



POLICIES AND PROCEDURES FOR THE
PROTECTION OF HUMAN SUBJECTS

Executive Summary

The current structure of the IRB consists of an IRB Chair and IRB Members. This is insufficient. The current structure of the IRB lacks consistency and infrastructure with regard to established policies, standard operating procedures (SOPs), training, education, and IRB guidance beyond the knowledge of the IRB Chair. The Office of Sponsored Programs and Research Services is proposing changes to the current structure and adaptation of processes to reduce exposure to risk, increase transparency and improve communication. Our goal is to develop a **Human Research Protection Program** at Roosevelt University that incorporates IRB as part of it, providing oversight for all research activities involving human participants, not only dependent upon IRB review. All policies herein are based on the guidance of the Belmont Report and 45 CFR 46, the code of federal regulations within the Department of Health and Human Services that provides guidance on protection of human subjects.

Given the assessment of the current IRB documentation, the Office of Sponsored Programs and Research Services recommends that the Director of Sponsored Programs and Research Services assumes the role of Human Research Protection Administrator. This role would be to serve as compliance officer, IRB administrator and liaison between the broader university community and the IRB.

The policies in this document will serve as the basis for establishing best practices in human research protections at Roosevelt University and include the following:

1. Policies on the Institutional Review Board: these policies provide guidance and procedures on all aspects of the IRB, including the roles and responsibilities of designated officials, the process by which individuals will be chosen to serve on the IRB, all of the duties of IRB members and their relationship to faculty.
2. Policies on the IRB Review Process: these policies establish how the IRB should be run, including how all information and communication will be documented, how to proceed with continuing review and modifications of approved protocols, and how to address any adverse events and unanticipated problems that may occur.
3. Policies on what constitutes expedited review and procedures for how to address the appeals process to an IRB decision.
4. IRB Records: procedures on how to document, maintain and disseminate records that make up IRB membership and all IRB meetings.

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Roosevelt University Institutional Review Board (IRB)

The IRB is an administrative body established to protect the rights and welfare of stakeholders in human subjects research that engages Roosevelt University (Roosevelt). Roosevelt has established and authorized the IRB to review, approve, disapprove, or require changes in non-exempt research activities involving human subjects. The IRB has been established in accordance with the requirements of current federal rules. Roosevelt will review the activity of the IRB on an annual basis and make a determination as to whether its activities remain in compliance with federal and state law and university policies and procedures.

AUTHORITY OF THE IRB

The IRB at the Roosevelt reviews and has authority to approve, require modifications in, or disapprove all research activities conducted under the auspices of the University. The IRB is required to ensure that appropriate safeguards exist to protect the rights and welfare of research subjects [45 CFR 46.111]. In fulfilling these responsibilities, the IRB has the responsibility to ensure human research protection review of all the research documents and activities that bear directly on the rights and welfare of the subjects of proposed research. The protocol, the consent/assent document(s) and, for studies conducted under the **Common Rule is a document that the IRB should review**. The IRB should also review the methods and material that investigators propose to use to recruit subjects.

Before any human subject is involved in research in relationship to the University, an IRB will give proper consideration to:

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

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

benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

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

4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116.

5. Informed consent will be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117.

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

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

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

The IRB has the authority to suspend, place restrictions, or terminate approval of research activities that fall within its jurisdiction that are not being conducted in accordance with IRB requirements or that have been associated with unexpected adverse events. The IRB has the authority to observe or have a third party observe the consent process and the research activities.

JURISDICTION OF THE IRB

IRB jurisdiction extends to ALL non-exempt research (funded and not funded) involving human subjects engaging Roosevelt. However, in the event Roosevelt personnel are conducting human subjects research in cooperation with another engaged institution, Roosevelt may elect to execute an Authorization/Reliance Agreement with the other engaged institution. An Authorization/Reliance Agreement, per federal regulations at 45 CFR 46.114, allows Roosevelt to rely on another institution that has a valid, current FWA and an IRB on which the FWA relies. By relying on another IRB, Roosevelt satisfies compliance with its FWA.

If an IRB chair, member, or staff person feels that the IRB has been unduly influenced by any party, then they shall make a confidential report to the Director of Sponsored Programs and Research Services, who serves as the Human Research Protections Administrator (HRPA), who will conduct a preliminary investigation. If circumstances warrant, then the HRPA shall, in communication and cooperation with

the IO and/or the IO's delegate, conduct a thorough investigation and develop and implement a corrective and preventative action (CAPA) plan in order to prevent additional occurrences.

IRB RELATIONSHIPS

The IRB functions independently of, but in coordination with, other institutional regulatory or administrative committees. The IRB makes its independent determination whether to approve or disapprove a protocol based on federal and institutional criteria for IRB approval. The IRB has review jurisdiction over all non-exempt human subjects research engaging Roosevelt.

Research that has been reviewed and approved by the IRB may be additionally subject to review and disapproval by officials of the University. However, those officials may NOT approve research if it has been disapproved by the IRB.

RELATIONSHIPS WITH INDIVIDUAL INVESTIGATORS

In instances when Roosevelt investigators intend to involve non-Roosevelt personnel as investigators in either a multi-site or a multi-center study, Roosevelt must ensure that non-Roosevelt personnel satisfy all Roosevelt requirements for credentialing and validating investigators conducting human subjects research in compliance with Roosevelt FWA. In these instances, Roosevelt may elect to extend its FWA protections to non-Roosevelt personnel via an Individual Investigator Agreement (IIA). The IIA will extend Roosevelt FWA compliance protections to both (1) the independent investigator and (2) the institutional investigator:

(1) Independent investigator is:

- (a) Not otherwise an employee or agent of the assured institution;
- (b) Conducting collaborative research activities outside the facilities of the assured institution; and
- (c) Not acting as an employee of any institution with respect to his or her involvement in the research being conducted by the assured institution.

(2) Institutional investigator is:

- (a) Not otherwise an employee or agent of the assured institution;
- (b) Conducting collaborative research activities outside the facilities of the assured institution;
- (c) Acting as an employee or agent of a non-assured institution with respect to his or her involvement in the research being conducted by the assured institution; and
- (d) Employed by, or acting as an agent of, a non-assured institution that does not routinely conduct human subjects research.

Roosevelt will abide by OHRP guidance found at
<http://www.hhs.gov/ohrp/policy/guidanceonalternativetofwa.html>

ROLES AND RESPONSIBILITIES

INSTITUTIONAL OFFICIAL

The Provost and Executive Vice President serves as the Institutional Official (IO) for Roosevelt's FWA. The IO acts on behalf of Roosevelt and assumes overall responsibility for compliance with the FWA. The IO has the legal authority to commit on behalf of Roosevelt and signs the FWA. The IO is responsible for designating a person to be responsible for carrying out various activities relating IRB administration, including appointing IRB members and Chair (based upon the recommendation of college deans and department chairs) and supports IRB decisions. The IO has authority to further review research projects following IRB review and can approve or disapprove research projects, but cannot approve any research that has been disapproved by the IRB. The IRB Chair, Vice Chair, Director of Sponsored Programs and Research Services/HRPA and IO designee report directly to the IO.

IRB CHAIR

The IO, in consultation and approval with the IRB members and the HRP, appoints an IRB member to serve in the role of IRB Chair. The term of service as Chair will coincide with the term of service as member. The IO may re-appoint the IRB Chair to consecutive terms not to exceed six consecutive years. Any change in appointment, including reappointment or removal, requires written notification.

In order to be eligible to serve as IRB Chair, the individual must have served for at least one year on the Roosevelt IRB or an IRB at another institution. Whenever possible, the IRB Chair will be a senior faculty member of Roosevelt.

The IRB Chair moderates IRB meetings and collaborates with the HRP in management of the IRB. The IRB Chair is a signatory for correspondence generated by the IRB.

The IRB Chair may designate other IRB members to perform duties, as appropriate, for review, signature authority, and other IRB functions. The IRB Chair advises the IO and/or IO's designee and HRP on IRB member performance and competence.

The IRB Chair and/or Vice Chair and HRP shall meet with University officials on a regular basis.

The IRB Chair acts on behalf of the IRB Committee and reports directly to the IO and/or IO's designee.

VICE CHAIR

The Vice-Chair serves as substitute when the IRB Chair is unavailable. The Vice-Chair and IRB Chair may share responsibilities, thus serving as Co-Chairs. The Vice Chair serves as IRB Chair when the IRB reviews a research for which the IRB Chair serves as the Study PI.

HUMAN RESEARCH PROTECTIONS ADMINISTRATOR (HRP)

The Human Research Protections Administrator (HRP) serves as Roosevelt's research ethicist and compliance officer for research subject to human research protections. The HRP manages the privileged and confidential institutional review approval process of all proposed research activities involving human subjects. The HRP receives all research protocols, communicates decisions to research investigators, and supporting documentation and forwards certification of IRB approval to appropriate research personnel. The HRP provides regular publications of meeting schedules and transmission of documents to and from investigators. The HRP ensures preparation and distribution of the agenda and review materials for IRB members prior to each meeting. The HRP ensures that minutes of IRB

meetings are adequately recorded and maintained. The HRP maintains all records of IRB action for at least three years after the conclusion of the research. The HRP reviews and approves all exemption-eligible human subjects research. The HRP acts on behalf of the IRB and Roosevelt when collaborating/cooperating with other institutions on matters of human research protections. The HPA reports directly to the IO and/or IO's designee.

SUBCOMMITTEES OF THE IRB

The IRB Chair or HRP may designate one or more other IRB members (i.e., establish a sub-committee) to perform duties, as appropriate, for review, signature authority, and other IRB functions. When appropriate, individuals outside of the IRB membership may be included in subcommittees.

DUTIES OF A SUBCOMMITTEE

Duties of a subcommittee may include the following:

1. Serve as designees to the IRB Chair for the expedited review of new or continuing protocols, and/or modifications of continuing protocols. The subcommittee must be experienced in terms of seniority on the IRB, and must be matched as closely as possible with their field of expertise to the study.
2. Review and approve the revisions submitted by investigators for a protocol given conditional approval by vote of the full IRB.
3. Ensure fairness and expertise of an inquiry process. A subcommittee is appointed consisting of IRB members, and non-members if appropriate, to ensure fairness and expertise of an inquiry process (See Section 11.3 for a discussion of the inquiry process). The subcommittee is given a charge by the IRB, which can include any or all of the following:
 - a. Review of protocol(s) in question;
 - b. Review of FDA audit report of the investigator, if appropriate;
 - c. Review of any relevant documentation, including consent documents, case report forms, subject's investigational and/or medical files etc., as they relate to the investigator's execution of her/his study involving human subjects;
 - d. Interview of appropriate personnel if necessary;
 - e. Preparation of either a written or oral report of the findings, which is presented to the full IRB at its next meeting;
 - f. Recommend actions if appropriate.
4. Conduct on-site review. Determination of the review interval and the need for additional supervision and/or participation is made by the IRB on a protocol-by-protocol basis. This applies in the case of an investigator performing particularly risky research, or has recently had a protocol suspended by the IRB due to regulatory concerns. In this case, an on-site review by an IRB subcommittee might occur or approval might be subject to an audit of study performance after a few months of enrollment, or after enrollment of the first several subjects.
5. Observe the consent process. When appropriate, the IRB may appoint a subcommittee to observe the consent process being used in a research project.

RESOURCES FOR IRB

The IO ensures that the IRB and HRPAs have adequate resources, including adequate meeting and office space, for conducting IRB business. Office equipment and supplies, including technical support, file cabinets, computers, internet access, and copy machines, will be made available to the IRB and staff. The resources provided for the IRB and staff will be reviewed during the annual budget review process.

CONDUCT OF QUALITY ASSURANCE/QUALITY IMPROVEMENT ACTIVITIES FOR IRB OPERATION

The IO and/or IO's designee, through appropriate mechanisms, will monitor and review the processes and procedures of the IRB to ensure effectiveness, efficiency and compliance with both federal regulations and these policies and procedures.

The HRPAs will conduct investigations and audits of ongoing research when the IRB directs an audit be conducted or a complaint or allegation of non-compliance is received. In addition, the staff will conduct "not for cause" audits of research. (See Complaints, Non-compliance, and Suspension or Termination of IRB Approval of Research policy and procedures.)

IRB MEMBERSHIP

COMPOSITION OF THE IRB

1. Roosevelt University (Roosevelt) will have at least five members with varying backgrounds to provide complete and adequate review of research proposals and issues related to approved research in process.
2. The IRB will be sufficiently qualified to complete its work. Membership appointments will be made with consideration for expertise, diversity, and sensitivity to community attitudes.
3. In addition to possessing the professional competence necessary to review specific research activities, the IRB will be able to ascertain the acceptability of proposed research in terms of institutional policies and regulations, applicable law, and standards of professional conduct and practice. The IRB will have access to consultants to provide review assistance when specific areas of expertise are not available through appointed committee members.
4. If the IRB regularly reviews research that involves participants classified as vulnerable (e.g., children, prisoners, pregnant women, or handicapped or mentally disabled persons), consideration will be given to appointing an IRB committee member with expertise in understanding the issues directly related to the specific vulnerable population.
5. Every effort will be made to ensure that the IRB does not consist entirely of men or entirely of women. Committee member appointments will not be made based on gender. IRB membership includes representation from disciplines on campus that actively submit research for review.
6. IRB membership includes at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
7. IRB membership includes at least one member otherwise unaffiliated with the University and not part of the immediate family of a person who is affiliated with Roosevelt.
8. One member may satisfy more than one membership category.

9. The IRB Chair and Vice Chair will serve as a committee member with voice and vote.
10. The Human Research Protections Administrator (HRPA) will serve as a committee member with voice and vote.

APPOINTMENT OF MEMBERS TO THE IRB

The IRB Chair, Vice Chair and HRPA will inform the Institutional Official (IO) when a need exists for a new or replacement member or alternate member. Deans, Department Chairs and others will forward nominations for committee members to the IO, the Human Research Protections Administrator, or the IRB Chair. The IO and the HRPA will communicate with Deans, IRB Chair, and Vice Chair to ensure nominees represent the content expertise to conduct adequate review.

The IO will communicate with nominees about their availability and willingness to accept appointment to the IRB. The IO and HRPA will confer with the IRB Chair and Vice Chair to ensure nominees satisfy appointment criteria and represent research interests. The IO will authorize appointments and work with the HRPA to document the appointment (i.e., appointment letter).

IRB appointment has a term of service of three years. The term of service is renewable for an additional three years. After two consecutive terms, an IRB member is ineligible for one year. A former IRB member may receive an offer for re-appointment after a minimum of one-year hiatus. Any change in appointment, including reappointment or removal, requires authorization from the IO and formal documentation (e.g., letter). Members may resign by providing written notification to the Chair.

ALTERNATE MEMBERS

The appointment and function of alternate members is the same as that for primary IRB members and the alternate's expertise and perspective are comparable to those of the primary member. The IRB roster identifies the primary member(s) for whom each alternate member may substitute. Alternates may attend any IRB meeting and are encouraged to attend as many meetings as possible. Although the alternate member will not be counted as a voting member unless the primary member is absent, they may freely participate in discussion. When an alternate member substitutes for a primary member, the alternate member will receive and review the same materials prior to the IRB meeting that the primary member received or would have received. The IRB minutes will document when an alternate member replaces a primary member.

USE OF CONSULTANTS (OUTSIDE REVIEWERS)

The IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB. Prior to committing to review, consultants will be informed of the Roosevelt University conflict of interest in research policy. Individuals who have a conflicting interest or whose spouse or family members have a conflicting interest in the research or sponsor of the research will not be invited to provide consultation. Ad hoc or informal consultations requested by individual members (rather than the full board) will be requested in a manner that protects the researcher's confidentiality and is in compliance with Roosevelt University policies and procedures.

CONFLICT OF INTEREST (COI) – IRB MEMBERS AND CONSULTANTS

No IRB member or consultant will participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. IRB members and consultants are expected to disclose conflicting interests. When a committee member or consultant identifies that a conflict of interest exists, the IRB Chair and/or Vice Chair and/or HRP will reassign the protocol.

Generally, a conflicting interest includes:

1. Participation in the project to be reviewed;
2. A financial interest (see below); and/or
3. Any other examples referenced below.

A conflict may arise because of an interest of the member or consultant or his/her family; the aggregate interest of the IRB member or consultant and family is considered.

“Participation in the project” generally means the member or consultant and/or family is listed on the protocol/project, or will be included as a co-author on a publication of the project’s results. This would include individuals or immediate family involved in the design, conduct, or reporting of the research. Participation in the project excludes a member of the IRB or consultant from reviewing and voting on the project under review.

The following financial interests may be considered a conflict of interest:

1. An ownership interest (equity or stock options) or other measures of fair market value to publicly traded prices in any one enterprise or entity in aggregate for the IRB member or consultant and his/her immediate family related to any project being reviewed.
2. Consulting fees, honoraria, speaking fees, travel expenses, stipends, dividends, salary, royalties, travel expenses, stock options, gifts or other payments for the IRB member or consultant and his/her immediate family from an external entity relating to any project being reviewed.
3. Compensation to the IRB member or consultant and his/her family of any amount based on a favorable outcome or unfavorable outcome. This includes compensation that is explicitly greater for a favorable result or compensation to the investigator in the form of an equity interest in the sponsor of a covered study or in the form of compensation tied to sales of the product, such as a royalty interest.
4. Proprietary or other financial interest by the IRB member or consultant and his/her family in the product to be used in clinical trials including, but not limited to, a patent, trademark, copyright or licensing agreement.

Other examples of conflicting interests include but are not limited to:

1. Having certain non-financial interests that may raise a real or perceived conflict. These will depend on the circumstances. They may include, for example, having direct supervision over the investigator conducting the project. NOTE:

- a) A department director does not have a conflict simply by virtue of the position; a conflict could arise, though, if the director had a closer, direct supervisory relationship over a department researcher;
- b) If a junior person in an IRB member or consultant's research group submits a protocol, the IRB member or consultant has a conflict and cannot review the protocol.

2. Any real or perceived conflict, or a concern that there may be a real or perceived conflict, that is not addressed above should be raised with either the IRB Chair, Vice Chair and/or the HRP. The IRB Chair, Vice Chair, and HRP have the authority to determine when COI exists as defined by institutional policy and to impose and enforce disciplinary action in the event that COI is not disclosed.

DUTIES OF IRB MEMBERS

IRB members have access to all materials and other study records through the Office of Sponsored Programs and Research Services. When a proposal requires full board review, all members will have access to the proposal at least one week before each meeting in order to participate fully in the review process. IRB members will treat the research proposals, protocols, and supporting data confidentially.

ATTENDANCE REQUIREMENTS

Members should attend all scheduled meetings. If a member is unable to attend a scheduled meeting, they should inform the IRB Chair or HRP. If the inability to attend two or more consecutive meetings, the committee member should submit a request for an alternate to the IRB Chair or HRP.

TRAINING AND ORIENTATION/CONTINUING EDUCATION OF IRB MEMBERS AND LEADERSHIP

A vital component of a comprehensive human research protection program is an education program for the IRB Chair Vice Chair, HRP, and committee members. Roosevelt is committed to providing training and an on-going educational process for IRB members related to ethical concerns and regulatory and institutional requirements for the protection of human subjects.

TRAINING AND ORIENTATION

Initial training and orientation of ALL IRB members include:

1. Completion of CITI Certification in Human Research Protections
2. Completion of training in any and all relevant software designed to manage and document human subjects materials;
3. Meet with HRP to;
 - a) Review Roosevelt IRB website
 - b) Review agendas and minutes from previous meetings;
 - c) Receive and review copy of "IRB Member Handbook";
 - d) Review "Policies and Procedures Manual";
 - e) Review administrative processes of IRB review
4. Meet with IRB Chair for;

- a) Overview of meeting organization and conduct; and
- b) Overview of project review processes.

HRPA must validate and document training and orientation of a prospective IRB member BEFORE that member conducts review.

CONTINUING EDUCATION

To ensure that oversight of human research is ethically grounded and the decisions made by the IRB are consistent with current regulatory and policy requirements, training is continuous for IRB members throughout their service on the IRB. Educational activities include, but are not limited to;

- In-service training at IRB meetings
- Training workshops
- Dissemination of current events articles relevant to human research protection
- Copies of “Institutional Review Board: Member Handbook”
- Maintaining CITI certification

The IO will provide formal (e.g., advocacy) and material (e.g., funding) support for the HRPAs and IRB members to attend local, regional and national conferences that promote professional development in human research protections.

The HRPAs must earn and sustain professional development continuing education unit credits, with the goal to obtain the Certified IRB Professional (CIP) credential.

LIABILITY COVERAGE FOR IRB MEMBERS

Roosevelt will indemnify and defend Roosevelt faculty and staff performing within the course and scope of their employment (e.g., IRB responsibilities). This coverage extends to those under the supervision of faculty and staff (e.g., students and staff), and volunteers (i.e., unaffiliated IRB members).

REVIEW OF IRB MEMBER PERFORMANCE

The IRB Member’s performance will be reviewed on an annual basis by the HRPAs in consultation with the IRB Chair and Vice Chair. Members who are not acting in accordance with the IRB’s mission or policies and procedures or who have an undue number of absences will be replaced.

IRB Review Process

These procedures and guidelines apply to all human subjects research engaging Roosevelt, regardless of sponsorship and performance site.

HUMAN SUBJECTS RESEARCH DETERMINATION. The responsibility for determining initially whether an activity constitutes human subjects research rests with the investigator. Because Roosevelt holds investigators responsible for incorrect determinations, investigators must consult with the Director of Sponsored Programs and Research Services, who assumes the role of Human Protections Research Administrator (HRPA) in order to make initial determination of human subjects research. Roosevelt

classifies research into four categories vis-à-vis federal regulations for human research protections review:

1. Not Human Subjects Research; A project does NOT satisfy the federal regulatory definition of “research” OR “human subjects research” and is not eligible for human research protections review.

2. Research Subject to Human Research Protections and Review

a) Exemption Eligible; A project satisfies the definitional criteria of “human subjects research” AND satisfies eligibility criteria for one or more of the federal regulatory exemption categories as set for in the policy on Institutional Authority.

b) Non-exempt Human Subjects Research

(i) Expedited review

(ii) Full board review

EXEMPT RESEARCH. Per current policy, Roosevelt delegates to the HRP A review and approval of exemption-eligible human subjects research. Please refer to the Institutional Authority Policy.

FULL BOARD REVIEW PROCEDURES. Except when an expedited review procedure is used, the IRB must review proposed research at convened meetings (also known as Full-Board meetings) at which a quorum (see below) is present.

SCHEDULE OF IRB MEETINGS. The IRB meets typically on the first Thursday of the month, except for January, June, July and August. The IRB will as needed schedule meetings during the summer months. The schedule for the IRB may vary due to holidays or lack of quorum. The schedule of meetings for the IRB will be posted on the IRB website.

CONDUCT OF MEETINGS. The IRB shall conduct its meetings according to the most recent version of *Robert’s Rules of Order*.

QUORUM. A quorum consists of a simple majority of the voting membership, including at least one member whose primary concern is in a non-scientific area. The IRB Chair or Vice Chair, in consultation with the HRP A, if present, will confirm that an appropriate quorum is present before calling the meeting to order.

A quorum must be present for each vote involving matters of human research protections review. The meeting minutes must document any change of quorum status (e.g., a member leaves) and quorum status at the time of a vote. In the event the IRB loses and cannot reestablish quorum and the IRB has scheduled votes yet to complete, the IRB will postpone remaining business and adjourn the meeting.

All roster members present at a convened meeting have full voice and vote, except in the case of a conflict of interest. Research protocols must receive the approval of a simple majority of the voting members present at the meeting.

IRB members should be physically present at convened meetings. If physical presence is not possible, then a member may participate virtually (e.g., Skype, telephone, etc.). In this case, the member must have had access and reviewed in IRB Manager all pertinent material prior to the meeting, and must be able to participate actively and equally in all discussions.

Members who plan to be absent may submit questions/comments for consideration during IRB deliberation to the IRB Chair, Vice Chair, or HRP. Members may NOT vote *in absentia*.

FULL BOARD INITIAL REVIEW PROCEDURES

SUBMISSION OF MATERIALS. Investigators must submit to the HRP all proposals for research subject to human research protections review (i.e., exempt eligible and non-exempt research). **Note:** Study PIs who have other individuals (e.g., student co-investigator) write their applications and responses to the IRB must recognize that the ultimate responsibility of any study lies with the Study PI. Therefore, Roosevelt requires the Study PI to monitor and authorize all materials and information submitted to the IRB for review.

ADMINISTRATIVE PREVIEW. The HRP conducts Administrative Preview in order to confirm IRB review eligibility, and identify errors and/or omissions requiring rectification in preparation for IRB review. The HRP will share Administrative Preview findings with investigators, and collaborate with investigators to address findings prior to forwarding complete application for human research protections review. **NOTE:** Administrative Preview does NOT constitute or substitute for IRB review.

DESIGNATED PRIMARY REVIEWERS. The HRP, in consultation with the IRB Chair or Vice Chair, designates two IRB members as primary reviewers of a proposal satisfy criteria for full board review. The HRP and IRB Chair/Vice Chair designate reviewers on the basis of reviewers' related expertise and experience with study specific population(s). The responsibilities of the designate primary reviewers are:

1. Prior to full board meeting, review per federal, state and institutional criteria for IRB approval all submitted proposal materials and information;
2. Identify deficiencies and require remedies prior, so that revised version of proposal satisfies approval criteria;
3. Report findings to full board during meeting. At the meeting, primary reviewers present an overview of the goals, design, study procedures, safety procedures, and qualifications of the investigators. Particular attention is paid to the risk/benefit ratio of the investigation and the adequacy of the consent form in conveying human subject issues and concerns.
4. Per Robert's Rules of Order, make motion for IRB vote.

PRE-MEETING REVIEW BY IRB MEMBERS. IRB members will receive notification of full board activities no less than one week prior to scheduled IRB meeting. The notification will include a meeting agenda with information about full board activities requiring review prior to the meeting. IRB members will access all meeting materials and proposal applications through the Roosevelt website and through outlook calendar invitations sent with detailed information on upcoming meeting activities from the Office of Sponsored Programs and Research Services.

CONSULTANTS. When necessary, the IRB may invite individuals with competence in special areas to assist in the review of issues, which require expertise beyond or in addition to that available on the IRB. The consultant's findings will be presented to the full board for consideration either in person or by the HRP. If in attendance, these individuals will provide consultation but will not participate in or observe the vote. Prior to committing to provide assistance to the IRB, consultants will be informed of the IRB regulations regarding conflict of interest. Individuals who have a conflicting interest or whose spouse or

family members have a conflicting interest in the sponsor of the research will not be invited to provide consultation. Ad hoc or informal consultations requested by individual members (rather than the full board) will be requested in a manner that protects the researcher's confidentiality and complies with the IRB conflict of interest policy.

ADDITIONAL CONSIDERATIONS

DETERMINATION OF RISK. At the time of initial and continuing review, the IRB will make a determination of the overall risk profile of the research protocol. The IRB will identify and evaluate the nature, probability and severity of risks vis-à-vis the design of the study to minimize known and foreseeable risks. The IRB will classify the research as either "at or less than minimal risk" or "greater than minimal risk" based on the IRB's assessment and interpretation of "minimal risk" as defined in the federal regulations. The meeting minutes will reflect the IRB's determination of overall risk profile.

PERIOD OF APPROVAL/FREQUENCY OF REVIEW. At the time of initial review and at continuing review, the IRB will make a determination regarding the frequency of review of the research protocols (i.e., the length of the approval period). All protocols will be reviewed by the IRB at intervals appropriate to the risk profile, but no less than once per year. Depending on the circumstances of a particular study, the IRB may approve a shorter and/or conditioned approval period (e.g., semi-annually, after accrual of a specific number of participants, etc.). The meeting minutes will reflect the IRB's determination regarding review frequency.

The following factors will determine which studies require review more frequently than on an annual basis:

1. Probability and magnitude of anticipated risks to subjects
2. Likely medical condition of the proposed subjects
3. Overall qualifications of the principal investigator and members of the research team
4. Specific experience of the principal investigator and other members of the research team in conducting similar research
5. The nature and frequency of adverse events observed in similar research at this and other institutions
6. The novelty of the research making unanticipated adverse events more likely
7. Other factors that the IRB deems relevant.

NOTE: IRB will NOT authorize an approval period of more than one year for studies that are greater than minimal risk!

INDEPENDENT VERIFICATION REGARDING MATERIAL CHANGES. Protecting the rights and welfare of subjects sometimes requires that the IRB independently verify study related information, utilizing sources other than the investigator. Types of information that may necessitate independent verification by the IRB includes (but is not limited to) adverse event reporting, data in the scientific literature, reports of drug toxicity, drug or device approval status, and adherence to the procedures described in the approved protocol.

The IRB will consider the following factors in determining which studies require such independent verification:

1. The probability and magnitude of anticipated risks to subjects
2. The likely condition of the proposed subjects
3. The probable nature and frequency of changes that may ordinarily be expected in the type of research proposed
4. Prior experience with the principle investigator and members of the research team
5. Any other factors that the IRB deems relevant.

In making determinations about independent verification, the IRB may prospectively require that such verification take place at predetermined intervals during the approval period, may retrospectively require such verification at the time of continuing review, or may require such verification at any time during the approval period in the light of new information.

CONSENT MONITORING. In reviewing the adequacy of informed consent procedures for proposed research, the Roosevelt University IRB may on occasion determine that special monitoring of the consent process by an impartial observer (consent monitor) is required in order to reduce the possibility of coercion and undue influence.

Such monitoring may be particularly warranted when the research presents significant risks to subjects or if subjects are likely to have difficulty understanding the information to be provided. Monitoring may also be appropriate as a corrective action when the IRB has previously identified problems associated with a particular investigator or a research project.

CATEGORIES OF RESEARCH INVOLVING CHILDREN. During review and deliberation of research involving children as the target population, the IRB will determine and document in the minutes the appropriate category as set forth in the federal regulations at 45 CFR 46 Subpart D:

Category I: Research not involving greater than minimal risk.

Category II: Research involving greater than minimal risk with prospect of direct benefit to participant.

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

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

Based on category determination, the IRB will also determine requirements/alterations for informed consent/assent/parental permission procedures.

MEETING PROCEDURES

1. Attendance and determination of quorum
2. Declaration of Conflicts of Interest
3. Review of proposal

- a) Introduction of and presentation by Study PI (optional)
 - (i) HRPAs and/or IRB Chair/Vice Chair invite Study PI to attend and give overview of study proposal;
 - (ii) Study PI give overview and addresses questions/concerns from IRB members
 - (iii) IRB Chair/Vice Chair excuse Study PI after presentation
- b) Designated primary reviewers present an overview of the goals, design, study procedures, safety procedures, and qualifications of the investigators. Particular attention is paid to the risk/benefit ratio of the investigation and the adequacy of the consent form in conveying human subject issues and concerns.
- c) Introduction of consultant and/or findings
- 4. Motion
- 5. Discussion, including controverted issues, revision requirements to satisfy approval criteria
- 6. Vote

MOTIONS/ACTIONS TAKEN BY VOTE

Approval: The study is approved as submitted.

Conditional Approval (Approvable Pending Revisions to Satisfy Approval Criteria): The proposal and/or consent form require minor revisions, such as wording changes, with replacement language provided. The needed revisions are agreed upon at the meeting. These revisions are presented to the Principal Investigator for incorporation by simple concurrence. The IRB Chair or Vice Chair and the HRPAs may approve the study upon receipt and approval of the revisions without further action by the full IRB.

NOTE: Approval of the proposal application will not be granted and certification will not be issued until all deficiencies, if any, are corrected to the satisfaction of the IRB. The date of approval is the date the minor changes were approved by the IRB Chair or Vice Chair AND the HRPAs.

Deferred for substantive issues: The proposal and/or consent form require major substantive revisions that must be addressed to the satisfaction of the IRB. This action is taken if substantial modification or clarification is required, or insufficient information is provided to judge the proposal application adequately (e.g., the risks and benefits cannot be assessed with the information provided). IRB approval of the proposed research cannot occur until committee members review the revised and complete protocol at a subsequent meeting of the convened IRB.

If review of the proposal is deferred the following will occur:

1. The decision to defer the review of the protocol is documented in the IRB meeting minutes;
2. The Roosevelt University Office of Sponsored Programs and Research Services informs the investigator in writing of the IRB's decision, questions and concerns;
3. The investigator's response is sent to the Roosevelt University Office of Sponsored Programs and Research Services. The Office distributes to the IRB members the investigator's response, the updated

and revised protocol and a copy of the previously submitted protocol. The item is placed on the agenda for the following meeting;

4. The protocol application is reviewed at a convened meeting of the IRB;
5. The outcome of the IRB's deliberations is communicated to the investigator in writing;
6. The IRB's determination is documented in the IRB meeting minutes.

Not Approved: The IRB may take this action when it finds that the risks to which the proposal exposes participants cannot be justified vis-à-vis potential benefits of participation and/or the risks cannot be minimized with further revisions. When the IRB motions and votes to approve this action, the IRB will NOT review the study again.

Approval in Principle [45 CFR 46.118]

The IRB may grant approval required by a sponsoring agency without having reviewed all of the study procedures and consent documents in two circumstances. One is if study procedures are to be developed during the course of the research, but human subjects' approval is required by the sponsoring agency. The other is if the involvement of human subjects depends on the outcomes of work with animal subjects. The IRB may then grant approval without having reviewed the yet undeveloped recruitment, consent, and intervention materials. If the proposal is funded, the Principal Investigator must submit such materials for approval at least 60 days before recruiting human subjects into the study, or into any pilot studies or pre-tests. Approval in principle is granted to satisfy sponsoring agency requirements or to allow investigators to have access to funding to begin aspects of the project that do not involve human subjects.

REPORTING IRB ACTIONS. All IRB actions are communicated to the Study Principal Investigator (PI), or designated primary contact person for the protocol, in writing within ten (10) working days by the HRP. The IRB will provide the Study PI with written notification regarding IRB decisions to approve or disapprove the proposed research activity or written details regarding any modifications required to secure IRB approval of the research activity.

For approved research, investigators are informed that:

1. Subsequent modifications to the approved research protocol must be reviewed and approved by the IRB before they are initiated;
2. Unexpected adverse events/reactions must be reported to the IRB within ten working days of receipt;
3. The IRB may monitor research activities. The type and frequency of monitoring will be determined by the IRB at the time of initial or continuing review. The IRB will inform the principal investigator of monitoring requirements in writing.

If the IRB decides to disapprove or require modifications to secure approval of a research activity, it will include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

The IRB reports its findings and actions to the institution in the form of its minutes, which are available upon request by Roosevelt University institutional officials. Minutes are kept by the Office of Sponsored Programs and Research Services.

CONTINUING REVIEW OF ACTIVE PROTOCOLS

Approved research is subject to continuing IRB review at least yearly, or more frequently if specified by the IRB [45 CFR 46.109(e)], but not sooner than 30 days prior to the protocol termination (expiration) date. This review must take place before the approval expiration date; any lapse in approval will result in suspension of subject recruitment, enrollment, data collection, and, if the research is DHHS-sponsored, notification of the funding Agency. The approval date and the termination (expiration) date are clearly noted on all IRB communications sent to the PI and must be strictly adhered to. Investigators should include in their project planning sufficient time for development and review of renewal submissions.

The Human Research Protections Administrator will send the principal investigator (or designated contact persons) project renewal notices at intervals of two months and one month in advance of the expiration date. It is the investigator's responsibility to ensure that the continuing review approval is secured prior to the expiration date. Information regarding submission guidelines for continuing review is available from the Roosevelt University IRB website. Following continuing review approval, the IRB will make a determination regarding the frequency of subsequent review(s). As previously noted, protocols will be reviewed by the IRB at intervals appropriate to the degree of risk but no less than once per year. By federal regulation, no extension to the project expiration date can be granted.

Research activities are subject to internal audit and verification from sources other than the investigator that no material changes have occurred since the last IRB review.

CONTINUING REVIEW PROCESS. In accordance with Department of Health and Human Services (DHHS) regulations at 45 CFR 46.108(b) and at 46.115(a)(2), continuing review by the convened IRB, with recorded vote on each study, is required unless the research is otherwise appropriate for expedited review under Section 46.110 (see below). Furthermore, DHHS regulations set forth the criteria that must be satisfied in order for the IRB to approve research (45 CFR 46.111). These criteria include, among other things, determinations by the IRB regarding risks, potential benefits, informed consent, and safeguards for human subjects. The IRB must ensure that these criteria are satisfied at the time of both initial and continuing review. The procedures for continuing review by the convened IRB may include a primary reviewer system.

In conducting continuing review of research protocols which are not eligible for expedited review, all IRB members should minimally receive and review a protocol summary (i.e., Description of Study) and a status report on the progress of the research. Status reports should include the following information from the past year (cumulative data must also be included after the first renewal):

- The number of subjects enrolled;
- Number of subjects who withdrew prematurely and reason(s) for their withdrawal;
- A current copy of the Description of Study;
- A summary of adverse events and any unanticipated problems involving risks to subjects or others and any withdrawal of subjects from the research or complaints about the research since the last IRB review;

- Summary of any relevant recent literature, interim findings, and amendments or modifications to the research since the last review;
- Any relevant multi-center trial reports;
- Any other relevant information, especially information about risks associated with the research;
- A copy of the current informed consent document, which has been signed by one research participant;
- Any newly proposed additions or changes to the consent document;
- The current HIPAA Authorization document.

At least one member of the IRB will receive a copy of the complete protocol, including any modifications previously approved by the IRB. Furthermore, upon request, any IRB member has access to the complete IRB protocol file and relevant IRB minutes prior to or during the convened IRB meeting.

When reviewing the current informed consent document(s), the IRB will ensure the following:

- The currently approved or proposed consent document is still accurate and complete;
- Any significant new findings that may relate to the subject's willingness to continue participation are provided to the subject in accordance with HHS regulations at 45 CFR 46.116(b)(5).

Review of currently approved or newly proposed consent documents must occur during the scheduled continuing review of research by the IRB, but informed consent documents should be reviewed whenever new information becomes available that would require modification of information in the informed consent document.

EXPEDITED REVIEW OF CONTINUING REVIEW. Generally, research that does not qualify for expedited review at the time of initial review does not qualify for expedited review at the time of continuing review. In some circumstances, a protocol initially reviewed using full review procedures may have changed or will change. If these changes result in the protocol meeting the criteria for expedited review described by expedited review categories (8) and (9) at 63 FR 60364-60367 (see Expedited Review Categories), the IRB may choose to complete the continuing review process using expedited procedures. It is also possible that research activities that previously qualified for expedited review in accordance with 45 CFR 46.110, have changed or will change. If these changes result in the protocol meeting the criteria for full review or if the IRB determines that the level of risk warrants, the IRB must complete the continuing review process using full review procedures.

HOW IS THE CONTINUING REVIEW DATE DETERMINED. Department of Health and Human Services (DHHS) regulations at 45 CFR 46.108(b) and 109(e) require, respectively, that:

- (1) except when an expedited review procedure is used, The IRB must review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas; and
- (2) an IRB must conduct continuing review of research at intervals appropriate to the degree of risk, but not less frequently than once per year. The IRB should decide the frequency of continuing review for each study protocol necessary to ensure the continued protection of the rights and welfare of research subjects.

At Roosevelt University, the protocol review interval and need for additional IRB supervision and oversight is determined on a protocol-by-protocol basis. For example, the IRB may elect to closely monitor the activities of an investigator who recently had a protocol suspended by the IRB because of regulatory concerns. The IRB may also elect to closely monitor research activities associated with particularly risky research protocol. Monitoring activities may include (but are not limited to) on-site reviews by a subcommittee of the IRB or scheduled audits of study performance at specified intervals (after a few months of enrollment, after enrollment of the first several subjects).

The date by which continuing review must occur depends on the date of the convened meeting at which IRB approval occurs. For protocols reviewed by the IRB at a convened meeting, several scenarios for determining the date of continuing review apply. These examples presume the IRB has determined that the project will expire in one year.

Scenario 1: The IRB reviews and approves a protocol without any conditions at a convened meeting on September 1, 2006. Continuing review must occur within 1 year of the date of the meeting, that is, by September 1, 2007.

Scenario 2: The IRB reviews a protocol at a convened meeting on September 1, 2006 and approves the protocol contingent on specific minor conditions that will be verified by the IRB chair. On September 31, 2006, the IRB chair confirms that the required minor changes were made. In this instance, the continuing review must occur within 1 year of the date of the convened IRB meeting at which the IRB reviewed and approved the protocol, that is, by September 1, 2007.

Scenario 3: The IRB begins their review of a research protocol at a convened meeting on September 1, 2006. Because of serious concerns about the protocol, the deliberation continues during the September 15 and September 29, 2006 meetings. At the September 29, 2006 meeting, the IRB completes the full review process and approves the study. Continuing review must occur within 1 year of the date of the convened meeting at which the IRB reviewed and approved the protocol, that is, by September 29, 2007.

For a study approved under expedited review, continuing review must occur within 1 year of the date the Expedited Reviewer gives final approval to the protocol.

Review of a change in a protocol ordinarily does not alter the date by which continuing review must occur. This is because continuing review is review of the full protocol, not simply a change to it.

The regulations make no provision for any grace period extending the conduct of research beyond the expiration date of IRB approval. Therefore, continuing review and re-approval of research must occur on or before the date when IRB approval expires. When continuing review occurs annually and the IRB performs continuing review within 30 days before the IRB approval period expires, the IRB may retain the anniversary date as the date by which the continuing review must occur. This would be, for example, September 1, 2007, in the above Scenarios 1 and 2, and September 29, 2007, in Scenario 3, even if the continuing reviews took place up to 30 days prior to these dates.

PROCEDURES IN THE EVENT OF A LAPSE IN CONTINUING REVIEW. The IRB and investigators must plan to meet required continuing review dates. If an investigator has failed to provide continuing review information to the IRB or the IRB has not reviewed and approved a research study by the continuing review date specified by the IRB, the research must stop, unless the IRB finds that it is in the best

interests of individual subjects to continue participating in the research interventions or interactions. Enrollment of new subjects cannot occur after the expiration of IRB approval.

As a courtesy, the Roosevelt University Office of Sponsored Programs and Research Services will send out renewal notices 60 and 30 days before a research protocol expires. However, it is ultimately the investigator's responsibility to initiate a renewal application (allowing sufficient time for the review and re-approval process to be completed) before the current approval expires. Retrospective approval for work done after the expiration date cannot be granted.

The continuation of research after expiration of IRB approval is a violation of the Federal Regulations. If the IRB has not reviewed and approved a research study by the study's current expiration date (IRB approval has expired), all research activities should stop. No new subjects may be enrolled in the study.

STUDIES THAT ARE APPROVED BUT NEVER STARTED. Written progress reports should be received from the investigator for all IRB approved protocols prior to the date of expiration. If a protocol is cancelled prior to participant enrollment, the principal investigator must submit a project closure report to the IRB. The IRB will maintain the protocol records for at least three years after cancellation.

MODIFICATIONS OF AN APPROVED PROTOCOL

Investigators must obtain IRB approval before making any changes to an approved protocol. The only exception to obtaining prior approval would be when changes are needed to eliminate an immediate hazard to research participants. If the principal investigator must make a protocol change to eliminate a hazard to the research participant, the IRB must be notified promptly following the change. The IRB will review the change to determine that it is consistent with ensuring the subjects' continued welfare.

Modifications may be approved if they are within the scope of the initial IRB authorization. For example, if a researcher proposes to add a population to an existing study, but not alter the study procedures or purpose, a modification request is usually appropriate. Likewise, modifying a procedure without changing the study's purpose or study population may also be appropriate. If changes are substantial (the researcher proposes to add a population and revise study procedures), the principal investigator must submit a new application for human subjects' approval. The *Application for Revision to a Previously Approved Protocol* form should be used by investigators who wish to request approval of amendments or minor modifications. If the initially approved study will not be conducted, a *Project Closure* form should be submitted.

The IRB may use expedited review procedures to review minor changes in ongoing previously approved research during the period for which approval is authorized [45 CFR 46.110; 63 FR 60364-60367, November 9, 1998]. An expedited review may be conducted by the IRB Chair or by one or more experienced reviewers designated by the IRB Chair from among members of the IRB.

PROPOSED CHANGES IN A RESEARCH STUDY THAT ARE NOT MINOR. Changes that are NOT considered by the IRB to be minor include multiple modifications to an existing protocol, the addition of research procedures that increase participant risk, and/or the addition of participation procedures that add or increase participant discomfort. The IRB must review and approve the proposed change(s) at a convened meeting before the revised protocol can be implemented.

ADVERSE EVENTS AND UNANTICIPATED PROBLEMS

Adverse events and data safety monitoring reports received by Roosevelt University

IRB Office are reviewed by the IRB Chair to determine the relationship between the event and subject participation in the research protocol. Adverse events evaluated as not directly related to study participation and/or not related to an increased level of participant risk can be reviewed using expedited procedures. All other Adverse Events reports are reviewed by the IRB at the next convened meeting.

The Human Research Protections Administrator (HRPA) initially reviews all reports of unanticipated problems. After reviewing the report, the HPA may contact the investigator for discussion or request further information about the problem. After determining the nature and scope of the problem, one or more of the following actions will be initiated:

1. If the unanticipated problem is serious, the HRPA will forward the report to the IRB Chair for review and immediate response
2. If the unanticipated problem is not serious, the HRPA will file the unanticipated problem report in the IRB protocol record.
3. The seriousness of the problem may result in the need to revise the consent document(s) or protocol.

EXPEDITED REVIEW OF RESEARCH

According to 45 CFR 46.110, the IRB may use expedited procedures to review research appearing on the list AND found by the reviewer(s) to involve 1) no more than minimal risk and/or 2) minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

An internet search for 45 CFR 46.110 will direct you to the section of the US Department of Health and Human Services Code of Federal Regulations document titled "Categories of Research That May Be Reviewed through an Expedited Review Procedure."

A minor change is one which, in the judgment of the IRB reviewer, makes no substantial alteration in:

- The level of risks to subjects;
- the research design or methodology;
- The number of subjects enrolled in the research (no greater than 10% of the total requested);
- The qualifications of the research team;
- The facilities available to support safe conduct of the research; or
- Any other part of the research that would otherwise warrant review of the proposed changes by the convened IRB.

When a protocol is reviewed using expedited procedures, the review is completed by the IRB Chair or Human Protections Administrator and one or more members of the IRB committee designated by the Chair or Human Protections Administrator. IRB committee members are selected to participate in the expedited review process based on their familiarity with the review criteria and subject area expertise. Alternate members will not be designated as expedited reviewers.

All IRB members participating in the expedited review process receive and review the complete protocol. Documentation that would normally be submitted for a full-board review is reviewed by the IRB.

Using expedited review procedures, the reviewers exercise all of the authorities of the IRB. The only exception is that research may not be disapproved by the IRB using expedited review procedures. A

research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in 45 CFR 46.108.

CATEGORIES OF RESEARCH ELIGIBLE FOR EXPEDITED REVIEW. The activities listed below should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects. The standard requirements for informed consent (or its waiver, alteration, or exception) applies regardless of the type of review--expedited or convened--utilized by the IRB. The categories in this list apply regardless of the age of subjects, except as noted.

- The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability. Expedited is not allowing if considered to 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.
- The expedited review procedure may not be used for classified research involving human subjects.

Research Categories one (1) through seven (7) are eligible for initial and continuing IRB review using expedited procedures.

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

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

b. Research on medical devices for which:

i. An investigational device exemption application (21 CFR Part 812) is not required; or

ii. The medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

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

a. From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

b. From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples include:

a. Hair and nail clippings in a non-disfiguring manner;

- b. Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
- c. Permanent teeth if routine patient care indicates a need for extraction;
- d. Excreta and external secretions (including sweat);
- e. Un-cannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue;
- f. Placenta removed at delivery;
- g. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
- h. Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
- i. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
- j. sputum collected after saline mist nebulization.

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

- a. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
- b. Weighing or testing sensory acuity
- c. Magnetic resonance imaging
- d. Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography
- e. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects (as described in Section 4.2.3 below). This listing refers only to research that is not exempt.

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

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category

may be exempt from the HHS regulations for the protection of human subjects (as described in Section 4.2.3 below). This listing refers only to research that is not exempt.

8. Continuing review of research previously approved by the convened IRB where:

- a. the research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects; or
- b. No subjects have been enrolled and no additional risks have been identified; or
- c. The remaining research activities are limited to data analysis.

[Of note, category (8) identifies three situations in which research that is greater than minimal risk and has been initially reviewed by a convened IRB may undergo subsequent continuing review by the expedited review procedure.

For a multi-center protocol, an expedited review procedure may be used by the IRB at a particular site whenever the conditions of category (8)(a), (b), or (c) are satisfied for that site. However, with respect to category 8(b), the criterion that "no additional risks have been identified" is interpreted to mean that neither the investigator nor the IRB at a particular site has identified any additional risks from any site or other relevant source.]

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Under Category (9), an expedited review procedure may be used for continuing review of research not conducted under an investigational new drug application or investigational device exemption where categories (2) through (8) do not apply. This will be in the case that the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified. The determination that "no additional risks have been identified" does not need to be made by the convened IRB.

All members of the IRB will be apprised of all expedited review approvals by means of the agenda for the next scheduled meeting. Copies of the expedited review approvals will be made available for any optional review at the request of any IRB member.

FURTHER REVIEW/APPROVAL OF IRB ACTIONS BY OTHER WITHIN THE UNIVERSITY

Research that has been approved by the IRB is subject to review and disapproval by institutional officials, but those officials may not approve research that has been disapproved by the IRB. [45 CFR 46.112]

INITIATION OF RESEARCH PROJECTS

All research involving human subjects must be reviewed and approved by the IRB prior to initiation of the research project. Approved research is subject to continuing review by the IRB at least yearly, or more frequently if specified by the IRB [45 CFR 46.109(e)]. The date of continuing review will be based on the date of IRB approval. [refer to the section on Continuing Review for further details.]

The approval date and the expiration date are clearly noted on all IRB certifications sent to the PI. Please allow sufficient time for development and review of renewal submissions. By federal regulation, no extension to the expiration date can be granted.

If a protocol has expired, it must be resubmitted for IRB review.

Research activities are subject to internal audit and verification from sources other than the investigator that no material changes have occurred since the last IRB review.

The IRB reserves the right to observe the consent process conducted under any research protocol and to inspect the records of investigators to ensure the protection of the human research subjects.

APPEAL OF IRB DECISIONS

If a subcommittee of an IRB makes a decision that the investigator believes to be unduly restrictive on the proposed research, the investigator may appeal, in writing, for review by the convened appropriate IRB.

If the convened IRB makes a decision that the investigator believes to be unduly restrictive on the proposed research, the investigator should first discuss the matter with the IRB Chair or the Human Protections Administrator, taking care to explain the reasons for believing that the proposed procedures are in compliance with University policy and with Federal regulations. If the issue cannot be resolved satisfactorily by negotiation, the investigator may appeal the decision of the IRB, in writing. The IRB will reconsider the appeal based upon the new information provided and will continue to re-review protocols as long as the investigator wishes to appeal.

Reference. This policy is an adaptation of a peer institution, Roosevelt University Human Protections Program, with language from the Office of Human Research Protections.

IRB RECORDS

The IRB prepares and maintains adequate documentation of committee activities.

Documents prepared and maintained by the IRB include (but are not limited to):

- Research proposals
- Recruitment materials
- Scientific evaluations (if any) that accompany the proposals
- Approved consent documents
- Approved HIPAA Authorization documents (if separate from the informed consent) proposed protocol amendments and the IRB action on each amendment
- Progress reports
- Reports of injuries to subjects
- Reports of serious and unexpected adverse events
- Documentation of protocol violations
- Documentation of non-compliance with applicable regulations

The IRB records must also include documentation of continuing review activities and copies of all correspondence between the IRB and investigators. Statements of significant new findings provided to

subjects must be maintained with the related research proposal and, when reviewed at an IRB meeting, must be documented in the minutes.

MINUTES OF AN IRB MEETING

Proceedings must be written and available for review by the next regularly scheduled IRB meeting date. Once approved by the members at a subsequent IRB meeting, the minutes must not be altered by anyone including a higher authority. Minutes of IRB meetings must contain sufficient detail to show:

1. The presence of a quorum throughout the meeting, including the presence of one member whose primary concern is in a non-scientific area;
2. Alternate members attending the meeting and, if voting, for whom they are substituting;
3. Actions taken by the IRB, including those involving full review. The IRB must use the minutes to notify IRB members of actions taken through expedited review and those studies that have been determined to be exempt from IRB review;
4. Separate deliberations, actions, and votes for each protocol undergoing continuing review by the convened IRB;
5. Documentation that the research meets the four required criteria [45 CFR 46.116(d)] for approval of a consent procedure that does not include or that alters some or all of the required elements of informed consent or when waiving the requirement to obtain an informed consent;
6. Documentation that the research meets the required criteria [45 CFR 46.117(c)] when the requirements for documentation of consent are waived;
7. When approving research that involves populations covered by Subparts B, C, or D of 45 CFR 46, the minutes will document the IRB's justifications and findings regarding the determinations stated in the Subparts or the Committee's agreement with the findings and justifications as presented by the investigator on IRB forms;
8. The vote on actions, including the number of members voting for, against, and abstaining;
9. A note indicating that when an IRB member has a real or potential conflict of interest relative to the proposal under consideration, that the IRB member was not present during the deliberations or voting on the proposal (and that the quorum was maintained);
10. The basis for requiring changes in or disapproving research and documentation of resolution of these issues when resolution occurs;
11. A written summary of the discussion of protocol, related challenges, issues and their resolution;
12. Review of additional safeguards required as a condition of IRB approval to protect vulnerable populations (if entered as study subjects) when this is not otherwise documented in IRB records;
13. The determination of the level of risk, if not recorded elsewhere in IRB records;
14. The frequency of continuing review of each proposal, as determined by the IRB, if not recorded elsewhere in IRB records;

15. Documentation, as required by 45 CFR 164(i)(2), indicating the approval of a waiver or alteration of the HIPAA Authorization.

MEMBERSHIP ROSTERS

A list of IRB members must be maintained. The list must contain the following information: member's name, earned degrees, affiliated or non-affiliated Roosevelt status, status as scientist (physician-scientist, other scientist, non-scientist or social behavioral scientist); voting status, alternate status, or status as chairperson. This list should also describe each member's chief anticipated contributions to IRB deliberations. A current Curriculum Vitae (CV) for the IRB member must also be maintained by the IRB.

The Roosevelt HRPAs must keep the IRB membership list current. The Roosevelt HRPAs must promptly report changes in IRB membership to Roosevelt administration and OHRP via update of the IRB registration.

RECORDS RETENTION REQUIREMENTS

The above detailed records must be stored securely in the office of the HRPAs and must be retained for at least 3 years after the completion of the research. All records must be accessible for inspection and copying by authorized representatives of the federal OHRP and other authorized entities at reasonable times and in a reasonable manner.

Electronic records are maintained by the HRPAs. Hard copy (e.g., paper, CDs, etc.) materials are maintained in locked file cabinets in the locked office of the HRPAs. Access to these files is generally limited to IRB members (including the Chair) and the IO (who serves as the IRB Institutional Official). File access logs are maintained to record the following information: files access (when other than an IRB member or designated Institutional Official), specific files accessed; date of access; and purpose of access.

WRITTEN PROCEDURES AND GUIDELINES

Roosevelt Policies and Procedures for the Human Research Protection Manual (i.e., Manual) details the policies and procedures governing research with human subjects in compliance with federal, local and institutional regulations, laws and ethical standards.

Policies and Procedures include:

1. Written procedures that the IRB follows for the following activities:
 - a. Conducting initial and continuing reviews of research and for reporting review findings and actions to the investigator and the University;
 - b. Determining which projects require review more often than annually;
 - c. Determining which projects need verification that no material changes have occurred since previous IRB review from sources other than the investigators;
 - d. Ensuring prompt reporting of proposed changes in a research activity to the IRB;
 - e. Ensuring that changes in an approved research protocol, (during the period for which IRB approval has already been given) may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

2. Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the Federal Department or Agency head of any unanticipated problems involving risks to subjects or others, or any serious or continuing noncompliance with 45 CFR 46 or the requirements or determinations of the IRB suspension or termination of IRB approval.

Reference. This policy is an adaptation of a peer institution, University of Indianapolis Human Protections Program, with language from the Office of Human Research Protections.