor to assist them, or a faculty member may be assigned.
3. *Continuing education:* Members are encouraged to participate actively in continuing education to assure continued excellence in the research review process.
4. *Reference materials:* Reference materials are provided in the eCollege NU-IRB orientation.

E. **Compensation of NU-IRB Members:** No financial compensation above faculty salary is provided for National University faculty for service. The Chair and Co-chair may be provided a one course release time. The external member is paid a stipend for onsite attendance at each meeting.

F. **Liability Coverage for NU-IRB Members**: With regard to potential legal action, NU-IRB members are protected under the auspices of NU which provides coverage for NU faculty and staff serving on the NU-IRB and also covers any person authorized to act on behalf of the NU-IRB as an external member or consultant. NU-IRB members function as employees or agents of NU. As such their actions are covered by the NU liability coverage if their actions arise within the course and scope of their NU-IRB responsibilities.

   IRB members who are unaffiliated with the University (sometimes referred to as "community members") are also covered by this same liability coverage when performing within the course and scope of their NU-IRB service. Refer to Director of Instructional Services and Research Compliance for additional information.

G. **Use of Consultants:** The NU-IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the NU-IRB. These individuals may not vote with the NU-IRB.

H. **Conflict of Interest:**
   1. *Member participation:* No member may participate in the initial or continuing review of a proposed research study in which the member has a conflicting interest, except to provide information requested by the IRB.
   2. *Definition:* Conflicting interest may include:
      a. having a Principal Investigator request that specific members of the NU-IRB review a research proposal.
      b. an NU-IRB member who:
         - is or will be an investigator in the research;
         - has a financial or managerial interest in a sponsoring entity or product being evaluated in the research;
         - has a close family relationship with an individual who is one of the investigators.
   3. *Mandatory recusal:* Those members with a conflicting interest must recuse themselves from the deliberation, discussion, and vote on that proposal. Such absence shall be noted in the NU-IRB minutes and regular post-meeting correspondence to the Principal Investigator.
   4. *Voluntary recusal* A member may voluntarily recuse him/herself for personal reasons without repercussion.

I. **Support and Resources:** Continuing education, training, space for meetings, and other resources will be provided by National University.

VIII. Operations of the IRB

The NU-IRB is charged in accordance with federal regulations to ensure the rights and welfare of human subjects in any research activity. The NU-IRB will operate in accordance with requirements as established in the NU Human Subjects Research Policy.

A. **Schedule of Meetings:** The full NU-IRB meets at least four times a year, once per quarter, and for special sessions as needed. Meetings of the Full Board of the NU-IRB most frequently deal with policy issues and those proposals that are considered to be beyond minimal risk. Additional meetings will be held based on need. At least on Chair must be present for meetings to occur. Scheduled meetings may be cancelled due to an inability to secure a quorum for attendance, or other reasons as may arise that make a scheduled meeting unnecessary or otherwise inappropriate. Members will be notified of meetings electronically via adobe connect invitation and listing in IRBNet.

B. **Pre-Meeting Distribution:** All agendas, minutes, and research proposal documents are available on IRBNet prior to the meeting date. In preparation for participation in meetings, all members are expected to access and review information.

C. **Conduct of the Meetings:**
   1. *Chair of meeting*: The Co-chairs shall lead the meeting of the convened IRB. This includes calling the meeting to order, leading the NU-IRB through the agenda, and calling for motions and votes. The Co-chair should ensure that all members have an opportunity to express their opinions and concerns on the research under review.
   2. *Quorum*: The meeting may not start absent a quorum, and if the quorum is lost during the meeting for any reason, no votes may be taken. It is the responsibility of the Co-chairs at that meeting to determine the presence of a quorum, including any special representation required for particular reviews. (For more information regarding quorum, see Section VIII-D).
   3. *Review of proposals*: The members are expected to have completed the reviewer checklist for listed research proposals before the convened meeting. In order for research to be approved, it shall receive the approval of a majority of the members present at the meeting.
   4. *Action on proposals:* The process to approve proposals proceeds as follows:
      a. the Co-Chairs may entertain a motion and a second that the NU-IRB take a certain action regarding a given proposal;
      b. the actions the NU-IRB may take on proposals are as follows: approval, approval with minor modifications, deferral, or disapproval;
      c. after a motion has been made and seconded, there will be an opportunity for discussion before a vote is taken;
      d. Those members present for the vote should be recorded as either voting for, against, or abstaining. Members who are rescued from the vote should physically leave the room, are not counted in the aforementioned tally, and should be identified by name in the minutes.
   5. *Alternates:* The NU-IRB may include alternates for specific board members. This enables members to share the workload associated with membership. However, if a member and his or her alternate are both present at the same meeting, only one may vote on each

proposal. In addition, only one member will count toward the quorum needed for Full Board actions.

6. *Closed meetings:* The meetings of the NU-IRB are not subject to "Open Meeting" laws.
7. *Attendance by PI*: Principal Investigators may be invited to attend the portion of the meeting at which their proposal is discussed. The PI may answer questions raised by the NU-IRB. The PI should not be present for the final deliberation and vote on his or her proposal.
8. *Teleconferencing and/or videoconferencing*: Teleconferencing and/or videoconferencing may be used to conduct meetings. When the NU-IRB makes use of this technology, all other normal meeting requirements apply. Additionally, whenever teleconferencing and/or videoconferencing is used, special care must be taken to ensure the security of the data transmissions so that the privacy of researchers and NU-IRB members is protected.

D. **Voting Requirements:** To adhere to the Human Subjects Research Policy guidelines specific voting requirements must be followed.
   1. *Quorum*: A quorum (50% of the members plus one) is required to transact business during quarterly or Full Board meetings.
   2. *Diversity requirements*: A quorum must first meet the following diversity requirements prior to voting for any purpose:
      a. attendance by at least one member whose primary expertise is in a non-scientific area and one whose primary expertise is in a scientific area;
      b. include representation of varying backgrounds through experience and expertise to promote complete and adequate review of research activities commonly conducted by the University;
      c. include sufficient representation of community, including consideration of race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.
   3. *Voting Requirements:* Once the diversity requirements have been met, the following voting requirements apply*:*
      a. IRB members may not vote by proxy (i.e., members not present at the convened meeting or not participating in the tele/videoconference call may not vote on an issue discussed during a convened meeting). However, members can provide written comments for NU-IRB consideration;
      b. voting may include a show of hands or written ballots at the discretion of the Chairs;
      c. at the time of voting, the Chairs ask members to vote separately for each motion with the following choices: for, against or abstain;
      d. members voting against or abstaining from action will be offered the opportunity to comment either verbally or in writing and have their comments added to the minutes;
      e. voting against a proposal should not be solely based on the quality of the writing, unless the writing mechanics are so poor that the NU-IRB cannot make a satisfactory determination of appropriate risk to human participants.
   4. *Voting Conditions:* Voting at a convened meeting takes place under the following conditions:
      a. a quorum of the members must attend for each review/action voted on at a convened meeting;

b. a passing vote must consist of a majority of members present (or connected via speakerphone/video) voting in favor of the motion;
c. an individual who is not listed on the official roster prior to the meeting may not vote;
d. ad hoc and consultants may not participate in the vote;
e. the non-scientist member must always be present for a vote;
f. if the outcome of the vote is to approve pending minor modifications, the NU-IRB may defer the final approval to the NU-IRB Co-chair or Administrator, who will then review and may approve the Principal Investigator's response on behalf of the NU-IRB.

E. Conflict-of-Interest Voting: No member may vote in a proposal deliberation which the member has a conflicting interest. This does not include the Faculty Sponsor role. For more information regarding conflict of interest refer to Section XVII-H.

IX. NU-IRB Record Requirements

The NU-IRB shall prepare and maintain adequate electronic documentation of the activities as listed below.

A. **Membership Roster Showing Qualifications:** A roster of members must include, but is not limited to the following: name; earned degrees; representative capacities; scientific/ nonscientific status; affiliation status (whether the member or an immediate family member of the member was affiliated with the organization); indications of experience (such as board certifications and licenses) sufficient to describe each member's chief anticipated contributions to NU-IRB deliberations; employment or other relationship between each member and the University. The roster includes voting members, both regular and alternate, as well as the member or class of members for whom each alternate member can substitute (e.g. scientific, non-scientific, child advocate, community, and prisoner representative).

B. Written Policies and Procedures:

1. *Policy:* The Human Subjects Research Policy as approved by the Board of Trustees of NU is made available for download from the NU website, IRBNet, and the eCollege Orientation. The formal policy indicates the legal and ethical guidelines of the NU-IRB.
2. *Procedures:* Written procedures as approved by the NU-IRB are available for download from the NU website, IRBNet and eCollege Orientation. The procedures (represented by this document) indicate guidelines and responsibilities to which NU-IRB members, Principal Investigators, and Administrators that these parties will adhere. These include:
   a. conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution;
   b. determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous NU-IRB review;
   c. ensuring prompt reporting to the NU-IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which NU-IRB approval has already been given, may not be initiated without NU-IRB

review and approval except when necessary to eliminate apparent immediate hazards to the subject;

d. communicating regulatory and other findings to the investigator and to the NU-IRB;
e. ensuring prompt reporting to the NU-IRB, appropriate institutional officials, and the department or agency head of NU-IRB actions, any unanticipated problems involving risks to subjects or others, any serious or continuing noncompliance with this policy or the requirements or determinations of the NU-IRB, and any suspension or termination of NU-IRB approval.
f. *Proposal Materials:* Copies of all documents that have been reviewed by the NU-IRB including the initial application, funding proposals, instruments, approved consent documents, progress reports submitted by investigators, reports of injuries to subjects, and statements of significant new findings provided to human subjects are stored in IRBNet.

3. *Review Materials:* Records of review status and correspondence and continuing review activities including any activity occurring after initial approval, including the frequency for the next continuing review, modifications, renewals, and reports of unanticipated problems or adverse events will be stored in IRBNet.
4. *Correspondence between the NU-IRB and the Principal Investigators:* The NU-IRB sends written/electronic notification of actions taken to the PIs and Faculty Sponsor (if student research). If revisions to new and continuing review proposals are required, correspondence is sent to the investigator detailing requests for revisions, clarification, or additional information as well as information regarding continuing review. Notification of approvals, terminations, and suspensions will be noted in IRBNet.
5. *Agendas:* An Agenda will be maintained for all meetings. Agendas of meetings will be posted and archived on IRBNet. The Agenda for the meeting will include:
   a. approval of minutes;
   b. a list of proposals under review with proposal title, package number, and Principal Investigator (PI) listed;
   c. and information on NU-IRB actions. Minutes of meetings will be posted and archived on IRBNet.
6. *Meeting Minutes*: Minutes will be kept for all convened meetings and are maintained in IRBNet with access by all members. Minutes will have sufficient detail to show the following:
   a. date and time meeting starts and ends;
   b. attendance at the meetings:
      - members present;
      - members absent (excused and unexcused);
      - alternates attending in lieu of specified absent members;
      - consultants present;
      - investigators present;
      - guests present.
   c. documentation of actions taken outside of convened meetings including the number of Exemptions and Expedited reviews and approval decided outside the convened meeting are reported to NU-IRB during the quarterly meeting. Specific information for approved projects is maintained and available on IRBNet;

d. actions taken during a Full Board review. Actions taken by the NU-IRB at a Full Board meeting as well as the vote on these actions are recorded. This includes:
   - the number of members voting for, against, and abstaining, and (if applicable) notation that any members with a conflict of interest (identified by name) were recused and were absent for the discussion and vote;
   - the approval period for projects approved by the IRB. In specifying an approval period of less than 6 months, the NU-IRB may define the period with either a time interval or a research milestone. The minutes will clearly reflect any determination requiring a review more frequently than 6 months. The NU-IRB minutes will state that all approval periods for student researchers are 6 months unless otherwise noted;
   - the basis for requiring changes in or disapproving research; for each application in which changes are stipulated by the IRB, a determination of whether the changes represent minor modifications that do not require verification by the convened IRB, or whether they are significant, requiring convened NU-IRB review;
   - a written summary of the discussion of controversial issues and their resolution.

e. NU-IRB findings and determinations: The following are required findings and determinations, and must be noted in the minutes with reference to the appropriate Federal regulations. Justification for these findings may be found in the NU-IRB application or related correspondence with the investigator.
   - determination of the level of risk for human subjects in the research stud;
   - justification of any deletion or substantive modification of information concerning risks or alternative procedures contained in the consent document;
   - justification for waiver or alteration of informed consent;
   - justification for the waiver of the requirement for written documentation of consent;
   - justification for approval of research involving vulnerable population (children, prisoners, pregnant women, mentally disabled persons or economically or educationally disadvantaged).
   - justification for approval of research planned for an emergency setting;
   - justification of use of special protections warranted in specific research projects for groups of subjects who are likely to be vulnerable to coercion or undue influence.

7. *NU-IRB Record Retention Requirements*: The study-specific records relating to research that is conducted shall be retained for at least 3 years after completion of the research. Specific record requirements include:
   a. if research is closed without enrolling participants, IRB records are maintained at least three years after study closure;
   b. upon expiration of their retention period, IRB records must be destroyed in accord with University policies and procedures for destruction of confidential records;
   c. for studies that the NU-IRB has Exempted from continuing review, study-specific records shall be retained for at least three years after the Exemption is granted;
   d. authorized persons shall be able to access records for inspection and copying at reasonable times and in a reasonable manner;
   e. PIs may be required to follow different record retention policies depending on research sponsorship.

8. *Public Records Request*: Some of the documentation reference in this section may be subject to public access under the California Public Records Act. University Counsel will be consulted prior to any public records being released.

X. Proposals that Require NU-IRB Review

The NU-IRB is charged with the responsibility for reviewing and monitoring Human Subjects Research conducted under the auspices of National University. This determination involves a multi-step process, including an assessment of whether an activity constitutes research, and then if human subjects are involved. The results of this determination will be communicated in writing to the investigator. The definitions of "research" and "human subjects" for this purpose are derived from Federal regulations. The criteria for "under the auspices of National University" have been determined by the University and may extend beyond what is required by Federal regulations.

Nevertheless, whenever humans are involved in a project, the researcher should err on the side of caution and contact the Administrator if there is any doubt about whether the activity is "research" and a review is required.

A. **Definition of Research:** DHHS regulations define research as "a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." As described in the Belmont Report, "...the term 'research' designates an activity designed to test a hypothesis [and] permit conclusions to be drawn..." Research is usually described in a formal protocol that sets forth an objective and a set of procedures to reach that objective". Federal Drug Administration (FDA) regulations define clinical investigation as "any experiment that involves a test article and one or more human subjects" as described in 21 CFR 50.3 (see definitions for further details). Activities that meet either definition constitute research for the purposes of National University policy.

   A key aspect of research is that there be a systematic design in advance, generally utilizing a scientific approach or protocol, for the defined purpose of contributing to generalizable knowledge. NU defines the term "generalizable knowledge" as "information or conclusions that can be applied beyond the specific setting and disseminated to other researchers or the general public" (Human Subjects Research Policy, 2010, Section VI-L). Examples of dissemination are sharing publically through presentation at a professional conference, publication as journalistic work, publication in a scholarly journal, or placement of the written research in a library" (Section VI- L).

   Research can encompass a wide variety of activities, including: experiments, observational studies, surveys, tests, and recordings. Research generally does not include such operational activities as: defined practice activities in public health, medicine, psychology, and social work (e.g., routine outbreak investigations and disease monitoring in public health); studies for internal management purposes such as program evaluation, quality assurance, quality improvement, fiscal or program audits, or marketing studies. It generally does not include journalism or political polls. However, some of these activities may include or constitute research in circumstances where there is clear advance intent to contribute to generalizable

knowledge with a scientific protocol. Intent to publish is one possible indication of intent to contribute to generalizable knowledge.

B. **Human Subjects Involvement:** A Human Subject is defined by Federal regulations as "a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual; or (2) identifiable private information." The FDA defines a Human Subjects as "an individual on whom or on whose specimen a device is used" or "an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may either be a healthy human or patient." Potential participant that meet either definition are considered human subjects for the purposes of National University policy.

"Identifiable private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation is taking place," (such as a public restroom or in a classroom) "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 health care record)." Although there is no definition of "identifiable" information in the Common Rule, HIPAA provides a list of 18 identifiers, the removal of which renders a data set de-identified for the purpose of determining if a Human Subjects is involved.

"Intervention" includes physical procedures, manipulations of the subject or manipulations of the subject's environment for research purposes. "Interaction" includes communication between the investigator and the subject. This includes face-to-face, mail, and phone interaction as well as any other mode of communication. "Private information" includes observation of behavior when an individual can reasonably expect that no observation is taking place, or information for specific purposes (such as a health care record or individual student records) that individuals can reasonably expect will not be made public. Simple observational studies of public behavior (including television and internet chat rooms) do not involve human subjects as defined, because there is no intervention or interaction and the behavior is not private.

Studies based on non-identifiable data collected for non-research purposes may not constitute human subjects research. Examples include programmatic data such as service statistics, publicly available school attendance data, crime statistics, or election returns. Studies based on data that are individually identifiable, but also are publicly available may not constitute human subjects research. However, the term "publicly available" is intended to refer to record sets that are readily available to the broad public, such as death certificates, but not student school records. Approaches involving only existing records or human specimens or observations may still constitute human subjects research requiring NU-IRB approval. The NU-IRB is responsible for making this determination.

C. **Research Conducted Under the Auspices of National University:** In the interest of protecting human subjects participating in research that is either under University auspices or would appear to be under University control, Human Subjects Research that meets any of the

following criteria will be subject to NU-IRB review and monitoring. This includes research (as defined above) that:

1. is sponsored by National University;
2. is conducted or directed by any employee, student, or faculty of the University in connection with his or her National University responsibilities;
3. involves access to any property or facility of National University other than access to open spaces on the University campus that are readily available to the public at large;
4. involves the use of non-public information in the custody of National University for the purposes of identifying or contacting human participants or prospective participants, such as email addresses or phone numbers.

D. **Exclusion from Human Subjects Research Review**: Although most projects involving human participants require NU-IRB review, there are a few notable exceptions. In general, if a project involves one or more of the following, NU-IRB approval is not necessary: projects in which humans are involved but not as participants; meta-analysis and literature reviews; certain forms of action research; activities intended solely for NU classroom instruction; NU institutional research; process improvement and best practices evaluations.
Each of these is described below in enough detail to make it clear how and why they may be excluded from the NU-IRB review process, because, technically, they are not *Human Subjects Research.*

1. *Humans are not used as Participants*: Activities that involve the use of other humans but are not using them as research participants (or research subjects) do not require NU-IRB approval. Examples include interviewing professionals or experts to gain personal knowledge, advising students, counseling groups or individuals as part of a professional career, or pilot testing. This last example of a "pilot test" should be distinguished from a "pilot study." A "pre-test" is not an example of pilot testing or a pilot study.
   a. a pilot test provides a potential list of questions or test items to a panel of experts or relevant persons for the purpose of determining clarity, readability, and/or appropriateness of questions. This cannot be given to potential participants.
   b. a pilot study is a preliminary investigation leading into a more fully developed project, and is given to a sample of participants for the purpose of determining appropriate research design, including reviewing the validity and reliability of the protocol and/or instruments. There are additional reasons for conducting a pilot study and, as such, pilot studies are also considered research (contributed to generalizable knowledge) and requires NU-IRB review.

2. *Meta-Analyses and Literature Reviews:* Meta-analyses and literature reviews of published studies involving human participants are not considered Human Subjects Research because no direct human contact is made by the researcher. Other researchers who conducted the original studies presumably did so with IRB approval from their host institutions.

3. *Action Research*: Action research is a term used to describe research that is conducted by a teacher/professional in his/her classroom/work environment. It is often done for the

purpose of improving one's practice. If the activities are research and will be used for generalizable knowledge, it must be submitted for approval.

a. Action Research studies require NU-IRB approval if the data:
   - will be used in a dissertation or thesis;
   - will be published (including at the NU library);
   - could potentially be published or shared publicly (including, but not limited to trade journals, electronic sharing mechanisms);
   - will be used to create a presentation or poster session that will be presented at peer-reviewed/professional conferences, or at NU symposiums/assemblies;

b. Action Research studies do not require NU-IRB approval if the data:
   - are used for improving teaching/professional skills;
   - will share the data only within the school/organization of which the individual works;
   - will present the data only to the principal/supervisor;
   - will be presenting the data only to instructor, class members, and other NU students and faculty (not for a thesis or dissertation) in a NU classroom setting.

4. *NU Classroom Activities*: Teaching NU students how to conduct research is an important educational goal. Instructors frequently use systematic data collection to teach students research skills. To be defined as research by the NU-IRB, an activity must be designed with the intent to develop or contribute to generalizable knowledge, and disseminated broadly (outside the classroom). If these assignments are solely designed as course requirements and not intended to advance generalizable knowledge, then it is not *research* and does not require NU-IRB review.

   It is the instructor's obligation to ensure that students conducting classroom projects with human participants are fully aware of their ethical responsibilities and that guidance is provided to safeguard the health, confidentiality, and wellbeing of the participants. Instructors and researchers are encouraged to contact the NU-IRB for additional guidance, including issues of privacy, confidentiality, informed consent, and professional ethics

   The following are general classroom activities or assignments that delineate what do and do not require NU-IRB review. These conditions include master's theses or doctoral dissertations involving human participants, which are subject to NU-IRB review.

   a. Educational Activities that a*re not* Human Subjects Research: Simulations of human experimentation and course-assigned data collection do not constitute human subjects research if the activities are designed for educational purposes only; and
      - involve secondary data analyses that are assigned and conducted as educational exercises, using data that are either publicly available, de-identified or otherwise impossible to be linked to personal identities;
      - involve secondary data analyses that are assigned and conducted as educational exercises, and that use of datasets that include private information and codes that link to identifiers, but the students do not have access to the identifiers;

- will not be generalized outside the student's classroom (reporting of data within the class is acceptable because the activities were performed solely for teaching purposes);
- will not result in, or be used for a master's thesis, research project, doctoral dissertation, poster session, abstract, or other publication (binding the document for use in the National University library is considered published), or presentations including National University conferences or symposia;
- include direct interaction (e.g. in person, postal mail, email, web surveys, or telephone) but the purpose is for training or educational exercise;
- inform student volunteers or other participants that the activities are an instructional exercise, and not actual research.

The instructor has a special obligation if the classroom activities involve the following:

- participants are from any vulnerable population (e.g., pregnant women, prisoners, minors, cognitively impaired);
- surveys or observations that contain sensitive personal questions (e.g., drug use, sexual behavior, criminal activities, medical conditions, embarrassing information or situations);
- identifying information is recorded or linked to the participant, especially if the information is of a harmful nature (e.g., harmful to reputation, employment, self esteem) and the individual gives consent prior to data collection;
- the information gathered may be recorded and available outside of the University class in which the assignment was made.

b. Educational Activities that *are **BOTH*** Classroom Activities and Human Subjects Research:
   - classroom activities or assignments that involve direct interaction (e.g. in person, postal mail, email, web surveys, or telephone) and is undertaken as both an educational experience and as research;
   - classroom activities or assignments that involve secondary analyses of private identifiable data and are undertaken as both an educational experience and as research;
   - any research that is a systematic clinical investigation or involves medical intervention or procedures even when they are part of a course curriculum always constitutes Human Subjects Research and requires prior NU-IRB review and approval.

c. Students or Instructors may wish to analyze the data with the intent of contributing to generalizable knowledge. If an instructor determines that there is a possibility that a student's proposed research project may result in a broader dissemination (e.g. formal presentation or publication) or when a student or instructor wishes to use data for research that was previously collected for educational purposes, a proposal must be submitted to the NU-IRB. Examples:
   - An instructor or student is surprised at some of the unique findings that appeared when students completed surveys as part of a classroom activity. The instructor would like to do additional analysis on the data and submit it for presentation or

publication when the course ends. The instructor's intent has changed and an NU-IRB application is necessary because the instructor will now be analyzing existing archival data that was collected for a non-research purpose.

- An undergraduate organizational leadership major wishes to conduct research in the hopes of having a publication to list on her application to graduate school. She plans to devise a study, enroll participants, analyze the results and write a manuscript. This is Human Subjects Research. Prior NU-IRB review and approval is necessary.

5. *NU Institutional Research*: Research conducted by the Office of Institutional Research and Assessment (OIRA) that is directed at improving institutional effectiveness and/or assessing institutional processes. Research under these categories that is conducted under the auspices of the OIRA does not require NU-IRB review or approval. This includes, but is not limited to, student surveys, faculty/staff surveys, course assessment, and Program Annual Reviews (PARs), and Five-Year Reviews. The OIRA has a memorandum of understanding with the NU-IRB that excludes these activities from NU-IRB review. Faculty scholarship and research is excluded from this provision. If faculty or administrators wish to share assessment results in a broader dissemination (e.g. formal presentation or publication), a proposal must be submitted to the NU-IRB.

6. *Process and Best Practice Evaluations*: Data collected for the purpose of improving internal department, school, program processes, or curriculum, do not require NU-IRB review. Examples include, but are not limited to, focus groups of critical stakeholders, staff action teams, and interviews with subject matter experts. Under no circumstances may data collected for program/process improvement be used for external publication or presentation **without** NU-IRB approval.

XI. The Review Process

All research projects involving human participants conducted by faculty, staff, and students associated with National University must receive NU-IRB approval prior to initiating the research. Research studies fall into three categories: studies that may be Exempt from IRB review, studies that could be reviewed through the Expedited IRB review process, and studies that must be reviewed by a convened Full Board. The Federal regulations do not allow an IRB to approve a study for more than one year. NU-IRB may choose to approve studies for a period shorter than one year based on the degree of risk. Most student research submissions are approved for six months.

There are multiple steps in the review process. The steps followed vary depending on the type of research proposal and whether it is being submitted for Initial Review, Continuing Review, Modification to Approved Study, or Study Closure.

A. **Initial Submission and Preliminary Review**:

1. *Initial Submission*: All submissions are made through IRBNet. All packages must be electronically signed by the Principal Investigator. For student research, the package will not be reviewed until the Faculty Sponsor has reviewed the package and electronically signed. NU faculty researchers are not required to have an additional Faculty Sponsor

signature. The Researcher User Guide includes step by step instructions on how to complete an initial submission (Appendix F).

2. *Preliminary Review* Once an initial research proposal has been submitted in IRBNet, the proposal package is locked for preliminary review. No changes to the study may be made until the NU-IRB has completed the preliminary review. During a preliminary review the Administrator first determines whether all documents are completed fully and in order. Packages that are found to be incomplete will be unlocked with a message sent to the PI (and Faculty Sponsor, when applicable) regarding what revisions are required. Once the PI has made the changes, the package must be relocked by signifying revisions complete.

B. Formal Review: Once a preliminary review has been completed and all documents are submitted, the proposal package is locked for formal approval review. No changes to the study may be made until the NU-IRB has completed the approval process for the original submission.

1. *Status Determination*: The completed package will be formally reviewed by the NU-IRB for potential risks to the human subjects. The Administrator of the NU-IRB shall evaluate status and then determine that the proposed research activity
   a. does not constitute Human Subjects Research, and, therefore, does not require IRB review.
   b. involves human subjects, but is exempt from IRB Expedited and Full Board review.
   c. is human subjects research that is eligible for Expedited review and involves no more than minimal risk to human subjects.
   d. is human subjects research that is not Exempt or eligible for Expedited review. Such proposals will be submitted to the Full Board for review and action at a convened meeting.
   e. is difficult to categorize as exemption status. If this occurs, the Administrator may submit such proposals to two NU-IRB members for them to evaluate exemption status
2. *Exempt Research Status Review Process***:** Exempt research is research that falls into a number of categories that excludes the research from more extensive review (see Section XI-G).
   a. Applicability: There are many exceptions and qualifications for exempt categories and whether a research proposal falls into an exempt category can only be determined by the NU-IRB (see Section XI-G).
   b. Process: If it is determined that a proposed research activity is eligible for Exempt Review, a specific process is followed.
      - Exempt category proposals are reviewed by one board member;
      - projects that the NU-IRB determined to be exempt from further review receive an exemption notice;
      - no continuing review or closure study are required;
      - if a project receives exempt status, the NU- IRB will need to review and approve any modifications to the study in advance;
      - all communication and status reports are posted in IRBNet.
3. *Expedited Review Process***:** Expedited Review is research that does not fall into one of the Exempt categories but presents “minimal risk” to the human subjects.

a. Applicability: When proposed research activities are expected to present no more than minimal risk to participating human subjects, and when they fit within one or more categories established by Federal regulations, they may be reviewed by the IRB through the Expedited review process that does not require the convening of the Full Board.
   - the Expedited review process 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 risks related to invasion of privacy and breach of confidentiality are no greater than minimal;
   - Federal and state guidelines dictate that in order for research to be considered eligible for Expedited review, certain criteria must be met and maintained. (see Section XI-C).

b. Process: If it is determined that a proposed research activity is eligible for Expedited Review, a specific process will be followed.
   - the Administrator shall select two members of the NU-IRB (one of whom shall be a member who best represents the area of research contained in the proposal) to review the research proposal;
   - the two members must reach consensus for the proposal to be accepted;
   - the two IRB members shall have the authority to take one or more of the following actions:
     - approve the proposal for one year or less;
     - defer the proposal to allow the researcher to modify the proposal as requested and resubmit;
     - submit the proposal to the Full Board for further review if the two members are unable to reach a consensus, or recognize that the proposal poses more than a minimal risk to human subjects, or note that another issue related to the proposal arises;
   - no approval is for longer than one year from the initial review;
   - near the end of the approval period, the PI will receive a reminder notice for continuation or closure;
   - if the research is continuing or data analysis is not yet completed, the PI must request renewal of approval using the *Request for Continuing Review* form. Projects are subject to continuing review through the data analysis phase; (see XI-D);
     - if the research is complete, the PI must inform the NU-IRB and complete the *Study Closure* form (see XI-F);
     - the Expedited Review approval actions shall be provided in electronic form through IRBNet.

c. *Under no circumstances should any research/data collection begin until it has been approved by the IRB.*

4. *Full Board Review*: Proposals that pose more than minimal risk to human subjects or involve certain vulnerable populations must be reviewed by the Full Board of the NU-IRB.

a. Applicability: When proposed research activities are expected to present more than minimal risk to participating human subjects, they shall be reviewed by the Full IRB. All submissions for initial review, continuing review, or review of modifications to previously submitted that are determined by the Administrator to not be eligible for Exemption or Expedited Review must be reviewed and approved at a fully convened NU-IRB meeting.
b. Process: The NU-IRB follows the process to conduct a thorough review of each proposal in accordance with Federal regulations.
   - the Full Board shall have the authority to take one or more of the following actions:
     - approve the proposal for one year or less;
     - defer the proposal to allow the researcher to modify the proposal as requested before the next evaluation period for resubmission;
     - disapprove the proposal and prepare a statement of action to the investigator and other involved agencies;
   - the actions of the Full Board shall be communicated in electronic form through IRBNet.
   - the NU-IRB shall document all actions and any required modifications or clarifications, and shall provide these electronic records and, if applicable, the NU-IRB Approval Form to the PI.
c. *Under no circumstances should any research/data collection begin until it has been approved by the IRB.*

C. **Criteria for IRB approval of Research (21 CFR 56.111):** In order to approve research the NU-IRB shall determine that all of the following requirements are satisfied:
1. *Risks to subjects*:
   a. Risks to subjects are minimized by using procedures that:
      - are consistent with sound research design and that do not unnecessarily expose subjects to risk;
      - are already being performed on the subjects for diagnostic or treatment purposes.
   b. Risks to subjects are reasonable in relation to anticipated benefits. In evaluating risks and benefits, the NU-IRB will consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that subjects would receive even if not participating in the research).
2. *Selection of subjects is equitable*: In making this assessment the NU-IRB will take into account the purposes of the research and the setting in which the research will be conducted. The Board should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, persons with handicaps, persons with mental disabilities, or the economically and educationally disadvantaged.
3. *Informed consent*: Informed consent will be:
   a. sought from each prospective subject or the subject's legally authorized representative, in accordance with and to the extent required by part 50, subpart D of the Code of Federal Regulations.
   b. appropriately documented, in accordance with and to the extent required by Federal Regulations and NU Human Subjects Research Policy.

4. *Monitoring the data collected*: Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
5. *Protect the privacy of subjects*: Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
6. *Safeguards for vulnerable populations*: When some or all of the subjects (such as children, prisoners, pregnant women, persons with handicaps, person with mental disabilities, or the economically and educationally disadvantaged) are likely to be vulnerable to coercion or undue influence additional safeguards have been included in the study to protect the rights and welfare of these subjects. If some or all of the subjects are children, an IRB must determine that all research is in compliance with part 50, subpart D of the Code of Federal Regulations.

D. **Criteria for Exemption of Review:** DHHS Guidelines (45 CFR Part 46.101(b) and (c)) define research as Exempt from further IRB review when the research involves no risk to the subject. Research that is considered Exempt from Board review must still be filed with the NU-IRB and screened for Exempt status.
   1. *Authority*: The authority to determine and confirm Exempt status rests with the NU-IRB and not with the PI or Faculty Sponsor. Thus, an NU-IRB research proposal is required for an Exemption to be confirmed and granted by the NU-IRB. Some minimal risk research is Exempt from Full Board review.
   2. *Definition*: Exemption waives only the need for Full Board review and does not negate the need for the consent of subjects where applicable.
   3. *Categories*: Research activities in which the only involvement of human subjects will be in one or more of the following six categories may be Exempt from Full Board review. If the human subjects research does not meet the precise requirements for one or more of the Exempt categories listed below then it will not qualify for Exempt research and will be reviewed under Expedited or Full Board review. These categories for Exemption as determined by the Federal government are research:
      a. conducted in established or commonly accepted educational settings, involving normal educational practices, such as: (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods (e.g. evaluating the use of accepted or revised standardized tests; testing or comparing a curriculum or lesson).
      b. involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior unless: (a) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (b) any disclosure of the human subjects responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation (e.g. surveying teachers or nurses about a technique or an outcome; interviewing managers about a management style or best practice; conducting a focus group about an experience or an opinion of a community program).
      c. involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior if: The

human subjects are elected or appointed public officials or candidates for public office; unless Federal statutes require the confidentiality of the personally identifiable information will be maintained (e.g. interviewing public officials about a local or global issue).

d. 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 PI in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects (e.g. analyzing de-identified tissue samples or data set; analyzing de-identified national test scores; analyzing census data about aging or housing).
e. and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (a) Public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.
f. involving taste and food quality evaluation and consumer acceptance studies, (a) if wholesome foods without additives are consumed or (b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

E. **Continuing Review:** Except for studies determined to be Exempt from IRB oversight, all Human Subjects Research studies are required to undergo continuing review based on the level of risk as assessed by the IRB. The Continuing Review process provides an important opportunity to ensure that changes in Federal or state policy or NU-IRB practices and expectations are reflected in the protocol and especially in the new consent form.

1. *Time frame*: This review takes place no less than annually, and may require more frequent review or reports as determined by the NU-IRB. For projects receiving Full Board review, the length of approval is calculated from the date of the Full Board review. The appropriate length of approval is considered as a part of the Full Board discussion. That review may take place up to thirty (30) days prior to expiration. For multi-year research, the PI is responsible for submitting a continuing review application prior to the expiration date of the current NU-IRB approval.
2. *Level of review:* Continuing Review of Expedited or Full Board approved research will be conducted with the same diligence as utilized with the initial review of the research. The review should be substantial and complete. Reviewers have access to the original submission, all documents submitted since the beginning of the research and any new documentation submitted with the continuing review application.
3. *Continuing Review of research approved via Expedited process*: For projects approved via the Expedited process, the Chair, Co-chair or Administrator conducts the review and determines the length of approval but, the approval time is still no greater than annual. Continuing NU-IRB review of research is required until such time as data collection and sufficient data analysis (e.g. preliminary findings can be identified) are complete.

4. *On Time Submission For Continuing Review*: At the 60 and 30 day mark before the expiration date, researchers and Faculty Sponsors will receive an automated reminder via the email address previously submitted that the expiration date is approaching. It is the responsibility of the researcher and Faculty Sponsor to take the appropriate steps for applying for continuing review (see Responsibilities of Principal Investigator in this document for further information). If the materials are received on time and no changes are projected the project will be extended.
5. *Notification of Decision*: PIs are notified in writing of the decision of the NU-IRB via IRBNet. Once approved, the PI is sent documentation indicating the date of the next study expiration. It is the responsibility of researchers and Faculty Sponsors to monitor IRBNet for updates.
6. *Approval Expiration*: If the approval period expires prior to submission of the continuing review application, the PI is required to suspend subject contact and data collection until the continuation is approved by the NU-IRB. For therapeutic studies where subject safety is a concern, Federal regulations allow some flexibility towards the continued treatment for currently enrolled subjects. However, no new subjects may be contacted, recruited, or enrolled in the study until the PI obtains current NU-IRB approval.

F. **Modification to Approved Study**: A modification is defined as any change to a protocol from what was previously approved during the period for which approval was given. Changes in research procedures, the informed consent process, and/or the consent/assent document cannot be initiated by the PI without NU-IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subject. Should protocol changes be made without prior NU-IRB approval to eliminate apparent hazards to the subject(s), submit to IRBNet a memorandum immediately to the NU-IRB addressing the nature of the change, why it was necessary, and the outcome.
   1. *Modification Categories;* There are two types of modifications requiring completion of a Modification to Study form
      a. Minor modification/change: A proposed change in research related activities that do not significantly affect assessment of the ethical and social issues presented in the approved study and does not substantially change the specific aims or design of the study. A modification/change to an approved human research study will generally be reviewed at the same level of review in which the study was first reviewed, either by the Expedited review process or by a Full Board review.
      b. Significant modification/change: A proposed change in research related activities that significantly affects the assessment of the ethical and social issues presented in the approved study or substantially changes the specific aims or design of the study. Significant modifications/changes require review by the Full Board.
   2. *Examples of Minor Changes*: Minor changes include but are not limited to, the following:
      a. the addition of research activities that would be considered independent from the main research protocol;
      b. an increase or decrease in proposed human research subjects' enrollment;
      c. narrowing the range of the inclusion criteria;
      d. broadening the range of the exclusion criteria;
      e. a decrease in the length or number of study visits, provided that such a decrease does not affect the collection of information related to safety evaluations;

f. alternations in human research participant payment or alteration of the payment schedule with proper justification;
g. changes to improve the clarity of statements or to correct typographical errors, provided that such a change does not alter the content or intent of the statement;
h. the addition or deletion of qualified PIs;
i. the addition of study sites (which may require a Federal Wide Assurance (FWA) and appropriate NU-IRB approval) or the deletion of study sites; or
j. minor changes specifically requested by the NU-IRB or other committees with jurisdiction over the research.

3. *Examples of Significant Changes*: Significant changes may include, but are not limited to, the following:
   a. broadening the range of inclusion criteria;
   b. narrowing the range of exclusion criteria;
   c. extending substantially the duration of exposure to the test material or invention;
   d. the deletion of laboratory tests, monitoring procedures, or study visits directed at the collection of information for safety evaluations;
   e. the addition of serious unexpected adverse events or other significant risks to the informed consent disclosure; or
   f. changes, which, in the opinion of the Chairpersons or Administrator, do not meet the criteria or intent of a minor modification;
   g. the addition of a qualified PI with a disclosable conflict of interest.
4. *External Sponsor Generated Modifications*: modification to studies funded by external grants or external sponsor requires review and approval by the NU-IRB. A sponsor may modify the research protocol before the study has received final approval from the NU-IRB. If this occurs, it is recommended that PIs await receipt of the NU-IRB approval letter before making changes to the research protocol. The PI should provide the NU-IRB with all sponsor documentation and summarize in the request how the changes affect the approved protocol, recruitment, enrollment, treatment and follow-up of human participants.

G. **Study Closures**: Principal Investigators are required by Federal law and NU-IRB policy to inform the NU-IRB when an Expedited or Full Board reviewed study has been completed (Exempt studies do not require closure).
   1. *Closure Status*: A study is considered to be open and active until the PI has submitted a Closure Form to the NU-IRB via IRBNet.
   2. *Notification*: PIs will be notified by the NU-IRB at least annually following the initial approval of the research. At these notification intervals, PIs are to submit either a continuation request or a Closure Form. *Faculty Sponsors for student research have the obligation to ensure that the Closure Form is filed with the NU-IRB in a timely fashion.*
   3. *When Closure Applies:* A study may be closed when all of the following apply:
      a. all subject recruitment and enrollment is complete (i.e., no new subject recruitment or enrollment are ongoing);
      b. all subject specimens, records, data have been obtained (i.e., no further collection of data/information from or about living individuals will be obtained);
      c. no further contact with subjects is necessary (i.e., all interactions or interventions are complete and no further contact with enrolled subjects is necessary)

   d. analysis of subject identifiable data, records, specimens are complete (i.e., use or access to subject identifiable data is no longer necessary.
4. *Submission:* The Study Closure Form must be submitted to the NU-IRB within 30 days of expiration date. (*Note: As per Provost directive no grade shall be recorded for any research conducted by students until the Study Closure is complete and the Board letter has been posted in IRBNET*.) For studies classified as Exempt, the NU-IRB does not require a Study Closure submission.

H. **Communication from the IRB:** The NU-IRB will utilize IRBNet for communication to:
   1. the PI for additional information;
   2. the PI conveying NU-IRB decision;
   3. institution administration conveying NU-IRB decision;
   4. sponsor of research conveying NU-IRB decision.

I. **Appeal of NU-IRB Decisions**: If the NU-IRB decides to disapprove a research proposal, it will include in its written notification a statement of the reasons for its decision, and give the PI an opportunity to respond in person and/or in writing. PIs may appeal an NU-IRB decision.
   1. *Appeal Process*: A Principal Investigator may appeal the decision by writing a letter to the NU-IRB requesting reconsideration. An appeal of a disapproved research project will only be reviewed at a Full Board meeting.
   2. *Final Decision*: In the case of a decision by the NU-IRB to disapprove, suspend, or terminate a project, the decision may not be reversed by the Institutional Official or any other officer or agency of National University, state government or Federal government.
   3. *Authority*: The NU-IRB retains the final authority for approval of proposed research with human subjects.

XII. Responsibilities of the Principal Investigator

The Principal Investigator (PI) is responsible for conducting objective research that generates independent, high quality, and reproducible results. The NU-IRB holds the PI responsible for the ethical, technical, administrative, and fiscal management and integrity of the design, conduct, and reporting of the research project and for managing, monitoring, and ensuring the integrity of any collaborative relationships. Additionally, the PI is responsible for the direction and oversight of compliance, financial, personnel, and other related aspects of the research project and for coordination with school, department, and central administration personnel to assure research in is conducted in accordance with Federal regulations and University and sponsoring agency policies and procedures. The PI may delegate certain tasks, but retains ultimate responsibility and accountability. Principal Investigators have the following responsibilities:

A. **Ethical:** The PI has specific ethical responsibilities that include that he or she:
   1. Abide by the ethical principles of respect for persons, beneficence and justice, as outlined in the Belmont Report;
   2. Acknowledge and accept their responsibility for protecting the rights and welfare of human research participants, including the equitable selection of research participants,

ensuring that risks to participants are minimized, and that the risks are reasonable in relation to anticipated benefits;
3. Understand the ethical standards and regulatory requirements governing research activities with human participants.

B. **General Administrative:** The PI has specific administrative responsibilities that include that he or she:
1. Read and abide by all regulations contained in the NU Human Subjects Research Policy;
2. Abide by all regulations and procedures as outlined in these procedures;
3. Fulfill the training requirement for the protection of human participants in research (CITI on-line training modules, www.citiprogram.org);
4. Complete the eCollege online Nu-IRB Orientation course;
5. Supervise all study personnel and ensure that all personnel abide by ethical principles and regulations (The PI may delegate certain tasks, but retains ultimate responsibility and accountability);
6. Ensure ethical, technical, administrative, and fiscal management of the study;
7. Report on the research project and complete all continuing or codification forms and closure report as required;
8. Manage, monitor, and ensure the integrity of any collaborative relationships;
9. Manage the direction and oversight of compliance, financial, personnel, and other related aspects of the research project;
10. Coordinate with school, department, and administrative personnel to assure research in is conducted in accordance with Federal regulations and University and sponsoring agency policies and procedures;
11. Ensure that all study personnel are knowledgeable of, and conduct the study in accordance with the approved protocol (including approved amendments).

C. **Research Preparation and Review:** The PI has specific responsibilities regarding the preparation and submission of a research package that require that he or she:
1. Prepare and submit human research project proposals or changes in accordance with Federal regulations and University and sponsoring agency policies and procedures. Use the most current version of NU-IRB forms and document templates, which can be found on the IRBNet website (www.irbnet.org). The NU-IRB reserves the right to require additional documentation as appropriate. At minimum, this package includes:
   a. IRB registration form
   b. Application
   c. Supplemental forms (as required)
   d. Informed consent documents
   e. CITI completion record
   f. Instruments;
2. Perform a comprehensive review of background and scientific literature prior to submitting research proposal;
3. Provide or coordinate with Faculty Sponsor to provide accurate human research participant approval information for all submissions and correspondence to the sponsoring agency;
4. Disclose and detail use of human participants in the research proposal;

5. Verify that the protocol and proposal for funding are identical, when applicable;
6. Submit any proposed changes to the project for approval as required and assure that changes are not implemented prior to approval;
7. Review project at inception and as required thereafter for completeness, accuracy, and improvement opportunities;
8. Ensure that all research activities have NU-IRB approval and other approvals required by the NU-IRB before human participants are involved;
9. Implement the research activity as it was approved by the NU-IRB;
10. Maintain written records of NU-IRB reviews, decisions, research records and informed consent documents;
11. Obtain NU-IRB approval for and notify the grant sponsor (if applicable) of any proposed change to the research protocol *prior to* its implementation, except when necessary to eliminate apparent immediate hazards to the participants;
12. Report any real or potential conflicts of interests of the Principal Investigator or any study personnel in compliance with conflict of interest policies and management plans;
13. Obtain re-approval by reporting progress of approved research to the NU-IRB, in the manner prescribed by the NU-IRB, but not less than once per year.

D. **Conducting Research**: The PI has specific responsibilities in conducting the research that require that he or she:
   1. Conduct research in accordance with federal regulations and university and sponsoring agency policies and procedures;
   2. Oversee the research team to help ensure ethical conduct in all aspects of the research process including but not limited to the treatment of human and animal subjects, conflicts of interest, data acquisition, management, sharing and ownership, publication practices, responsible authorship, and collaborative research and reporting;
   3. Promote the ethical conduct of research by reporting good faith suspicions of misconduct in research as defined within NU's *Human Subjects Research* policy and other misconduct as described in the NU policy;
   4. Verify that IRB approval has been obtained from all participating institutions in collaborative activities with other institutions, and that continuing review by other institutions is maintained;
   5. Ensure the confidentiality and security of all information obtained from and about human participants, and the privacy of participants is maintained;
   6. Manage budget and expenditures related to the study to ensure that adequate resources are available, including staff, equipment supplies, storage space etc., to conduct the study at the nu and any other performance site for which the pi is responsible;
   7. Obtain insurance (e.g. medical research) if applicable; ensure charges assessed to insurance carriers are for procedures for illness or injury directly resulting from the research procedures of the study;
   8. Communicate, when applicable, the PI's plans to meet with representatives of the community from which individuals will be recruited, about community concerns, values and expectations;
   9. Obtain a certificate of Confidentiality, when appropriate.

E. **Obtaining Informed Consent**: The informed consent process includes one or more of the following: adult informed consent forms, child and youth assent forms, parental consent forms, site permission forms, and any additional informational letters. PIs are required to use the approved consent templates found on IRBNet. The PI must:
   1. Prepare and maintain all documents related to the informed consent process;
   2. Submit informed consent documents to NU-IRB for review and approval;
   3. Once NU-IRB approval is received, obtain informed consent from participants before participants are involved in the research
   4. Document consent as approved by the NU-IRB;
   5. Provide participants with a copy of the form after it has been signed, unless the NU-IRB has specifically waived this requirement;
   6. Retain documented evidence of informed consent of the participants or their legally authorized representative in a manner approved by the NU-IRB;
   7. Adhere to the required elements of the consent process:
      a. A discussion of the study by the person obtaining consent and the participants;
      b. An opportunity for participants to read the consent form (please note that it is never appropriate to forgo the discussion, even if participants will then read the consent form; participants must be given the opportunity to have the consent form read to them if they have difficulty reading);
   8. Assure accurate execution of the informed consent process, including obtaining all on-going re-consent documentation.

F. **Obtaining Waiver of Informed Consent**: The PI must formally request a waiver of informed consent by completing and submitting a supplemental form with the NU-IRB research proposal. The NU-IRB may waive documentation of informed consent or may waive some elements of informed consent for some or all of the participants (45 CFR 46.116 [c], [d], and 46.117[d]). Ordinarily, NU-IRB requires all learners to obtain and document informed consent fully as part of its function. However, it may occasionally be in the best interests of the participants of a study not to be required to sign the informed consent documentation or not to be exposed to some elements of the informed consent process.
   1. The NU-IRB may waive the requirement for written consent if the consent document is the only link between the subject and the research and the principal risk of harm would come from a breach of confidentiality.
   2. A waiver of the informed consent process does not imply that the PI has no ethical responsibilities to subjects in such research.
   3. The NU-IRB may waive consent if:
      a. the research involves no more than minimal risk to the subjects;
      b. the waiver will not adversely affect the rights and welfare of the subjects;
      c. the research could not practicably be carried out without the waiver;
      d. if appropriate, the subjects will be provided with additional information after participation.
      e. the research involves types of research regarding public service programs.

G. **Obtaining a Certificate of Confidentiality:** Data collection about sensitive issues (such as illegal behavior, alcohol or drug use, or sexual practices or preferences) requires the protection of confidentiality beyond preventing accidental disclosures. Under Federal law,

Principal Investigators can obtain a Certificate of Confidentiality from the National Institute of Health (NIH) that will provide protection against compulsory disclosure, such as court orders and subpoenas, for research data. A Certificate of Confidentiality can encourage participation in research by granting certain protections to human participants divulging possible compromising information. However, it does not exempt Principal Investigators from performing ethical research nor does it allow PI to abdicate the responsibility to act in the public good. (See Appendix B)

H. **Reporting:** In order to **c**omply with technical, progress, and compliance reporting requirements in accordance with Federal regulations, University policies, and sponsoring agency policies and procedures, the PI must:
   1. Promptly report to the NU-IRB any adverse events, protocol deviations or other unanticipated problems involving risks to participants or others. Principal Investigators should not undertake any action with an external funding agency regarding an unanticipated problem or noncompliance without first contacting the NU-IRB Administrator in order to determine the correct course of action;
      a. Unanticipated Problems - May or may not include specific events experienced by individual subjects, but are developments within the research activity that suggest a potential for increased risks to subjects or others. Please review the form found in IRBNet for more information
      b. Protocol Violation - Any change or deviation from your approved NU-IRB Application. For example, enrolling a participant who fails to meet the inclusion criteria—enrolling a 70-year-old when the protocol states 65 as the upper age limit. Protocol violations can also include non-emergency departures from the procedures you described in your approved NU-IRB Application. For example, adding a follow-up interview that was not part of your approved application. Please review the form found in IRBNet for more information.
   2. Provide the NU-IRB with audit or inspection reports or findings issued by regulatory agencies, cooperative research groups, contract research organizations, the sponsor or the funding agency.

I. **Completing Research Modification and Continuing Reviews**: If appropriate it is the PI's responsibility to complete a Continuing Review form, and Modification to Study form in a timely manner or the study may be suspended, terminated or inactivated as determined by the Administrator. Projects involving high risk may require more frequent review. The NU-IRB may require frequent review or reports on a specific number of cases. The terms of the review and the written documentation required for that special review are delineated at the time the original approval is granted.
   1. *Modification to Study:* A modification is defined as any change to a protocol from what was previously approved during the period for which approval was given. These procedures apply to a Modification to a Study:
      a. Changes in research procedures, the informed consent process, and/or the consent/assent document cannot be initiated by the PI without NU-IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subject.

b. Should protocol changes be made without prior NU-IRB approval to eliminate apparent hazards to the subject(s), submit a memorandum immediately to the NU-IRB addressing the nature of the change, why it was necessary, and the outcome.
c. Procedures for submitting a modification: The PI must follow the procedures for a modification. The PI must create a revised package in IRBNet (see Research User Guide for specific instructions) and complete the following:
   - upload updated NU-IRB Application;
   - upload Request for Modification to Study (available in IRBNet);
   - upload modified attachments (when applicable);
   - re-sign the package as Principal Investigator;
   - obtain additional signatures as required (for student research, Faculty Sponsors must also review and sign the revised package);
   - submit to NU-IRB.

2. *Continuing Review*: Regulations state that the NU-IRB must conduct a Continuing Review of an approved project (under Expedited or Full Board only) at intervals appropriate to the degree of risk, typically within 6 months. The purpose of this process is to review an entire project and determine that the anticipated risks and benefits are reflected in the actual experience of subjects and that the safeguards in place at the time of original approval are, in fact, adequate to ensure the safety of subjects. These processes apply to Continuing Review:
   a. automated reminders are sent via IRBNet to the PI and the Faculty Sponsor at 60 days and 30 days;
   b. for research that needs additional time for completion of data collection and analysis past the original expiration date, PIs are required to complete and submit a request at least 30 days before the expiration date of the original approval;
   c. if approval of a project expires without renewal, PIs may not enroll any new participants and all research activities involving interaction with human participants or their records must end until NU-IRB extension has been granted;
   d. Procedures for submitting a revised package: Create a revised package in IRBNet (see Research User Guide for specific instructions) and complete the following:
      - upload updated NU-IRB Application;
      - upload Request for Continuing Review (available in IRBNet);
      - modified Attachments (when applicable);
      - re-sign your package as Principal Investigator. For student research, Faculty Sponsors must also review and sign the revised package;
      - submit to NU-IRB.
   e. data collection may not proceed until the request for Continuing Review has been approved by the NU-IRB;
   f. if the Faculty Sponsor is no longer available, it is the student's responsibility to immediately contact the appropriate Department Chair or program lead for assistance;
   g. the NU-IRB will not be held responsible for research approvals lapsing due to lack of follow through.

J. **Project Study Closure:** This section is specifically for Expedited or Full Board reviews. At completion of research, PIs are required by Federal law and NU policy to inform the NU-IRB

that the data collection and analysis is completed so the NU-IRB does not continue to inquire about renewal. These processes apply to Study Closure:

1. Exempt research studies do not need to submit a Study Closure Report;
2. All research approved under Expedited or Full Board reviews must complete a Study Closure Report when the data collection and analysis of the research study is complete;
3. For studies that involve Federal agencies or grant funding, the PI must contact those agencies for additional requirements and specific instructions.
4. Procedures for submitting a Study Closure Report:
    a. Secure and maintain or coordinate with Faculty Sponsors to secure and maintain all documentation for the study in accordance with Federal regulations, University policies, and sponsoring agency policies and procedures.
    b. Create a revised package in IRBNet. Do not create a new package in IRBNet (see Appendix D- *Researcher User Guide* for specific instructions) and complete the following:
        - Upload the Request to Close Study form
        - Upload the signed informed consent documents (if applicable). This includes student assent forms, parental permission forms, and site permission forms. Depending on the number of participants, a sample of each signed document is sufficient.
        - Upload any additional documentation requested by the NU-IRB.
        - PI and Faculty Sponsor must review and electronically sign the revised package.
        - Submit to NU-IRB.
5. *Faculty Sponsors are NOT to submit any grades for students who received an Expedited approval until the closure request has been approved by the NU-IRB.*

XIII. Responsibilities of the Faculty Sponsor and School Personnel

Many different individuals and organizations play a role in the protection of human research subjects. Protection of human subjects is the responsibility of all individuals and organizations involved in the research and are not the sole responsibility of any one individual or organization.

A. **Faculty Sponsor:** A critical role is played by the Faculty Sponsor if the research is conducted by or with students.
    1. In many institutions, students cannot serve as the Principal Investigator in a research project. At National University, students can serve as the Principal Investigator for their own research projects provided that they have a Faculty Sponsor.
    2. The Faculty Sponsor's role includes many of the same responsibilities as the Principal Investigator, with the added component of serving as a mentor and advisor to the student (Section XIII).
    3. NU Faculty members conducting research do not require a Faculty Sponsor.
    4. *Primary Responsibilities of Faculty Sponsor* include that he /she:
        a. ensures that student PIs abide by the ethical principles of respect for persons, beneficence and justice, as outlined in the Belmont Report;
        b. assume responsibility for protecting the rights and welfare of human research participants, including the equitable selection of research participants, ensuring that

risks to participants are minimized, and that the risks are reasonable in relation to anticipated benefits;

c. ensures student PIs have completed all training requirements as listed in Section XIII of this document;
d. ensures that all requirements listed in Section XIII of this document are met;
e. oversees the research process and the conduct of the PIs and research staff at all study sites;
f. ensures compliance with research protocols, applicable Federal, state, and local laws and regulations, and NU policies and procedures;
g. ensures compliance with the study protocol and reports adverse events to the NU-IRB;
h. ensures that informed consent is appropriately obtained from all subjects and that subjects are treated with respect and dignity;
i. completes all required human subjects protection training and ensures that student PIs and key study personnel complete required training;
j. routinely reviews the new or revised NU-IRB policies and procedures;
k. ensures that study features are consistent with current research data and do not place research participants at unnecessary risk;
l. ensures the adequacy of all submissions to the NU-IRB including applications, amendments, closure reports, and adverse event reports;
m. ensures the submission of the Continuing Review if necessary;
n. ensures that the student researcher submits proposed changes to the research to the NU-IRB before the changes are implemented, except when such changes must be implemented immediately to avoid or eliminate a risk or hazard;
o. ensures that the student investigator maintains all study-related documentation in accordance with NU policies and procedures, and Federal regulations;
p. provides an electronic signature to the student investigator's project submission, indicating that the application and <u>all</u> relevant documents have been reviewed and properly prepared; (includes the initial proposal, any revisions, modification, continuing reviews, and close outs);
q. ensure that the student PI submits a request to close the study to the NU-IRB and it is approved prior to submitting grades.

B. **School Deans, Department Chairs, and Faculty Members:** Protection of human subjects is the responsibility of all individuals involved in the research and is not the sole responsibility of any one individual in the organization. School Deans, Department Chairs, and Faculty Members play a crucial role in creating a culture of research in their respective schools. It is essential that they ensure that the ethical research principles of respect for persons, beneficence and justice be adhered to by all faculty and students.

1. *Responsibilities of School Deans, Department Chairs, Faculty Members:* School Deans, Department Chairs, Faculty Members share responsibility to:
   a. model appropriate human subjects research methods;
   b. assure that human subjects researchers are familiar with The Belmont Report and any other rules or procedures governing human subjects research;
   c. delegate authority for review of projects involving research on human subjects to the NU-IRB;

d. complete CITI modules required by the NU-IRB in human subject's protection;
e. if the research is being conducted for a graduate thesis or a doctoral dissertation, each school must require that proof of NU-IRB approval (for Exempt, Expedited and Full Board) and closure (for Expedited and Full Board) with the published document

2. *Additional Responsibilities of School Deans and Department Chairs*: School Deans and Department Chairs also share responsibility to:
   a. ensure that all Faculty Sponsors complete the CITI modules required by National University prior to teaching research courses;
   b. ensure adequate representation of faculty members from their academic schools on the IRB;
   c. ensure all students and faculty are completing the appropriate steps for closing a study.

XIV. International Research

Research involving human subjects conducted outside the United States creates additional areas of concern for both the Principal Investigator and the NU-IRB. Cultural, economic, or political conditions of the host country may alter the risk for participants and researchers compared to the same research conducted within the United States. Other countries, and institutions within foreign countries, may have Institutional Review Boards or Ethics Committees which require review of the research before it can be conducted in that country. Refer to Appendix C and http://www.hhs.gov/ohrp/international/ for more information. The NU-IRB encourages graduate students to engage in research only in the United States. (Please see Appendix C)

XV. Violations of Human Subjects Policies

Information regarding noncompliance in or violations of Human Subjects Research studies may come to the attention of the NU-IRB through several pathways. These include information contained in new applications, continuing reviews, adverse event reports, and reports from collaborators, employees, or subjects. The NU- IRB investigates alleged violations of these policies, and report its findings to government agencies as required by law (See 45 CFR 46.113), the Judicial Affairs Officer (for student violations), the Provost, and the President.

A. **Studies Conducted Without NU-IRB Approval:** Occasionally the NU-IRB is made aware of research using human subjects that is or has been conducted without NU-IRB review and approval of the research protocol prior to conducting the study. If the Principal Investigator is conducting Human Subjects Research without NU-IRB approval, this is a violation of Federal Regulations and subject to non-compliance reporting both to University officials as well as Office of Human Research Protections (OHRP). It also puts the University at risk of having its research privileges suspended.

B. **Post hoc Approval:** If the Principal Investigator did not receive approval from the NU-IRB prior to starting the project, it will not receive approval once it is completed. Federal regulations and guidelines do not allow for review and post hoc approval of studies that have already been conducted involving human participants, human biological materials, or identifiable data that can be connected to any living individual. NU's Federal wide Assurance

(FWA) with the Federal government states that the NU-IRB must review and approve data collection procedures and protocols before the study begins. The FWA is a legally binding contract that the University has signed with OHRP, and it obligates National University to comply with the ethical principles of The Belmont Report and the Federal regulations for the protection of human participants.

C. **Sources of Information and Disposition of Reports:** Principal Investigators may report to the NU-IRB themselves about unapproved Human Subjects Research in which they are involved. Other reports may come from administrators, faculty, staff, research participants, and anonymous persons. Reports may be oral or in writing and should include as much factual information as possible. Reports should be submitted to the Director of Instructional Services and Research Compliance (or to the NU-IRB chair in the Director's absence).

D. **Procedures for Noncompliance:** The Director of Instructional Services and Research Compliance will investigate why the PI did not have the project reviewed by the IRB. The PI is interviewed by the Director and the emphasis is on fact finding. If it is determined that no infraction has occurred then no further action is taken. If it is determined that an infraction has occurred, the PI is notified in writing of the procedures he or she must follow to comply with institutional policy regarding the review of human subjects research.

E. **Documentation and Review of Non-approved Research:** Should research using human subjects be conducted without NU-IRB review and approval of the research protocol prior to conducting the study, the PI is in violation. Specific documentation and review steps will occur based on the level of research.
   1. *Exempt Research in Violation*: Should Exempt Research be in violation:
      a. the PI is required to suspend the Exempt research and, if the PI plans to continue the research, he/she must submit an NU-IRB application package within 7 days.
      b. if the research has been completed, or if the PI does not plan to continue the research then the research must document as completely as possible the research that was conducted without NU-IRB review and approval. This report should include a description of the procedures followed, the number of participants, and results of the study.
      c. the Department Chair is notified of the above action.
      d. data collected prior to NU-IRB approval will not be approved for publication or presentation purposes.
      e. if the PI fails to submit a protocol within the designated time, the NU-IRB sends a written report including a description of the NU-IRB action taken, to the Department Chair for appropriate action within 5 days.
      f. failure of the Department Chair to act or comply is reported to the Dean, Provost, and President with a recommendation for appropriate action. Student violations will be reported to Judicial Affairs.
   2. *Non-Exempt Research (Expedited and Full Board review):* Should Research requiring Expedited or Full Board review be in violation:
      a. the PI is required to suspend the research immediately;
      b. if the PI plans to continue the research an application must be submitted for NU-IRB review within 7 days;

c. if the research has been completed or the PI does not plan to continue the research, the PI is required to document as completely as possible the research that was conducted without NU-IRB review;
d. the documentation should include a description of the procedures that were followed, number of participants studied, and results of the study; This report must be submitted within 7 days;
e. in some cases, the NU-IRB may require that PIs inform participants of the PI's lack of compliance with the NU-IRB procedures, and solicit permission from the participants to use the data or biological materials collected;
f. if there is a question because of increased risk to participants the Director of Instructional Services and Research Compliance counsels with the Department Chair;
g. in case of failure to agree on suspension of the research, the decision of the Director of Instructional Services and Research Compliance is final;
h. the Dean and Provost are notified of the above action;
i. when a PI wishes to continue the non-approved research and a packet has been received by the NU-IRB, it is reviewed and approved in the usual manner for Non-Exempt research;
j. the minutes of the NU-IRB meeting will indicate the protocol was submitted as a result of determination by the NU-IRB the PI had been conducting research without NU-IRB approval and the results of the current review recorded;
k. if the PI fails to submit a protocol within the designated time, the NU-IRB sends a written report including a description of NU-IRB action to the department chair and Dean for action within 3 days;
l. failure to comply is reported to the Provost and President with recommendation for appropriate action; Student violations will be reported to Judicial Affairs;
m. data collected prior to NU-IRB approval will not be approved for publication or presentation purposes.

F. **Determination of an Allegation of Repeated Infraction of Institutional Policy**: The procedures outlined above will apply for repeated infractions. If it is determined by the Director of Instructional Services and Research Compliance that a second or additional infraction has occurred, the NU-IRB promptly notifies the Provost and President with the recommendation that the PI's privilege to do research be suspended at once and if conducted as part of a grant that the unused funds be returned to the funding agency. Student violations will be reported to Judicial Affairs.

XVI. Emergency Research Consent Exception

With the concurrence of a licensed physician serving as a member of or consultant to the NU-IRB and who is not otherwise participating in the clinical investigation, the NU-IRB may approve a medical investigation without requiring that informed consent of all research subjects be obtained. The NU-IRB must find that the PI had adhered to all regulations in accordance with 21 CFR 50.24 and 56.115. For more information regarding these regulations, refer to http://www.hhs.gov/policies/index.html.

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Appendix A

Definitions

As used in this Procedures Guidelines, the following words shall have the meanings indicated below:

1. *Assent*: When the informed consent document is signed by a *legally authorized representative,* the Human Subjects may be required to sign a document stating that they assent to their participation (e.g., a child under the age of 18 may assent to participating in a study in which a parent has provided consent).

2. *Beyond Minimal Risk*: The establishment of beyond minimal risk is when the probability and magnitude of harm or discomfort anticipated in the project is greater than the harm or discomfort ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Some examples of "beyond minimal risk" are electric shock, deception, procedures that may elicit a strong emotional reaction, and any invasive procedure. Beyond minimal risk usually, but not always, involves the potential for *long-term consequences* or *highly sensitive information/issues*).

3. *Certificate of Confidentiality***:** Data collection about sensitive issues (such as illegal behavior, alcohol or drug use, or sexual practices or preferences) requires the protection of confidentiality beyond preventing accidental disclosures. Under Federal law, Principal Investigators can obtain a Certificate of Confidentiality from the National Institute of Health (NIH) that will provide protection against compulsory disclosure, such as court orders and subpoenas, for research data.

4. *Closure of Study:* Principal Investigators are required by Federal law and NU-IRB policy to inform the NU-IRB when an Expedited or Full Board reviewed study has been completed (Exempt studies do not require closure). A study is considered to be open and active until the PI has submitted a Closure Form to the NU-IRB via IRBNet. A study may be closed when specific criteria is met.

5. *Conflict of Interest*: When the PI, a family member, or a member of the research team has a personal, professional, or financial relationship with the funding source or with the participants at the location of the study (e.g., the PI is in a position of authority over the participants).

6. *Consent Form*: A document designed to give the researcher knowledge that the subject is participating in the research willingly, knowingly and without coercion or influence. The form should describe the research to be undertaken by the researcher and listing and describing in detail the level and scope of anticipated risk involved and how the research proposal plans to protect the confidentiality of the subject. The form, which also contains contact information about the researcher and institution, needs to be signed by the subject before the research can be initiated (but after NU-IRB approval is issued).

7. *Confidential Information* – Information pertinent to the individual or groups of individuals including personal data, or information about attitude, perspective or behavior that is not expected or anticipated to be made public and which the individual has the right and choice to withhold from the public.

8. *Continuing Review:* Except for studies determined to be Exempt from IRB oversight, all Human Subjects Research studies are required to undergo continuing review based on the level of risk as assessed by the IRB. The Continuing Review process provides an important opportunity to ensure that changes in Federal or state policy or NU-IRB practices and expectations are reflected in the protocol and especially in the new consent form.

9. *Cooperative Research*: Cooperative research projects are those projects covered by this policy which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy.

10. *Deception*: Research studies that withhold information from the human subjects or provide misleading information to the subjects. Deception is used in certain studies to ensure the validity of the results (e.g., concealing or misleading subjects about medical treatment to avoid placebo effects, or withholding information to prevent the Hawthorne effect). Such research must undergo a high level of IRB scrutiny, but can be justified if the scientific value warrants the waiver of *informed consent.*

11. *Exempt Research*: All research must be reviewed by the IRB for potential risks to the human subjects. "Exempt" research is research that falls into a number of categories that excludes the research from more extensive review (see *Expedited Review* and *Full Review*). The categories for exempt research are delineated in procedures. There are many exceptions and qualifications for the exempt categories and whether a research proposal falls into an exempt category can only be determined by the IRB.

12. *Expedited Review:* Research that does not fall into one of the "exempt" categories (see Exempt Research) but presents "minimal risk" to the human subjects *(see Minimal Risk)* may qualify for a streamlined review process that does not require the convening of the full IRB *(see Full Review).*

13. *Full Board Review:* Research that poses more than minimal risk *(see Minimal Risk)* to the human subjects *(see Beyond Minimal Risk)* must be reviewed at a formally convened meeting by the full membership of the NU-IRB (defined as a quorum or more than 50% of the voting members).

14. *Funding Source: T*he organization (agency, institution, etc) that supplies financial resources for conducting the research (not applicable if the research is supported by personal funds).

15. *Generalized Knowledge:* Information or conclusions that that can be applied beyond the specific setting and disseminated to other researchers or the general public.

16. *Highly Sensitive Information/Issues*: A proposal contains information or issues that are "highly sensitive" in nature when there is the potential to (1) offend or harm a specific cultural group or individual, or (2) to embarrass the participant, (3) place the participant at risk of criminal or civil liability, (4) damage the participant's financial standing, employability, or reputation.

17. *Human Research*: Any scientific investigation that utilizes living human beings as subjects of the study. Any study that performs procedures on human beings, seeks to have human subjects perform tasks that go beyond the bounds of their normal routine, or uses data about identifiable individuals is subject to IRB policies and guidelines.

18. *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.

19. *Informed Consent*: The human subjects are provided sufficient information regarding the research to allow them to make a fully informed decision about their willingness to participation. This is usually, but not always, in the form of a document signed by the subject.

20. *Institutional Review Board* (*IRB):* A board established to review research submissions with the purpose of protecting the rights and privacy of the human subjects. The IRB determines the level of protection and safeguards, based on what is provided in the research submission and approves, requires modifications, or disapproves the implementation of the research. The IRB also follows the progress of approved research to ensure that the proposed protections are not altered.

21. *Intervention and Interaction:* 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. Interaction includes communication or interpersonal contact between investigator and subject.

22. *Principal Investigator:* an individual who assumes full responsibility for a Human Subjects research study, including but not limited to, obtaining information about living individuals by intervening or interacting with them for research purposes, and protecting the welfare of human research participants. Some research studies are conducted by more than one investigator, and usually one investigator is designated the "principal investigator" with overall responsibilities for the study.

23. *IRB Approval:* The determination by the IRB that the research has been reviewed and may be conducted as proposed at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

24. *IRB Submission*: A proposal that is given to the IRB for review with all of the supporting materials (e.g., informed consent form, formal application, evidence of IRB training).

25. *Legally Authorized Representative:* An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective Human Subjects who falls into the classification of *vulnerable population* (e.g., a parent providing consent for a child, a legal custodian providing consent for a mentally disabled subject).

26. *Long-Term Consequences*: The establishment of potential for long-term consequences is when there is a reasonable probability that, as a result of participating in the study, a subject may experience ongoing physical or psychological consequences. Some examples of are: (1) rapid smoke techniques for smoking cessation, which can cause cardiac problems in some individuals; (2) subjects becoming aware of the results of an intelligence test, which can cause the subjects to make long-term negative self-attributions concerning their mental aptitude; or (3) a subject becoming aware of the results of a test of psychopathology, which may indicate severe chronic psychopathology.

27. *Minimal Risk:* 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.

28. *Modification to Study:* A modification is defined as any change to a protocol from what was previously approved during the period for which approval was given. Changes in research procedures, the informed consent process, and/or the consent/assent document cannot be initiated by the PI without NU-IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subject.

29. *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 (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.

30. *Research:* A systematic investigation (including research development, testing, and evaluation) designed to contribute to generalizable knowledge. For conclusions to be generalizable, they must actually or potentially be disseminated for research purposes (or be part of a program of investigation that will be disseminated). Examples of dissemination are sharing publically through presentation at a professional conference, publication as journalistic work, publication in a scholarly journal, or placement of the written research in a library. Activities that meet this definition constitute research for purposes of NU-IRB policy, whether or not they are conducted or supported under a program which is considered research for other purposes.

31. *Risk* Exposure to harm, be it physical, mental, emotional or psychological. Risk is considered minimal if the exposure does not surpass in probability, scope and intensity that experienced in daily, routine activities.

32. *Sponsor*: The person designated as the supervisor of the research when the principal investigator is a student or subordinate researcher.

33. *Vulnerable Populations*: When some or all of the subjects who are relatively or absolutely incapable of protecting their interests, or are likely to be vulnerable to coercion or undue influence (including but not limited to: children, prisoners, pregnant women, mentally disabled persons, terminally ill, or economically or educationally disadvantaged persons), additional safeguards must be included in the study to protect the rights and welfare of these subjects.

Appendix B

Certificate of Confidentiality

Obtaining a Certificate of Confidentiality is not an IRB requirement for all Human Subjects Research and is a choice made by the PI. Those who choose not to obtain a Certificate must include a statement in the consent form that alerts potential subjects of the legal and ethical mandate compelling researchers to report certain information.

A. *Confidentiality*: Certificates of Confidentiality protect the privacy of human participants and identifiable research information from forced disclosure. They allow the researchers, the institution, and others (e.g. research assistants, co-investigators, transcribers) who have access to sensitive research records to refuse to disclose identifying information on human participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the Federal, state, or local level. Any individual may apply to National Institute for Health (NIH) for a Certificate of Confidentiality if she/he is engaged in research in which sensitive information will be gathered from human participants and whose project has been approved by the NU-IRB.

B. *Sensitive Research*: Certificates are issued only "when the research is of a sensitive nature where the protection is judged necessary to achieve the research objectives." The Public Health Service policy defines "sensitive" research as involving the collection of information falling into any of the following categories:
   1. Information relating to sexual attitudes, preferences, or practices;
   2. Information relating to the use of alcohol, drugs, or other addictive products;
   3. Information pertaining to illegal conduct;
   4. Information that if released could reasonably be damaging to an individual's financial standing, employability, or reputation within the community;
   5. Information that would normally be recorded in a subject's medical record, and the disclosure of which could reasonably lead to social stigmatization or discrimination;
   6. Information pertaining to an individual's psychological well-being or mental health.
   7. Information in other categories not listed may also be considered sensitive because of specific cultural or other factors, and protection can be granted in such cases upon appropriate justification and explanation.

C. *When is a Certificate appropriate*: Obtaining a Certificate of Confidentiality is not required for all human subjects research. PIs may obtain a certificate if a determination is made by the researcher that the research is of a sensitive nature and protection is necessary to reach the objectives of the research. The NU-IRB reserves the right to require a researcher to obtain a Certificate prior to beginning data collection. The NIH website (http://grants.nih.gov/policy/coc/faqs.htm) provides additional information including frequently asked questions.

D. *The Application Process to Obtain a Certificate of Confidentiality*: The first step in the certificate application process is to first submit the research proposal to the NU-IRB, following the proper procedures. Research that has been determined to need additional protection of a Certificate of Confidentiality may receive conditional approval by the NU-IRB. This conditional approval does not allow for data collection to begin. The conditional approval is necessary in order for researchers to be able to apply for and obtain the certificate. PIs must work with NU-IRB Administrator to initiate and complete the Certificate of Confidentiality application. The length of time for Certification approval is determined by the appropriate Federal agency and may delay the research timeline for data collection.

E. *Approval of Certificate of Confidentiality*. Once a Certificate application is approved, PIs will work with NU-IRB Administrator to make modifications to the research proposal, including the consent process and data collection methods. Once the NU-IRB has approved the modifications, the PI will receive the formal approval letter and data collection may begin

F. *Limitations on the Certificate of Confidentiality*:
   1. Voluntary Disclosure. The Certificate does not apply to voluntary disclosure of identifying information by either a subject or an investigator. Therefore, even if a study is covered by a Certificate of Confidentiality, the subject may voluntarily disclose information about himself or herself. The investigator may also voluntarily disclose issues such as child abuse involving a subject or a subject's threats of violence to self or others. Subjects should be advised about the existence of a Certificate of Confidentiality, and the consent form should clearly outline the exceptions to the protection it offers.
   2. Intentional or Inadvertent Breaches of Confidentiality. The existence of a Certificate of Confidentiality does not prevent other types of intentional or inadvertent breaches of confidentiality. PIs and the NU-IRB must make certain that adequate procedures exist to protect the confidentiality of identifiable private information that will be obtained in the research.
   3. Audits and Investigations. The NU-IRB and other Federal agencies may request identifying information for purposes of performing audits, carrying out investigations of grant recipients, or evaluating Federally-funded research.
   4. Non-transferability of Obtained Certificate. An Obtained Certificate is not transferable from one study to another. Any major changes to the research process must be reviewed by the NU-IRB and the issuing agency notified.

Appendix C

International Research

The NU-IRB, when reviewing protocols which will be conducted outside the U.S., may not be familiar with the current political and social climate in every other part of the world even though committee members have broad expertise. In order to facilitate the review of projects that involve human subjects in international settings, the following questions must be addressed in the protocol when it is submitted for NU-IRB review:

- Are there any aspects of the cultural, political or economic climate, in the country where the research will be conducted, which would increase the risks for participants compared to the risk for participants in the U.S.? If yes, what steps will the PI take to mitigate that risk?
- Is there an IRB or Ethics Committee in the country, or at the institution, where the research will be conducted? A list of registered international IRBs may be found on the OHRP web site at: http://ohrp.osophs.dhhs.gov. Many of these IRBs may review biomedical research but not social science research. If a review committee exists and review by that IRB is required, please submit a copy of the approval or evidence that the protocol has been submitted to the IRB for review when your protocol is sent to the NU-IRB.
- Federal regulations require that the participant be given the opportunity to ask questions. The NU-IRB requires that the name and phone number and email address of the principal investigator (and sponsor if the project is student research) be provided on the consent form in case the subject has questions after the research has ended. In addition, the NU-IRB contact information must be provided on the consent form for subjects who have questions about their rights as a research subject. When research is conducted outside the U.S., the PI should consider the best method for providing a contact point for participants. In some cases the participants may have access to computers and an email address may be an acceptable method for them to communicate with the PI or the NU-IRB. If the subjects do not have access to telephones or email, if they do not have the financial resources to make an international call, or if they do not speak English, it may not be helpful to provide the name and phone number for contacts in California. In those cases, providing the name and contact information for a person or organization in the location where the research will be conducted may be the best thing for subjects. This local contact must be willing to relay questions or complaints from subjects to the PI or the NU-IRB and should be a stable person or organization that will be easily available to subjects.
- Consideration should be given to the most appropriate method of obtaining informed consent, taking into account the literacy level of the subjects and confidentiality concerns. In some cases, oral consent may be more appropriate than written consent because signing a consent form would put the participants at greater risk. Consent should always be obtained in the native language of the participants. The consent form or oral consent script must be provided to the NU-IRB in the participant's native language and an English translation must be provided. The appropriate supplement on certification of translation must be completed.
- If the research includes enrollment of children in other countries, the principal investigator is responsible for providing the NU-IRB with sufficient information to verify the age at which participants in such jurisdictions have the ability to consent to participation in research, including any medical treatments or procedures if applicable. The NU-IRB may, if it appears

advisable, require the submission of an opinion rendered by an attorney from any applicable jurisdiction on age at which an individual can consent to participation in research.

- If local customs and regulations are such that active parental permission would be culturally inappropriate, the PI must supply the NU-IRB with proof that such permission is not culturally appropriate. Examples of such proof would be specific regulations (in English and certified to be accurate) that indicate that such permission is not required, an official letter from a ranking official in the country of interest indicating that such permission is not culturally appropriate, by an NU faculty member who can attest to the cultural inappropriateness of the requirement for active parental permission. In those cases where seeking active parental permission for minors to participate in research is culturally inappropriate, a waiver of such permission may be granted at the discretion of the NU-IRB, as long as the research does not place the participants at untoward risk. Regardless, the participants in the research retain the right to discontinue participation, without penalty, at any time during the gathering of data. If a waiver of active parental permission is granted, a letter informing the parents of the research, written at a literacy level that would be understood by the parents, may be required and should be prepared and sent to the parents by the most expeditious method possible.
- Letters of agreement from the appropriate officials (e.g., government officials, school officials, community officials, Chief Executive Officers, etc.) indicating that the research protocol and any and all instruments to be used (including any biomedical equipment) have been reviewed and are acceptable to those officials are to be submitted. The certification letter must be on letterhead stationery and carry an original signature.
- All key personnel, including key personnel from outside the U.S. are required to have completed training in Human Subjects Research before the protocol is submitted for review by the NU-IRB.
- In many cases, it may not be possible to expedite projects which are conducted outside the U.S. Allow enough time for the full review process. Additional information may be required by the NU-IRB depending on the nature of the research and the level of risk to subjects.

Appendix D

Reference Links

- The tables below summarize the various safeguards which must be considered by all investigators in the clinical research process. Tables are organized by specific topic areas and organizations for each type of regulatory measure (law, regulation, policy and guidance).

Topic Area	Org.	Name of Law or Regulation
Institutional Review Boards (IRBs)	FDA	CFR: Title 21 Part 50; Sec 50.50 IRB Regulations **Access and Additional Information** http://www.fda.gov/oc/ohrt/irbs/default.htm http://www.accessdata.fda.gov/ scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=50.50
	OHRP	DHHS's CFR: Title 45 Part 46, regarding the protection of human subjects **Access and Additional Information** http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html
Adverse Events (AE) Reporting		
	OHRP	DHHS's CFR: Title 45 Part 46.103(b)(5) regarding written procedures for ensuring prompt reporting for unanticipated problems involving risks to subjects DHHS's CFR: Title 45 Part 46.111(a) IRB determinations regarding risk and data monitoring **Access and Additional Information** http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html
Informed Consent and Health Insurance Portability & Accountability Act (HIPAA)	FDA	Part 50 Protection of Human Subjects: Subpart B—Informed Consent of Human Subjects **Access and Additional Information** http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=50&showFR=1&subpartNode=21:1.0.1.1.19.2
	DHHS	Office for Civil Rights - HIPAA: Medical Privacy - National Standards to Protect the Privacy of Personal Health Information **Access and Additional Information** http://www.hhs.gov/ocr/hipaa/
General Responsibilities of Principal Investigators	FDA	CFR: Title 21 Part 312 Subpart D **Access and Additional Information** http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312&showFR=1&subpart

		Node=21:5.0.1.1.3.4

Topic Area	Org.	Name of Policy or Guidance
Institutional Review Boards (IRBs)	FDA	Guidance for Sponsors, Clinical Investigators, and IRBs; Waiver of IRB Requirements for Drug and Biological Product Studies **Access and Additional Information** http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM080613.pdf (PDF)
	ICH	Guideline for Good Clinical Practice E6 (R1): Sections 1.31, 3 **Access and Additional Information** http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6_R1/Step4/E6_R1__Guideline.pdf (PDF - 380 KB)
	NIH	Revised Policy for IRB Review of Human Subjects Protocols in Grant Applications **Access and Additional Information** http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-031.html
	OHRP	IRB Guidebook **Access and Additional Information** http://www.hhs.gov/ohrp/archive/irb/irb_guidebook.htm
Independent Data Monitoring Committees	FDA	Guidance on Data Monitoring Committees Guidance for Clinical Trial Sponsors Establishment and Operation of Clinical Trial Data Monitoring Committees **Access and Additional Information** http://www.fda.gov/OHRMS/DOCKETS/98fr/01d-0489-gdl0003.pdf (PDF - 193 KB) http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm
	ICH	Guideline for Good Clinical Practice E6 (R1): Sections 1.25, 5.5 **Access and Additional Information** http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6_R1/Step4/E6_R1__Guideline.pdf (PDF - 380 KB)
	NIH	NIH Policy for Data and Safety Monitoring NICHD Policy Document on Clinical Research Monitoring **Access and Additional Information** http://grants.nih.gov/grants/guide/notice-files/not98-084.html
	OHRP	Guidance on Data Safety Monitoring Boards (DSMBs), Data Monitoring Committees (DMCs), other similar bodies or sponsors **Access and Additional Information** http://www.hhs.gov/

		ohrp/policy/ contrev0107.html
Adverse Events (AE) Reporting	ICH	Clinical Safety Data Management Definitions and Standards for Expedited Reporting E2A Guideline for Good Clinical Practice E6 (R1): Section 5.17 **Access and Additional Information** http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E2B/Step4/E2B_R2__Guideline.pdf (PDF - 145 KB) http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6_R1/Step4/E6_R1__Guideline.pdf (PDF - 380 KB)
	NIH	Guidance on Reporting AEs to IRBs for NIH Supported Multicenter Clinical Trials Genetic Modification Clinical Research Information System (GemCRIS) provides AE reporting templates **Access and Additional Information** http://grants.nih.gov/grants/guide/notice-files/not99-107.html http://oba.od.nih.gov/rdna/adverse_event_oba.html
	OHRP	Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and AEs **Access and Additional Information** http://www.hhs.gov/ohrp/policy/advevntguid.html
Informed Consent and Health Insurance Portability & Accountability Act (HIPAA)	ICH	Guideline for Good Clinical Practice E6 (R1): Sections 1.28, 4.8 **Access and Additional Information** http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6_R1/Step4/E6_R1__Guideline.pdf (PDF - 380 KB)
	NIH	HIPAA Overview and Resources Certificates of Confidentiality Kiosk and Information National Cancer Institute (NCI) Guidance on Children's Assent National Library of Medicine (NLM) information on Clinical Research involving Human Subjects **Access and Additional Information** http://privacyruleandresearch.nih.gov/ http://grants2.nih.gov/grants/policy/coc/ http://www.cancer.gov/clinicaltrials/understanding/childrensassent0101 http://www.nlm.nih.gov/archive/20061214/pubs/cbm/hum_exp.html#50
	OHRP	Policy Guidance by topic: Informed Consent **Access and Additional Information** http://www.hhs.gov/ohrp/policy/#informed

General Responsibilities of Principal Investigators	FDA	FDA Guidance Documents Format for study protocols with an IND **Access and Additional Information** http://www.fda.gov/oc/gcp/guidance.html
	ICH	Guideline for Good Clinical Practice E6 (R1) ICH E3: Guideline for Industry Structure and Content of Clinical Study Reports **Access and Additional Information** http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/efficacy/E6_R1/Step4/E6_R1__Guideline.pdf (PDF - 380 KB) http://www.fda.gov/AboutFDA/CentersOffices/OC/OfficeofScienceandHealthCoordination/GoodClinicalPracticesProgram/default.htm
	NIH	Guidelines for the conduct of clinical research within the NIH Intramural Research Program NIH Office of Extramural Research Ethical Guidelines and Regulations NIH Office of Extramural Research Guidelines for Research Involving Vulnerable Populations **Access and Additional Information** http://www1.od.nih.gov/oir/sourcebook/ethic-conduct/ Conduct%20Research%206-11-07.pdf (PDF - 68 KB) http://grants.nih.gov/grants/policy/hs/coded_synopsis.htm
	OHRP	Policy Guidance by topic **Access and Additional Information** http://www.hhs.gov/ohrp/policy/
	WMA	Declaration of Helsinki, which provides a set of ethical principles for the medical community regarding human experimentation **Access and Additional Information** http://ohsr.od.nih.gov/guidelines/Helsinki.html

http://www.nichd.nih.gov/health/clinicalresearch/regulations/

Appendix E

OHRP Flow Charts

Human Subjects Regulations Decision Charts

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

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

Considerations

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

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

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

Chart 1: Is an Activity Research Involving Human Subjects?

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

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

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

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

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

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

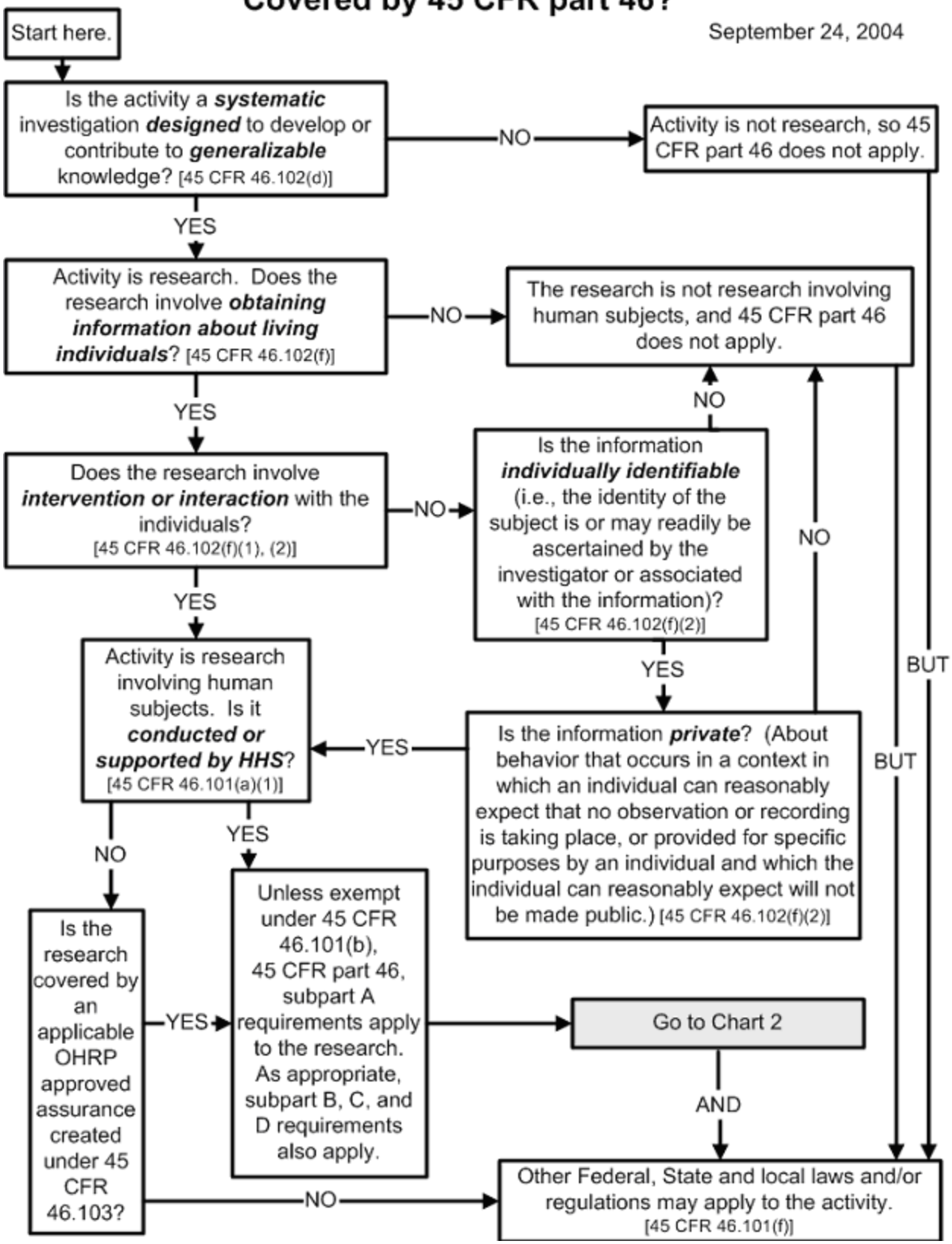
Chart 8: May the IRB Review Be Done by Expedited Procedures?

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

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

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

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



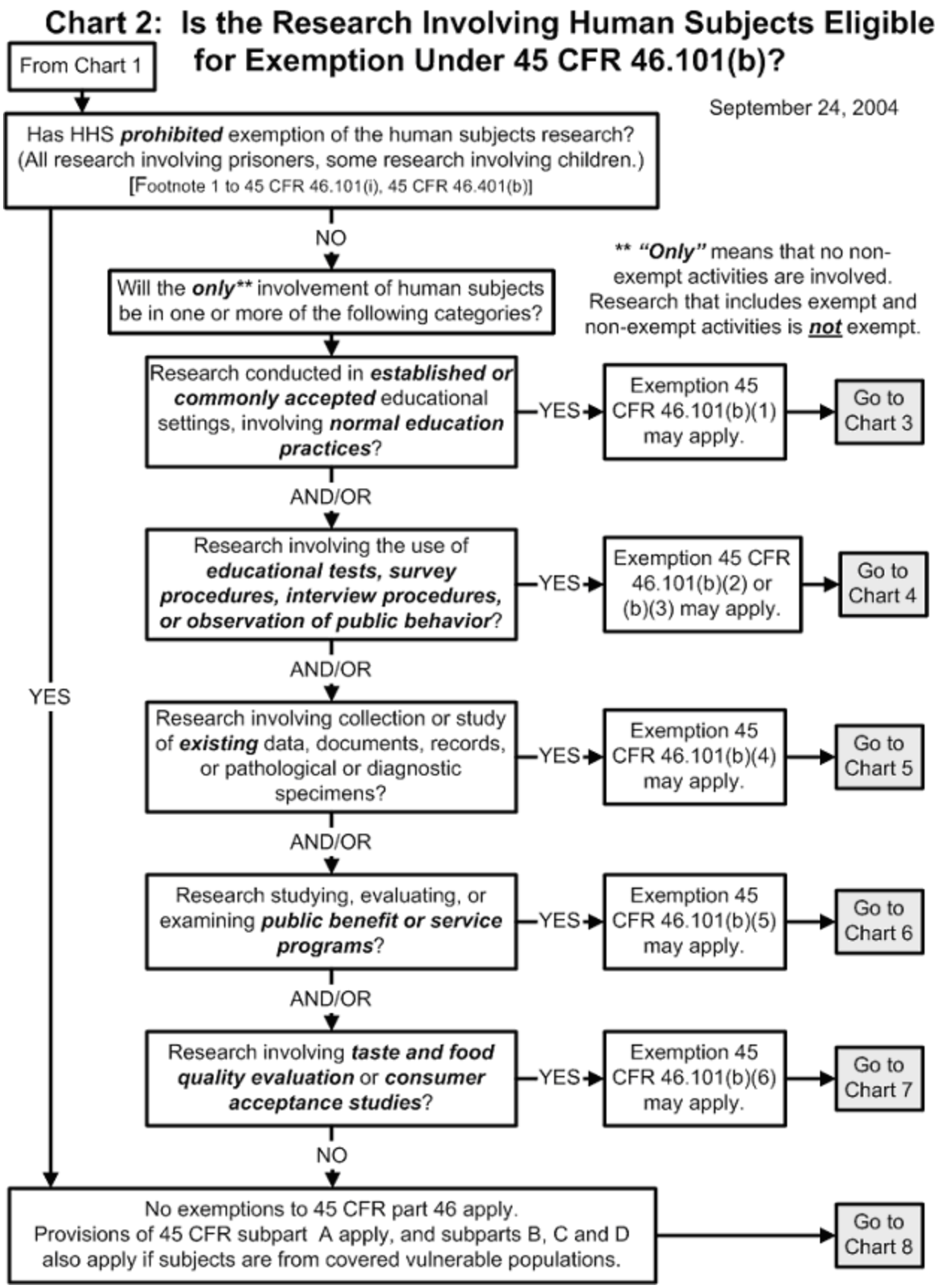


Chart 2: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.101(b)?
From Chart 1
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Has HHS prohibited exemption of the human subjects research? (All research involving prisoners, some research involving children.) [Footnote 1 to 45 CFR 46.101(i), 45 CFR 46.401(b)]
NO
YES
** "Only" means that no non-exempt activities are involved. Research that includes exempt and non-exempt activities is not exempt.
Will the only** involvement of human subjects be in one or more of the following categories?
Research conducted in established or commonly accepted educational settings, involving normal education practices?
YES
Exemption 45 CFR 46.101(b)(1) may apply.
Go to Chart 3
AND/OR
Research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior?
YES
Exemption 45 CFR 46.101(b)(2) or (b)(3) may apply.
Go to Chart 4
AND/OR
Research involving collection or study of existing data, documents, records, or pathological or diagnostic specimens?
YES
Exemption 45 CFR 46.101(b)(4) may apply.
Go to Chart 5
AND/OR
Research studying, evaluating, or examining public benefit or service programs?
YES
Exemption 45 CFR 46.101(b)(5) may apply.
Go to Chart 6
AND/OR
Research involving taste and food quality evaluation or consumer acceptance studies?
YES
Exemption 45 CFR 46.101(b)(6) may apply.
Go to Chart 7
NO
No exemptions to 45 CFR part 46 apply.
Provisions of 45 CFR subpart A apply, and subparts B, C and D also apply if subjects are from covered vulnerable populations.
Go to Chart 8

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

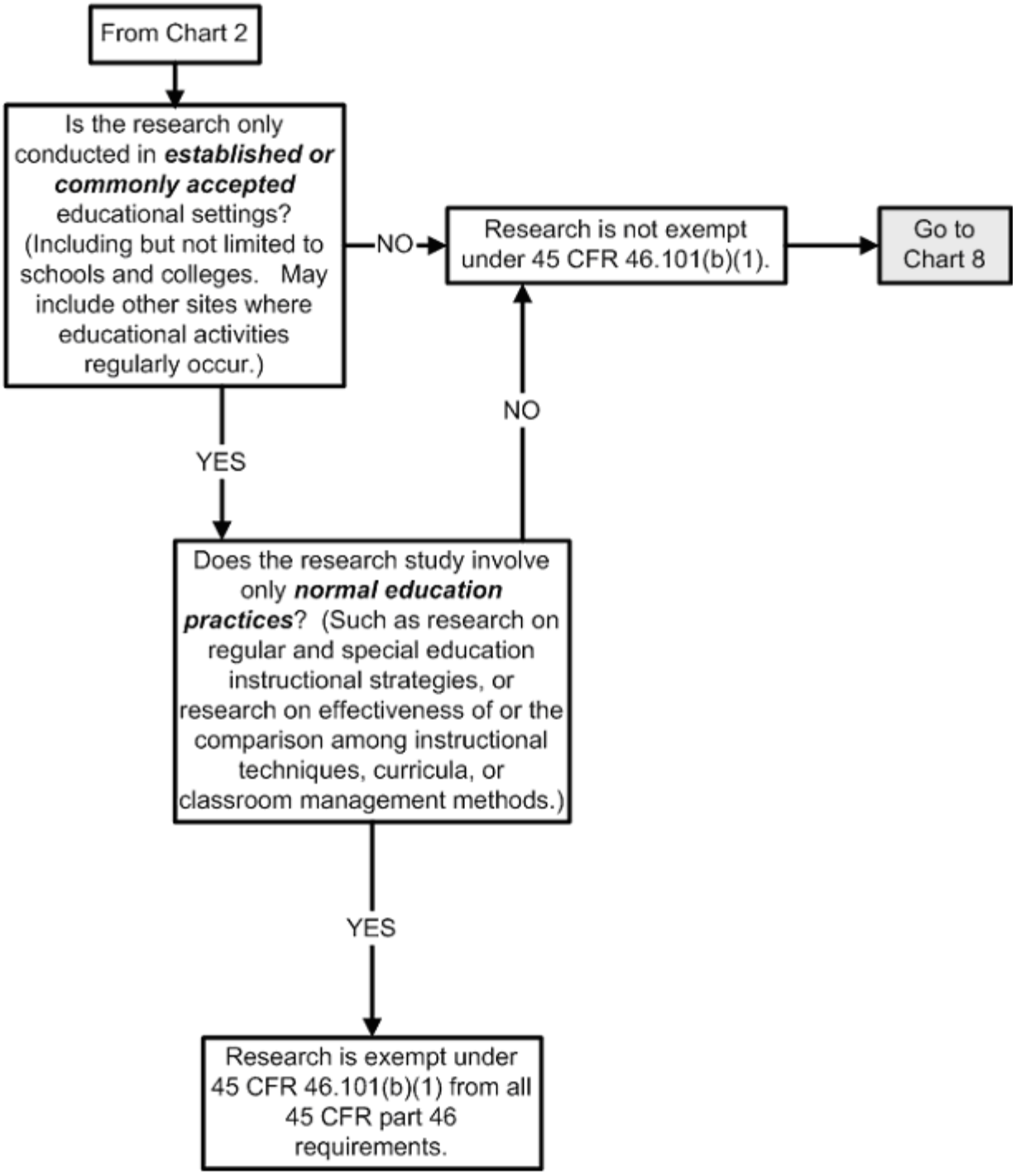

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Chart 4: Does Exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?

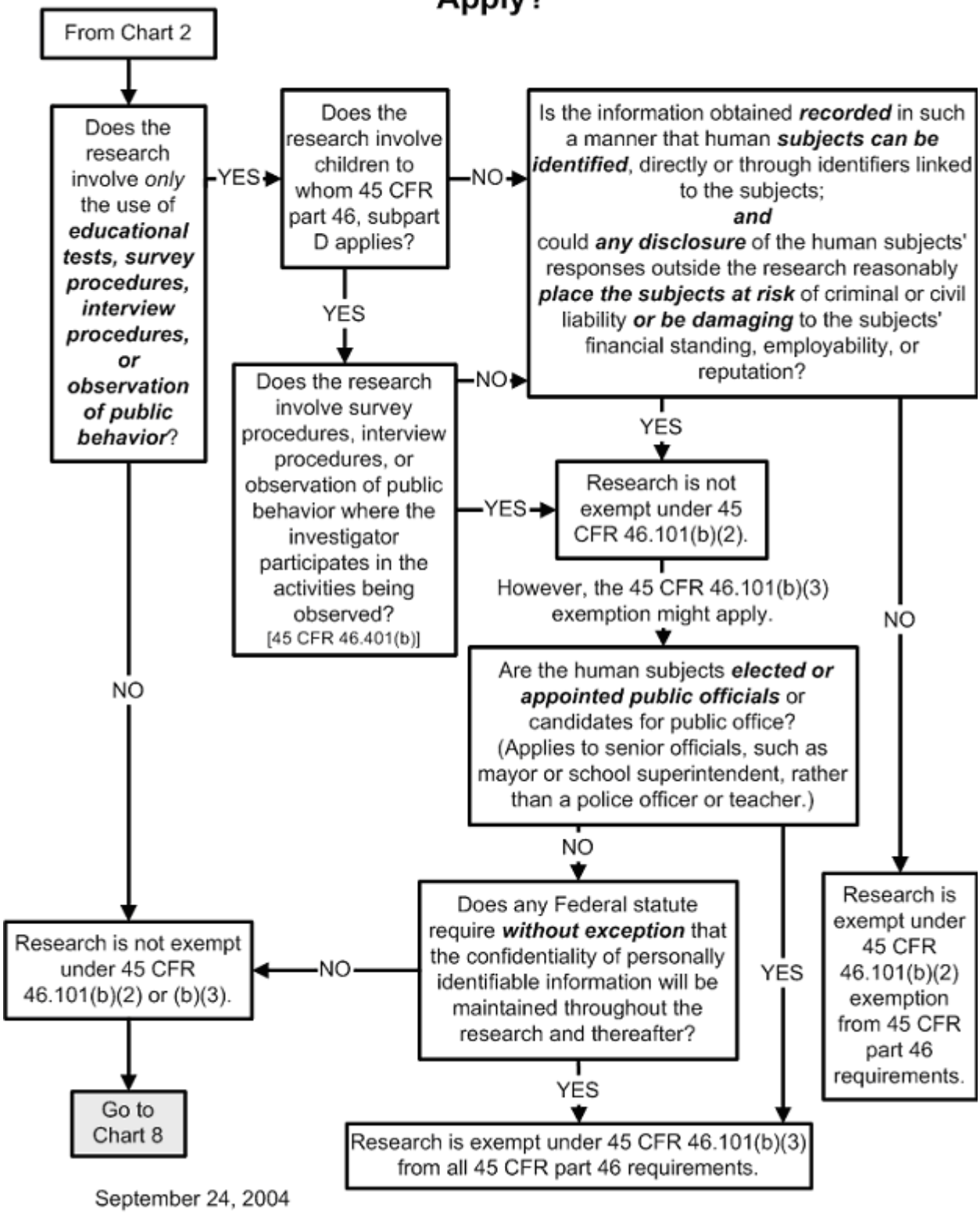

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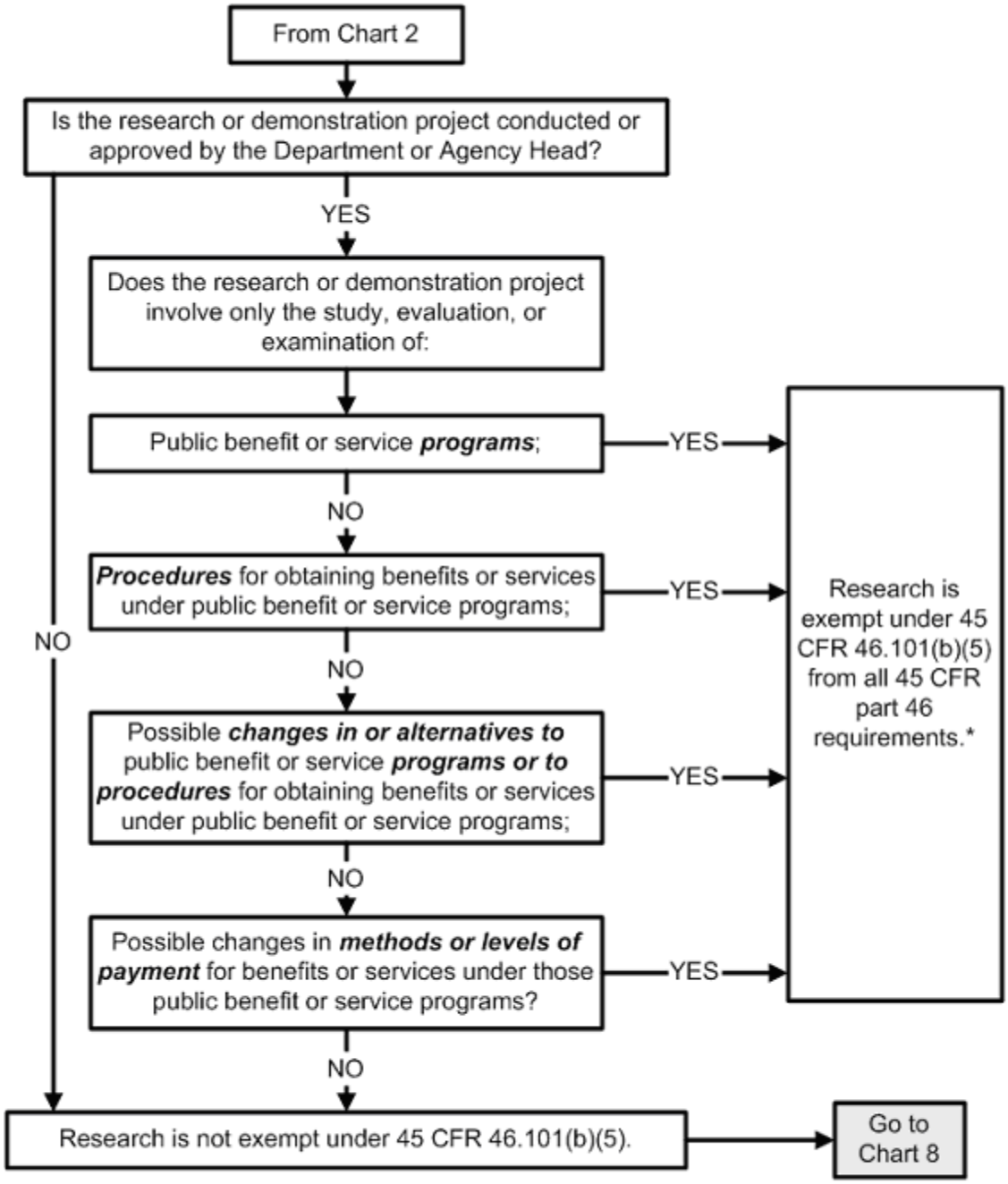
Chart 6: Does Exemption 45 CFR 46.101(b)(5) (for Public Benefit or Service Programs) Apply?



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

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

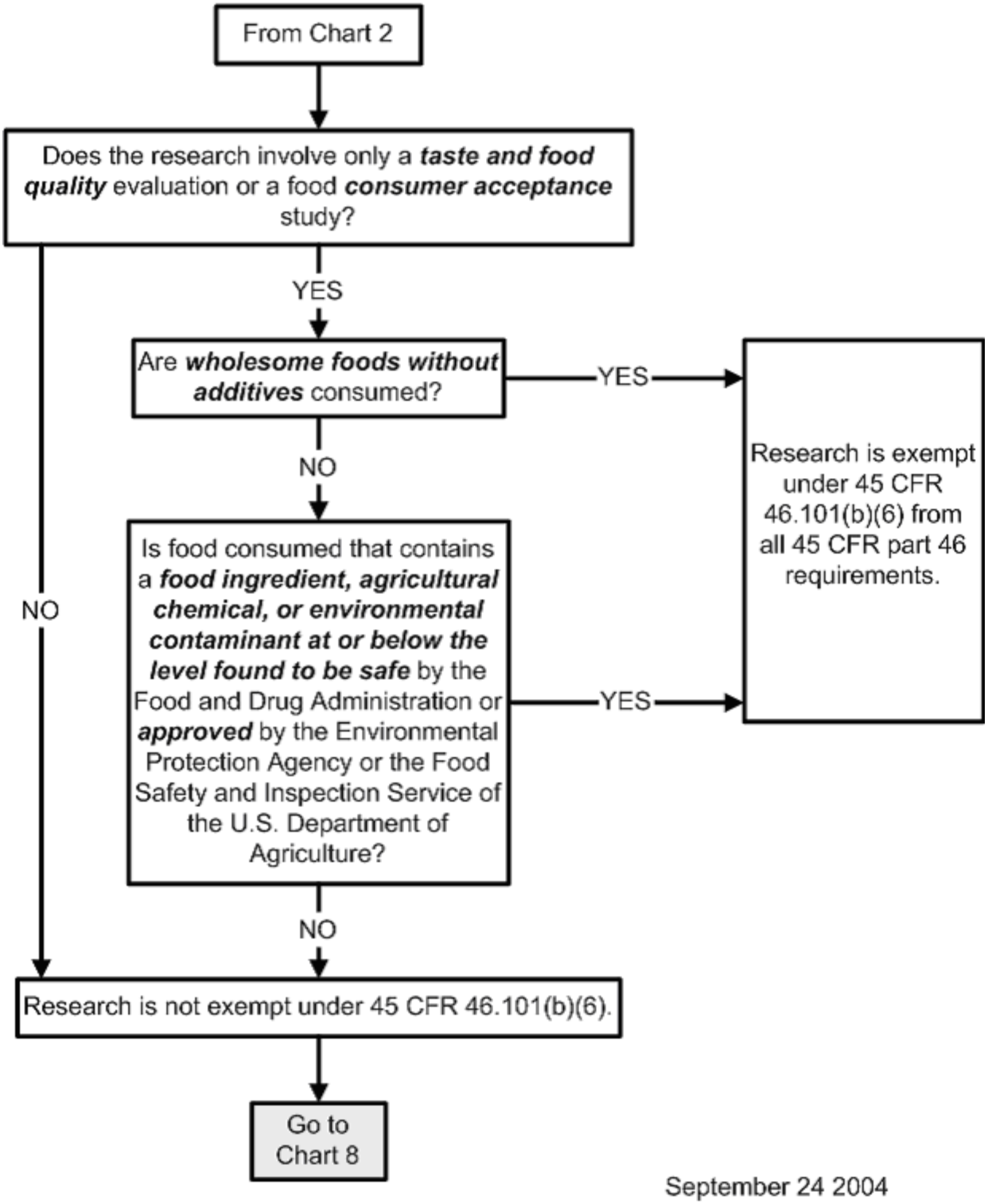

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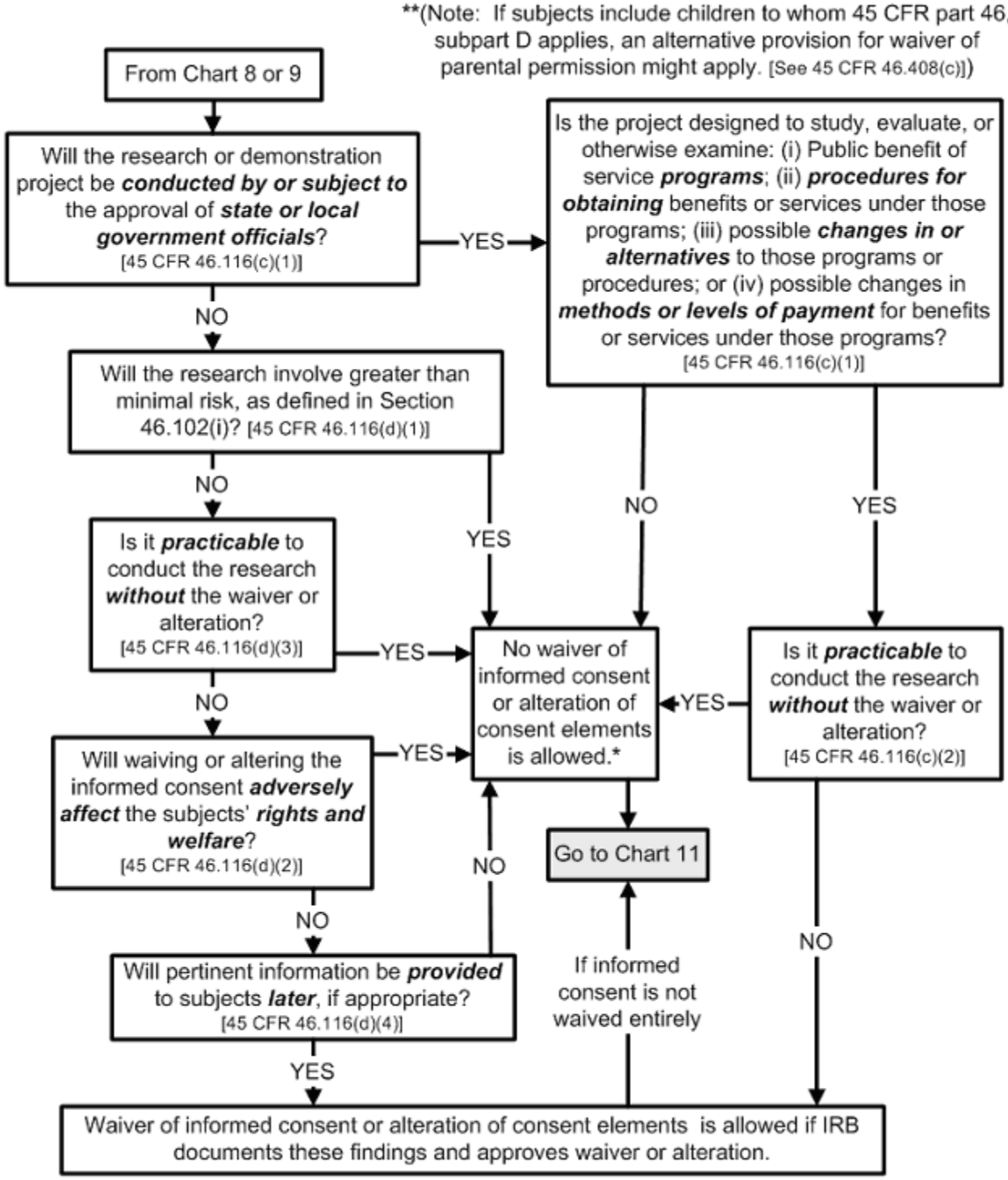
Chart 10: Can Informed Consent Be Waived or Consent Elements Be Altered Under 45 CFR 46.116(c) or (d)?**



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

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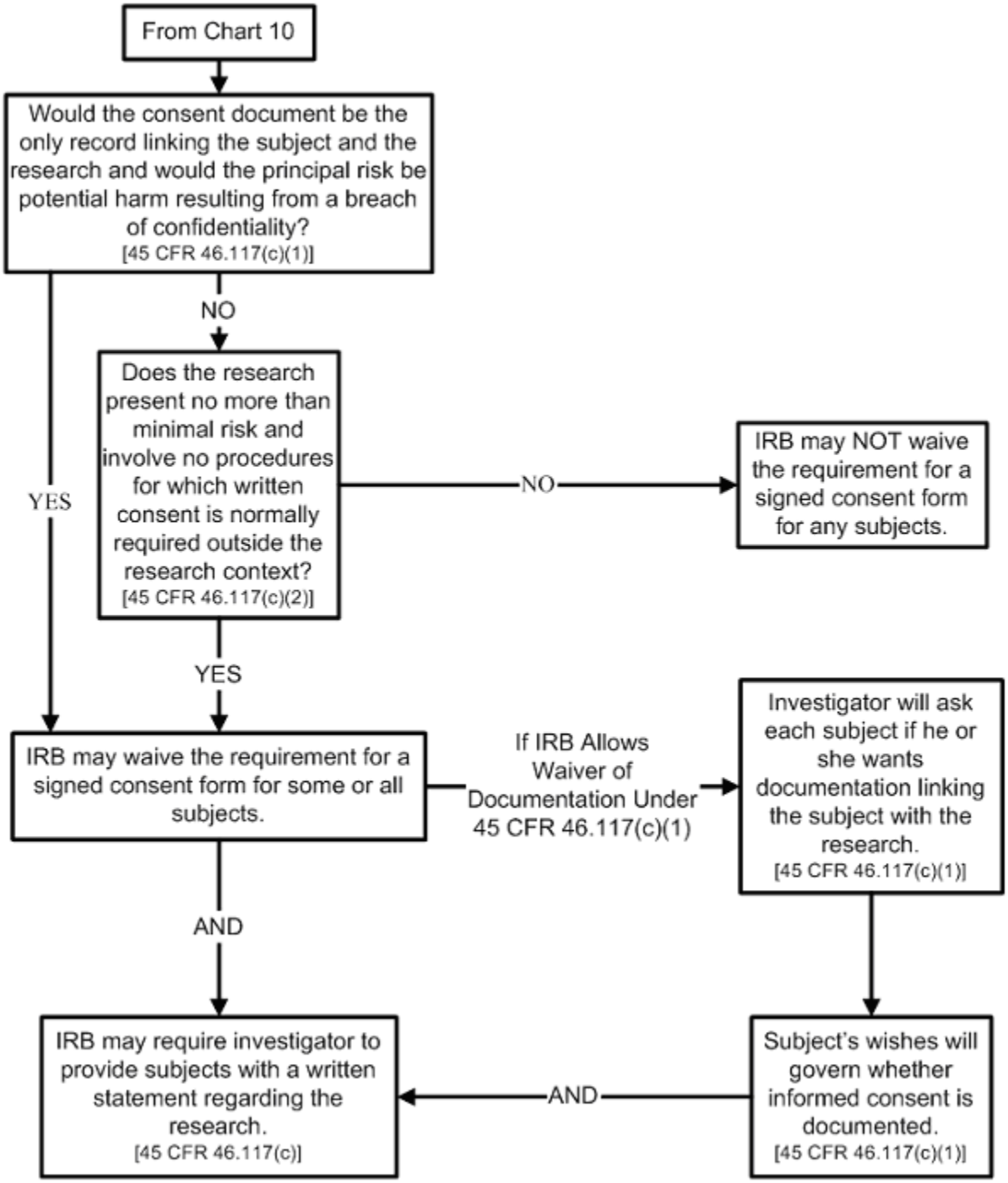
Chart 11: Can Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?



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