# Table of Contents

Introduction ........................................................................................................................................................................... 3  

Section 1: General Information .................................................................................................................................................. 3  
1.1 Current Member and Staff Lists ........................................................................................................................................ 3  
1.2 IRB Meeting Locations ...................................................................................................................................................... 4  
1.3 IRB Resources ..................................................................................................................................................................... 4  

Section 2: Introduction to the HRPP and IRB ............................................................................................................................ 5  
2.1 What are the HRPP and IRB? ............................................................................................................................................. 5  
2.2 Brief History of the Development of Federal Regulations and IRBs .................................................................................. 5  
2.3 Ethical Principles for the IRB ............................................................................................................................................... 6  

*Respect for Persons: The Voluntary Participation of Experimental Subjects* ........................................................................... 6  
*Beneficence: The Risk-Benefit Ratio* ......................................................................................................................................... 7  
*Justice: The Fair Selection of Research Subjects* ..................................................................................................................... 7  
2.4 Make-Up the IRB ................................................................................................................................................................. 8  
2.5 Visitors .................................................................................................................................................................................. 8  

Section 3: Types of Review .......................................................................................................................................................... 8  
3.1 Submissions Requiring Review ......................................................................................................................................... 8  
3.2 Levels of Review ................................................................................................................................................................. 9  
3.3 Overview of IRB Review Process ..................................................................................................................................... 10  
3.4 Basic IRB Review Flowchart ............................................................................................................................................. 10  

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Section 4: Quick Guide for IRB Member Review of Human Research Studies ........................................................................... 11  
4.1 Quick Guide for IRB Member Review of Human Research Studies ..................................................................................... 11  

*Attendance* .............................................................................................................................................................................. 11  

*Review and Meeting Preparation* .......................................................................................................................................... 11  

*Meeting Participation* ............................................................................................................................................................. 12  
4.2 Federal Criteria for IRB Approval of Research (45 CFR 46.111 and 321 CFR 46.111) ......................................................... 12  

Section 5: IRB Member Review Responsibilities and Guidance ................................................................................................ 13  
5.1 IRB Meeting Attendance and Agendas ............................................................................................................................... 13  
5.2 Primary Reviewer System and Meeting Review Process .................................................................................................. 14  

*New Full Committee Studies and Studies Returned for Additional Information* .................................................................. 14  

*Full Committee Major Modifications, Continuing Reviews (Renewals), and Post- ................................................................. 15
Introduction

Institutional Review Board: Member Handbook.

This guide provides members with important information needed in order to help them in the collaborative effort to protect the rights and welfare of research subjects. Topic-specific chapters list the criteria IRB members should use to determine how to vote on specific kinds of studies and offer practical advice on what IRB members should do before and during committee meetings. This guide is in paper form available on the website. Reviewers should be familiar with and consult this as needed when conducting their reviews. This guide contains regulatory information and other issues that reviewers should take into consideration when reviewing protocol.

Section 1: General Information

1.1 Current Member and Staff Lists

<table>
<thead>
<tr>
<th>Committee Member List:</th>
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<tbody>
<tr>
<td><strong>Member Name</strong></td>
</tr>
<tr>
<td>Judy Gouwens</td>
</tr>
<tr>
<td>IRB Chair</td>
</tr>
<tr>
<td>Gregory Hauser</td>
</tr>
<tr>
<td>Amy Dexter</td>
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<tr>
<td>Judy Dygdon</td>
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<tr>
<td>Susan Torres Harding</td>
</tr>
<tr>
<td>Julie Hilvers</td>
</tr>
<tr>
<td>Zoe Bell, student member</td>
</tr>
<tr>
<td>Kathie Kane Willis,</td>
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Roosevelt University
IRB Guidebook

| Community Member | gourbanleague.org |

Staff Member List:

<table>
<thead>
<tr>
<th>Name</th>
<th>Phone Number</th>
<th>Email Address</th>
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</thead>
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</tr>
</tbody>
</table>

1.2 IRB Meeting Locations
The committee meets at the Chicago campus at the designated date and time agreed upon by the IRB Chair, Vice Chair, with input and coordination of staff. The e-mailed PDF meeting agenda will announce the location of the meeting. Contact the IRB HRPA or Coordinator for additional information or directions.

1.3 IRB Resources
The following informational resources are available for members:

**HRPP Website:** This website is the primary source of communication between the IRB and campus investigators and staff. IRB news and policy decisions are posted on the web site. The site also includes links to various ethical codes, federal agencies, research ethics organizations, and other IRBs as well as a comprehensive list of Federal Regulations, State Statutes and Other Guidance.

**Member Checklists, Decision Charts and Guides:** A checklist and decision charts are available to assist members in their reviews. Members should be familiar with the information in the checklist and decision charts and refer to them as needed when reviewing studies (see Appendix A and Human Subjects Regulations Decisions Charts).

**Handouts Distributed at Regular Meetings or Via Email:** The HRPP regularly distributes materials of interest to IRB members, such as newspaper articles, editorials from professional journals, and publications, such as *IRB: Ethics & Human Research*. These handouts are included for information and general discussion.

**Institutional Review Board: Member Handbook:** Each new member receives a copy of the IRB Member Handbook. It contains information necessary to fully participate as an IRB Member. It will be made available via hard copy at meetings and provided to each member electronically.
HRPP Bulletins: The HRPP announces major changes or updates via the HRPP bulletin. For example, bulletins may include information on updates to application forms, revised policy and guidance that impacts human subject research, and educational opportunities. In addition to being posted on our website, this bulletin also is distributed by email to all active IRB Manager Users.

Section 2: Introduction to the HRPP and IRB

2.1 What are the HRPP and IRB?

The Roosevelt University Human Research Protection Program (HRPP) is a unit within the Office of Sponsored Programs and Research Services. The HRPP unit is responsible for reviewing and monitoring research involving human subjects at Roosevelt to safeguard the rights and welfare of human subjects in research. Roosevelt has established policies and procedures to assure compliance with all federal regulations, state laws, and Roosevelt University policies governing the use of human subjects in research and it provides education, training, and assistance to the Roosevelt research community conducting human research.

The Roosevelt IRB, which is currently comprised of faculty, student and community representation, reviews and approves (or disapproves) research projects involving human subjects at Roosevelt. The Roosevelt IRB operates in compliance with relevant state and federal regulations.

2.2 Brief History of the Development of Federal Regulations and IRBs

Key Historical Events Leading to the Establishment of the IRBs in the USA

Below you will find information on key events in the development of human subject research regulations.

The Nuremberg Code (1948): The Nuremberg Code was established a result of the trials against Nazi physicians and administrators for their willing crimes against humanity. The non-binding Nuremberg Code included such basic ethical principles as the requirement that subjects freely consent to participate in research.

World Medical Associations Declaration of Helsinki (1964): The declaration established recommendations guiding doctors in biomedical research involving human participants.

Henry Beechers article Ethics and Clinical Research in the New England Journal of Medicine (1966): In his article, Beecher provided 22 examples of medical research in the United States in which researchers had not told research subjects about the nature of their participation, had not obtained their informed consent, and put their health at risk.

Tuskegee Syphilis Study (1932-1972): Conducted with Public Health Service funding, this study included 400 rural black men in Alabama with syphilis who were deliberately left untreated even after effective antibiotics became available so that the natural progression of syphilis could be studied. It has been cited as one of the most infamous studies in U.S. history.

The National Commission of 1974: Legislation was enacted that established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commissions principal charge was to review the practices and problems associated with the protection of the human subjects in research sponsored by the federal government.
The Belmont Report (1979): Issued by the National Commission, the Belmont Report outlines basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects. Two years later, the U.S. Department of Health and Human Services (45 CFR 46) and the Food and Drug Administration (21 CFR, parts 50 and 56) issued regulations requiring the establishment of IRBs to ensure compliance with the ethical principles outlined in the Belmont Report.

National Bioethics Commissions (1974-present) and Secretary's Advisory Committee on Human Research Protections (2001-present): These groups helped shape bioethics policy in the United States.

Research Scandals in the 1990s and 2000s: Because of two research-related deaths of healthy subjects and a highly publicized death of a research subject in a gene therapy program, the national press and the government again began to scrutinize human research at major research institutions. Several institutions had all of their human research approvals suspended, some for several months, until they could bring their human subjects protection programs up to federal standards.

History of the Human Research Protections

Since 1966 the United States Public Health Service (PHS) has required prior review and approval of all PHS-funded research using human subjects. Review boards known as Institutional Review Boards (IRBs) were established to fulfill this function.

2.3 Ethical Principles for the IRB

The IRBs primary responsibility is the protection of subjects from undue risk and from deprivation of personal rights and dignity. The Committee considers research in the light of three ethical principles summarized in The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 1979). The three principles are as follows:

- **Respect for persons**: voluntary participation by the subjects, indicated by free and informed consent, must be assured;
- **Beneficence**: an appropriate balance must exist between potential benefits of the research to the subject or to society and the risks assumed by the subject; and
- **Justice**: there are fair procedures and outcomes in the selection of research subjects.

Respect for Persons: The Voluntary Participation of Experimental Subjects

Research subjects should understand as completely as possible what is to be done to them, what information will be gathered about them, and what the potential risks and benefits are. The person must give his/her consent freely, without pressure or inappropriate inducement. The IRB attempts to ensure free and informed consent of subjects through careful review of the recruitment and consent process, including the consent form or information sheet to be used with subjects. The Committee's concern is to verify that the consent process and document are likely to assist prospective subjects to make an informed decision that will be in their own interests.

For studies in which subjects are not able to give personal consent for themselves, the consent document is addressed to those who have been designated responsible for the subject's well-being. For example, parents must give consent for children, as minors are not legally authorized to give consent.
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(�xcept in special circumstances). Federal regulations also require, however, that capable minors be asked to assent to being in a study.

The Committee exercises special care when considering subjects whose ability to give free and informed consent may be compromised in any way. Prisoners, for example, have limited choices in their lives and are vulnerable to coercive pressures. Demented or mentally ill subjects may have impaired ability to act in their own interests, so a guardian often must be consulted.

Beneficence: The Risk-Benefit Ratio
The IRB must decide whether risks to a study subject are outweighed by the combination of potential benefits to the individual subject and the importance of the knowledge to be gained from the study (the study's societal benefits).

Risks of injury or discomfort to individuals can be physical, psychological, and/or social. There can be potential benefits to the individual, to a group to which the individual belongs, and/or to society. In reviewing applications, the Committee assesses the types and degrees of both risks and benefits for a given subject population, as well as the investigator's communication of these risks and benefits in the consent process and form.

Justice: The Fair Selection of Research Subjects
Both the risks and the potential benefits of research should be spread fairly among potential individual subjects and subject groups. Study design and selection of subjects should avoid bias for or against particular social, racial, sexual, or ethnic groups.

Sharing Research Risks: The guiding principle in the ethical selection of subject groups is that any risks of the research should fall upon the groups who might benefit from the research. If the results of a risky protocol might benefit the general population, it would be unethical to focus subject recruitment on vulnerable or disadvantaged groups (institutionalized people or prisoners; patients at free clinics primarily patronized by people unable to afford other care) simply because they are easily accessible or can be persuaded to participate. When research involves persons whose autonomy is compromised, it is expected that the research bear some direct relationship to the conditions or circumstances of the subject population.

In addition, groups fully able to consider research risks and informed consent should be asked to face research risks before more vulnerable populations are asked. Investigational drugs usually are tested in adults before they are tested in children. Consenting adults are preferred as subjects before adults for whom a guardian must consent.

Sharing Research Benefits: In recent years, increasing attention has been paid to the rights of various groups to be included in research. As individuals and through advocacy groups, many patients have come to insist on having access to experimental treatments as these experimental treatments may potentially provide the best medical care available. In addition, researchers, ethicists, and public officials have recognized that because many clinical trials focused primarily on white male middle-class subject groups, the results of some trials were of questionable value for members of other social, racial, sexual, and ethnic groups.

As a result, both the Food and Drug Administration and the National Institutes of Health now require that study design include as broad a range of subjects as feasible and ask that data be analyzed to uncover responses that differ between groups. For example, where women of child-bearing potential
and pregnant or nursing women previously were routinely excluded from new drug trials, it is now required that whenever possible these women be asked to make their own choices after being fully informed of the risks of the research.

2.4 Make-Up the IRB
Each committee is sufficiently qualified through the experience, expertise, and diversity of its members including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. With a few exceptions, IRB members must hold appointments of Associate Professor or higher, as this helps to promote respect for the IRBs.

The membership of each IRB committee typically includes, at a minimum: At least five (though typically 12-18) members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution.

At least one member whose primary concerns is in scientific areas and at least one member whose primary concerns is in non-scientific areas. At least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution. These members will be designated as non-affiliated on committee rosters.

Members are from a wide enough variety of disciplines to review the vast majority of research submitted to the IRB, including individuals who are knowledgeable about and experienced in working with vulnerable populations, such as children, prisoners, pregnant women, or individuals with cognitive impairments. The necessity and number of members with sufficient knowledge and experience working with these vulnerable populations will be determined by the amount of applications received that propose to enroll vulnerable populations and through the review of membership.

A member may satisfy more than one of the above criteria. No IRB may have a member participate in the IRBs initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

2.5 Visitors
On a case-by-case basis, visitors may attend IRB meetings. Visitors attend at the members convenience, must sign a confidentiality agreement, and must agree to attend a brief introduction to before or debriefing after the meeting.

A request for a visitor to attend an IRB meeting must be submitted in writing to the HRPP and include the name of the guest(s), the purpose of the visit and the preferred date of attendance. The request will be reviewed and approved by the IRB chair or the HRPA.

Section 3: Types of Review
3.1 Submissions Requiring Review
Below are the major categories of submissions that require review by the IRB. The Submissions section of the HRPP website has more detail, including when these types of submissions are needed and what information should be included.
New Studies (Initial Submissions): All new studies requiring review must receive IRB approval before they can begin.

Modifications: All changes to a study, even minor ones, must be approved by the IRB before they are implemented. For example, changes in screening criteria, procedures, recruitment materials, consent forms, questionnaires and other study materials all require IRB review and approval.

Note: The only exception to the requirement for prior IRB review and approval is when the changes are necessary to eliminate apparent immediate hazards to the subject (45 CFR 46.103.b.4, 21 CFR 56.108.a). Investigators must still notify the IRB when such changes are made.

Continuing Review: Re-review of all projects involving human subjects is required at least annually for many studies. Minimal risk studies that are not subject to federal oversight may be eligible for extended approval (up to 3 years). Otherwise, continuing review is required even if no changes are made, even if the only study activity is patient follow-up, and even if the only study activity is data analysis.

Post-Approval Events, Including Adverse Events, Protocol Violations and

Incidents, or Safety Information: Federal regulations and the IRB require investigators to report any post-approval research-related event or information that may meet the HRPPs institutional definitions of unanticipated problem involving risk to participants or others, or serious or continuous noncompliance. The HRPPs policies on noncompliance describes when these events need to be submitted.

Study Closeout Reports

Emergency Use and Compassionate Use of Experimental Drugs and Devices

3.2. Levels of Review

Submissions receive various levels of review based upon an assessment of the study risks. The levels of review are based on the level of risk of the overall study compared to minimal risk as defined below and are as follows: full committee, expedited and exempt.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 CFR 46.102(i) and 21 CFR 56.110).

Additional information is available on the Levels of Review page, but is summarized below:

Full Committee Review is for submissions such as:

- New studies involving greater than minimal risk to subjects or minimal risk studies that do not qualify for expedited review;
- Responses/revised applications that the committee asked to be re-reviewed at a convened meeting (review outcome of Returned for Additional Information);
- Continuing review applications for studies that require full committee review;
- Major modifications to approved full committee studies; and
- Post-approval events such as adverse events or protocol violations that require full committee determinations.
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- **Expedited Review:** The following submissions when they involve procedures that are no more than minimal risks can be reviewed via expedited review. An expedited review procedure consists of review by a committee member (usually an HRPP staff member) and/or one or more experienced IRB reviewers as needed.

- **New studies** that involve no more than minimal risk to subjects and fit into one of nine specific categories, as defined by the federal government

- **Responses/revised applications** that do not require re-review by the full committee (review outcome of Revisions Requested);

- **Continuing review** applications that qualify for expedited review;

- **Minor or administrative modifications** of approved studies; and

- **Post-approval events** that do not require full committee review.

- **Exempt Certification:** The following types of submissions do not require IRB review involve no more than minimal risks and are exempted from 45 CFR 46.101(b). The HRPP is responsible for reviewing the preliminary determinations of exemption by investigators and for making the final determination and certification.

- **New studies** that fit into one of the exempt review categories.

- **Modifications or other submissions** for exempt studies.

Additional information about what materials are required for each type of review on the HRPP website under the Submissions section for each type of review.

3.3 Overview of IRB Review Process

Below you will find information on the basic IRB review process. For more detailed information, review Section 4 below as well as IRB Review Process page.

**Screening:** The HRPA follows each individual submission from initial submission to final approval and conducts an administrative pre-review screening to ensure the submission is complete before forwarding it to IRB reviewers. When the submission is complete and meets basic submission standards (inclusion of funding protocol, drug brochure (if applicable), recruitment and consent documents and correct sections of the application completed), the HRPA will assign the submission to IRB reviewer(s). Although the HRPA may try to clarify major issues with the PI before the meeting, the HRPA does not conduct an initial review.

**IRB Member Review Process:** Review assigned studies in depth according to information in the IRB Reviewer's Checklist and the IRB Member Reviewer's Guide. Specifically, members should:

- **Apply the criteria required by federal regulations** for IRB approval of a human research study and the appropriate regulatory determinations (i.e., for inclusion of children in research, the inclusion of pregnant women, neonates and fetuses in research, the inclusion of prisoners in research, criteria for waiving and/or altering consent, criteria for making non-significant risk determinations for devices). These are included in IRB Manager in the Member Comment section.

- **Be familiar with the funding agency documents** (sponsor protocol, NIH grant, drug brochure) to assist in answering questions and to affirm consistency between and among documents. If possible, contact investigator before a meeting to clarify major issues that could result in a return if left unanswered.

- **Put comments in IRB Manager** Member Comment Section. See below for details about this process.
When reviewing the study, the IRB reviewers will be asked to identify any outstanding issues that must be addressed by the PI prior to approval. **IRB requests for changes or additional information should be clearly related to one or more of the federal criteria for approval of human research studies or to achieve compliance with State regulations and/or University policies.** If there are no outstanding issues, the reviewers should indicate that the submission can be approved.

**Post-Review Stipulations:** If the IRB reviewers identify issues that need to be addressed prior to approval, the HRPP staff will draft post-review stipulations and send them to the PI. (Note: The staff may forward the stipulations to the IRB Chair or other reviewer(s) before sending them to the PI to ensure accuracy.) After the PI responds and the response is complete, the HRPP staff will forward the response to either the full committee or the designated IRB reviewer(s), as applicable. If the reviewer(s) find the response acceptable, and the study meets the federal criteria required for IRB approval of a human research study, the IRB will approve the submission. If the response is not adequate, the HRPP staff will send additional stipulations to the PI and approve the submission only after the response is deemed acceptable by the reviewer(s).

**Section 4: Quick Guide for IRB Member Review of Human Research Studies**

**4.1 Quick Guide for IRB Member Review of Human Research Studies**

This is a brief but important guide for your IRB reviews. Your following this guidance will help ensure an effective and efficient discussion of the studies on the IRB agenda and is based on many years of experience and feedback from other members, Chairs and HRPP staff.

Sections 3, 4 and 5 of the IRB Member Handbook below provide information that is more detailed and guidance.

**Attendance**

Attend IRB meetings on a regular basis (at least 75% of scheduled meetings). Arrive on time and stay for the entire session whenever possible. Update attendance records in IRB Manager in a timely fashion and before agendas are assigned. Communicate well in advance if you’re going to miss two or more meetings in row so submissions being held for your expertise can be assigned to a different review committee.

**Review and Meeting Preparation**

Before the meeting, read and review the studies assigned to you thoroughly and be familiar with all the items on the agenda so that you may participate in the discussions. Evaluate assigned protocols to ensure they meet the criteria for IRB approval of research found in 45 CFR 46.111 and 321 CFR 56.111 (see below). **IMPORTANT NOTE:** The Committees requests for changes or additional information should be clearly related to one or more of the criteria for approval, or to achieve compliance with State regulations and/or University policies. When reviewing a protocol, use the attachments including the sponsors protocols and investigators brochures to answer questions you may have. If you need additional information that is not provided in the study application or submission attachments, contact the HRPP analyst to request the missing information prior to the meeting so the review can proceed.

Be familiar with HRPP guidelines and template consent documents. If a consent form fulfills the requirements for informed consent as described in 45 CFR 46.116, please refrain from requesting
editorial changes to improve it or fix minor typographical errors. Complete your reviews as early as possible. The HRPP staff screen IRB reviewers comments prior to the meeting, looking for issues that could be resolved with additional clarification or concerns that may lead to the study being Returned for Additional Information. Enter review comments and questions in IRB Manager at least 24 hours prior to the IRB meeting, Write comments in such a manner that HRPP analysts can quickly and easily relay any significant concerns to the PI and study team either in advance of the meeting, if it seems like doing so could result in a more productive review or after the meeting in a letter. Whenever possible, the HRPP encourages IRB reviewers to discuss major concerns directly with the study PI prior to the meeting to facilitate review of new protocols and prevent unnecessary returns.

**Meeting Participation**

Review Section 5.2 Primary Reviewer System and Meeting Review Process below for details about how to lead the discussion at the meeting. Please stay focused with your review comments. Questions raised at the meeting should be relevant to subject safety and ethics. Questions raised out of curiosity can derail or extend the discussion unnecessarily and are not conveyed to the investigator unless related to safety. Please contribute to committee discussions by sharing any knowledge and expertise you have that could address the concerns and questions of other members even if you are not an assigned reviewer.

For members assigned to Expedited Review submissions, please:

Complete review assignments within 7 days of receipt. If you receive an assignment and you are not available or otherwise unable to do reviews, promptly contact the analyst who assigned it to you to allow for timely reassignment to an alternate reviewer. Evaluate assigned protocols that may be reviewed under an expedited review procedure according to the criteria for IRB approval of research found in 45 CFR 46.110 and 321 CFR 56.111 (see below).

4.2 Federal Criteria for IRB Approval of Research (45 CFR 46.111 and 321 CFR 46.111)

All conditions must be satisfied:

*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.

*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.

*Selection of subjects is equitable*. Inclusion/exclusion criteria are adequate. Research purpose and setting are appropriate. Recruitment process is fair.

*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, and 21 CFR 50.25 for FDA-regulated research.

*Informed consent will be appropriately documented*, in accordance with, and to the extent required by 45 CFR 46.117, and 21 CFR 50.27 for FDA-regulated research.

When appropriate, the *research plan makes adequate provisions for monitoring the data* collected to ensure the safety of subjects.
Provisions to protect the privacy of subjects and to maintain the confidentiality of data are adequate. 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.

Section 5: IRB Member Review Responsibilities and Guidance

5.1. IRB Meeting Attendance and Agendas

Meeting Attendance:

A list of meeting dates [42] is available on both the HRPP website and in IRB Manager. You will need to specify whether you can attend each meeting using the attendance calendar in the Meeting Availability section of IRB Manager. Please update your attendance at least 2 weeks prior to the next meeting. You will be asked: a) whether you can attend the meeting; and b) if you are available to review submissions (whether or not you are attending). Note: If you do not update your attendance, you will be automatically marked as available to review submissions.

Late Cancellations:

If you must cancel attendance after having been assigned as a reviewer, contact the HRPA immediately so your protocols can be reassigned.

Meeting Agendas:

The HRPP staff finalizes the agenda at least one week before the upcoming meeting. You will be notified by email when the agenda is finalized, and a PDF copy of the agenda will be attached to the email. You can access an electronic copy of the agenda and all of the submissions on it by going to the Meeting Agenda section in IRB Manager. The full committee meeting agenda may include the following types of submissions: initial submissions (new studies), responses to studies that the committee previously returned for additional information (see Section 5.1), continuing reviews for full committee studies, major modifications of approved studies, and post-approval events that require a full committee determination.

The agenda also may include miscellaneous items for discussion, and members may be asked to approve the minutes from previous meetings. The electronic agenda in IRB Manager also displays submissions that have been reviewed under an expedited procedure. These submissions are listed for reporting purposes only and will not be discussed at the IRB meeting, unless the members have questions or comments.

Reviewer Assignments:

You will receive an email notification and see a Reviewer Assignment task in IRB Manager for each of your reviewer assignments. For technical help on how to complete your reviewer assignments, review the IRB Member Quick Guide in the Help section in IRB Manager. The staff does its best to assign studies according to member interests and expertise. However, to balance the number of reviews, members may be assigned to review studies not within their immediate area of expertise. In addition, a member may find a study of particular interest and decide to comment. If members notice they are not being assigned the type of studies they are particularly interested in, they should let the HRPA know.
5.2 Primary Reviewer System and Meeting Review Process
At the meeting, submissions generally are discussed in the order in which they appear on the meeting agendas. Roosevelt uses a primary reviewer system, in which up to three or four members will be assigned as reviewers of a particular submission. However, all members in attendance at an IRB meeting are expected to be familiar enough with each study so that he or she can either follow or contribute to the discussion. The number of assigned reviewers depends on the type of submission, and the roles of the reviewers vary, as described below.

New Full Committee Studies and Studies Returned for Additional Information
First Reviewer: The first reviewer presents a brief overview of the study so the other members will be able to have a sense of the subject population, purpose, and design of the study. This presentation should be no more than a minute or so and should not go into great detail. Then the reviewer should:

- Identify the funding source(s), if any.
- Describe the major risk/s.

Follow with the most salient concerns or comments about the study protocol with a focus on the risk/benefit ratio, other risks and/or procedures to minimize risks.

Consider all criteria required by federal regulations for IRB approval, although discussion should be limited to questions, problems, or concerns with:

- Subject selection,
- Informed consent documents,
- Data safety monitoring provisions,
- Protection of privacy and confidentiality, and/or
- Adequate protections of vulnerable populations.

Initiate discussion about

- Any needed clarifications, justifications and/or additional information in the protocol,
- Requested revisions and/or stipulations in the protocol, and/or
- Major problems or concerns with consent documents.

NOTE: Minor issues are noted as comments within IRB Manager and need not be discussed. HRPA staff will include in letters as appropriate.

NOTE: Easily correctable consent form recommendations should be listed in the Reviewers Checklist (see Appendix A) or member notes rather than discussed at the meeting.

Second Reviewer: The second reviewer may either concur with the first reviewer or make additional comments or raise additional concerns, first with respect to the protocol, then the consent form. The second reviewer is also back up for the first reviewer if the first reviewer has to cancel unexpectedly. Thus, the second reviewer should be prepared to present the protocol.

Third Reviewer: The third reviewer serves as back up to the second reviewer, in case either the first or second reviewer has to cancel unexpectedly. The third reviewer should review the consent form, but need not be prepared to present the protocol in depth unless informed in advance of the meeting of a
reviewer cancellation. Also, new members are assigned as third or even fourth reviewers. The third or fourth reviewer is not expected to make comments about the study but may do so, of course.

All Members: All members are expected to be familiar enough with all studies in order to follow and/or contribute to the discussion.

Full Committee Major Modifications, Continuing Reviews (Renewals), and Post-Approval Events

First Reviewer: The first reviewer does not need to present an overview of the study, though he or she could provide a very brief summary of changes (not the details, unless they are a matter of safety). The discussion should begin with if and how the risks and benefits of the study have changed. Comments or concerns should be addressed, first with respect to the protocol and study status, then the consent form. Confirm regulatory determinations. Unless serious oversights occurred at initial review, avoid asking for changes in design or the consent unless related to changes in the actual study.

Second Reviewer: The second reviewer either concurs with the first review or presents his or her additional comments or questions.

All Members: All members should be familiar enough with the materials in order to follow or contribute to the discussion.

Chairs and Human Research Protections Administrator (HRPA):

IRB Chair: Although IRB chairs are sometimes assigned as primary reviewers, they generally review all the studies and so may comment on studies as well, and provide back up if needed. The vice chair should be readily available to assume the role of IRB chair in the event the IRB is not able to conduct the meeting.

HRPA: The HRPA (also a member) at the meeting also reviews the new studies and may comment at the time of review. The HRPAs also provide backup.

Expedited Review by IRB Full Committee Members

Normally studies reviewed by full committee are studies involving more than minimal risk, though there may, of course, be minimal risk components within a full committee study.

Minimal Risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests (45 CFR 46.102). Studies in which all procedures are no more than minimal risks and which fit into one of the nine expedited review categories may be reviewed using the expedited process, that is, reviews by one or more designated IRB members.

Expedited Initial Reviews

Designated IRB members who are also HRPP staff review the majority of the minimal risk, expedited studies. However, the HRPP staff members sometimes assign minimal risk studies to IRB Chairs or Vice Chairs or other full committee members for expedited review. This is done to take advantage of member expertise when reviewing studies that are minimal risk.
Roosevelt University
IRB Guidebook

For example, members with relevant expertise may be assigned to review minimal risk studies involving vulnerable populations, controversial subject matter, foreign study sites, or extensive interaction with patients.

The expedited review process for these types of studies is as follows:

Expedited review assignments will appear in the members IRB Manager™ task list just as full board reviews do. The reviewer also will receive an e-mail notification from the IRB Manager™ system.

The reviewer should use the Reviewer Checklist to make comments.

Reviewers are asked to complete these reviews within a week. If a more rapid turnaround is needed, staff will check with the reviewer before assigning.

Reviewing Responses via Expedited Review

After the IRB meeting, the HRPP staff will forward the committees comments to the researcher. Unless the response needs to be returned to the full committee for re-review, a designated IRB member will review the response or forward the response to a Chair, Vice Chair, or a member who raised concerns or has particular expertise to decide if the response is sufficient. This will be done using Internal Routing in the IRB Manager™ system, described in the IRB Member™ Quick Guide. If the response is adequate, the reviewer should inform the staff by documenting this in IRB Manager. If additional changes are needed, the reviewer should include that information in the comments.

5.3 Member Review Tools

The Reviewers Checklist: This checklist is viewable in IRB Manager when you open the study. Section 2 of the checklist contains the 9 required federal criteria for IRB approval of human research (also included above in Section 4), which reviewers should use to guide their presentation of the study (as discussed above). It also contains study-specific regulatory determinations about the inclusion of women, prisoners, pregnant women, neonates and prisoners in research as well as information about waivers and alterations of consent, nonsignificant risk determinations for devices and HIPAA that the IRB must make during its review. Reviewers should consider these regulatory determinations, but are not required to mark any final determinations in the checklist. However, member comments should be clearly related to one or more of the criteria for approval, or to achieve compliance with State regulations and/or University policies. The completed checklists can be displayed during the IRB meeting to help guide the presentation of the protocol. In addition, the HRPA often use the checklists to supplement their own notes of the meeting deliberations. NOTE: The HRPA does not consider the completed checklists to be a record of the committee’s deliberations and actions only individual members thoughts recorded before the meeting. For assistance completing a Reviewers Checklist, reviewers should consult the IRB Member Quick Guide (available in the Help section of IRB Manager) or contact the HRPP staff.

5.4 Putting Comments in IRB Manager™

Reviewers should enter their review comments in IRB Manager™ before the meeting. The comments may be projected during the meeting for other members to review during the discussion and may be used by HRPP staff to help prepare the letters to investigators after the meeting.

There are two ways to put reviewer comments into IRB Manager:
You can add comments while reviewing the application by clicking on the green plus sign in the right column. You can also write your comments in a Word doc while doing your review, then cut-and paste them into the final page of your Submission Review Form by clicking the Add new comment green plus sign.

For assistance completing a Reviewers Checklist, reviewers should consult the IRB Member Guidebook or contact the HRPA. Note that for consent form comments reviewers can print the consent documents and hand mark typographical errors, grammatical changes, or other easily correctable items directly on the consent forms themselves so meeting time does not have to be spent discussing these issues. Reviewers are asked to turn in the marked up consent documents and any other relevant handwritten notes to the HRPA at the meeting.

5.5 IRB Member or Consultant Potential Conflict of Interest

Member or Consultant Conflict of Interest

Guiding Principle: It is important that the members of the IRB, including alternate members, or expert consultants, regardless of voting privilege, do not have or appear to have a conflict of interest, including a significant financial interest, related to any of the studies in which they participate in the review process. The term conflict of interest in research refers to situations in which financial or other personal considerations may compromise, or have the appearance of compromising, a member’s professional judgment in reviewing or evaluating a research project. The goal in adhering to this principle is to prevent conflicting interests from interfering with the review process either by competing with an IRB members or consultants obligation to protect participants or by compromising the credibility of the review process. A conflict of interest depends on the situation, and not on the character or actions of the individual member.

Policy: It is the policy of the Roosevelt IRB that all conflicting interests of an IRB committee member, including alternates, or consultants, regardless of voting privileges, be declared before review of any research under IRB jurisdiction. IRB committee members, alternates, and consultants with a conflicting interest may not participate in any portion of the review of research activities except to provide information requested by the IRB and must absent themselves from the meeting during the IRBs deliberative discussion and vote on the affected research.

Considerations: As an IRB panel member or consultant, you should consider the following conflicts of interest and determine whether a particular role or relationship could affect your objectivity before reviewing, participating in the panel discussion or deliberation, and voting on a protocol.

IMPORTANT NOTE: Affirmative responses to questions one through five below indicate a conflict of interest requiring recusal of a member from reviewing or voting on a particular protocol (see Procedures below).

1. Are you an investigator listed on the protocol or a member of the research team?
2. Are you a direct supervisor of an investigator or a faculty sponsor of the protocol director?
3. Do you have a familiar or close personal relationship with an investigator on the protocol, e.g., a spouse, a child, a registered domestic partner, a significant other?
4. Do you (or your spouse, child, registered domestic partner, or significant other) have a significant financial interest (see definition below) in the drug, device, assay or product being tested?
Roosevelt University
IRB Guidebook

5. Are you an executive or director of the agency or company sponsoring the research?

NOTE: An affirmative answer to questions six and/or seven below does not automatically disqualify a panel member or consultant from reviewing and voting, but does require careful consideration. If a panel member or consultant answers yes to these questions and believes the situation poses a conflict of interest, he or she should adhere to the policy and procedures outlined in this guidance.

6. Do you have a competing interest with the protocol being reviewed?

7. Do you have other concerns that in your judgment warrant abstaining from review, deliberation, and voting on a protocol Examples of other concerns may be a commitment to a particular research approach or objections to a particular type of research.

Definition of Significant Financial Interest: Significant Financial Interest means anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria): equity interests (e.g., stocks, stock options or other ownership interests); and intellectual property rights (e.g., patents, copyrights and royalties from cash rights). For example, the following meet the Roosevelt IRB criteria for having a Significant Financial Interest that needs to be reported to the IRB and which requires that the member recuse him or herself from voting on an IRB application: An equity interest that when aggregated for you, your spouse and dependent children meets the following tests:

- Exceeds $10,000 in value as determined through reference to public prices or other reasonable measures or fair market value, and
- Represents more than a five percent set ownership in a single entity.
- Salary, royalties or other payments what when aggregated for you and your spouse and dependent children over the next twelve months are expected to exceed $10,000.
- Executive or director positions (compensated or uncompensated related to the research).
- Compensation of any amount that could be affected by the outcome of the research.
- This term does not include:
- Any ownership interest in the institution if the institution is an application under the SBIR Program.
- Income from seminars, lectures or teaching engagements sponsored by public or nonprofit entities.

Procedures for Protocol Review and Attendance at the IRB Meeting

Please be aware of the following procedures as part of your membership or consulting responsibilities:

Please inform the HRPA at the beginning of your service of any existing conflicts of interest, as discussed above. The HRPA will track these conflicts and not assign you studies to review if you have indicated you would have a conflict of interest. If at any time during the period of IRB service new conflicts of interest arise, please alert the HRPA. You should not participate in the review of a study for which you have a significant financial interest. If you indicate at any point during your service of any significant financial interests, the HRPA will not assign you as a reviewer on the study. If you are inadvertently assigned, please notify your HRPA immediately so that the study may be reassigned. You are not allowed to be in the room during the deliberations or the vote on the outcome of a study for which you have a significant financial interest, but you may answer questions about the study. At the top of every agenda is a printed reminder that anyone attending the meeting who has a conflict of interest, including a significant
Roosevelt University
IRB Guidebook

financial interest, related to a study on the agenda must leave the room during the deliberations and voting on that protocol.

The Chair will remind members of this requirement at the beginning of the meeting. At the IRB meeting, the panel member or consultant with the conflict must inform the panel that he or she cannot act as a reviewer, participate in the discussion, or vote on the protocol. It is not required that the member or consultant state what the conflict is, only that there is a conflict. The fact that the member or consultant was disqualified as a reviewer at the meeting due to a conflict of interest will be noted in the minutes. The IRB panel member will not be counted as part of the quorum for the protocol. If quorum is not present because of this absence, then the IRB panel may not take further action or vote on this protocol. It will have to be re-reviewed at a meeting for which there is quorum.

**Coordination of Review between the IRB and the Conflict of Interest Advisory Committee for Investigator Conflict of Interest (Research Council)**

**Guiding Principle:** The goal of coordinating the reviews of the Research Council and the IRB is first and foremost to prevent financial interests from adversely affecting the protection of participants and secondly to protect the credibility of Roosevelt and the Human Research Protection Program. Detailed information about investigator conflict of interest is included on the university website. Procedures are in place for coordinating reviews of potential conflicts of interest between the IRB and the Research Council. Once financial interests are disclosed, the Research Council evaluates them and a management plan is put in place or the interests are eliminated.

**Important Notes:**

The IRB has final authority to decide whether the financial interest and its management, if any, is acceptable and will adequately protect the safety and rights of the participants. The IRB will be advised if the Research Council recommends that the study not be funded and/or conducted at Roosevelt. In that case, the study will be withdrawn and not reviewed any further by the IRB.

**Human Subjects:** On May 5, 2004, DHHS issued revised Guidance for Human Subjects Protection. This guidance proposed the establishment of an Institutional Conflict of Interest Committee, a committee Roosevelt has in place, and it also includes recommendations for the IRB. This guidance is in partial response to the DHHS guidance as it addresses the need to develop policies and procedures for addressing conflicts of interest for IRB members.

**Roosevelt Policies Regarding Conflict of Interest:** Detailed information about Roosevelt policies with respect to conflict of interest are posted on the Roosevelt Office of Sponsored Programs and Research Services website.

**Small Business Innovation Research (SBIR) Program** means the extramural research program for small business that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Pub. L. 97-219, the Small Business Innovation Development Act, as amended. For purposes of this subpart, the term SBIR Program includes the Small Business Technology Transfer (STTR) Program, which was established by Pub. L. 102-564.

5.6 Member Appointment, Evaluation and Accelerated Advancement

**Appointments:** Members are nominated by various sources including but not limited to the
Roosevelt University
IRB Guidebook

Department Chairs, Deans, the HRPP Director, IRB Chair, Vice Chair, and other IRB Members. Members are chosen to represent the types of research being reviewed by the IRB. Appointments are typically for three years. Following the initial three year term, an IRB member will rotate off of the IRB. Should an IRB member be interested to renew their service after rotating off, they may return. Their return will depend on the needs of the IRB and the results of the yearly member evaluations.

**Member Evaluations:** The HRPP conducts annual member evaluations in order to provide feedback to members on the quality of their reviews. The evaluation is based primarily on the points described in Section 4 above.

**Accelerated Advancement:** The evaluation includes information on how your service with the IRB can qualify as *exceptional* performance when you are considered for advancement (see below for more information).

*IRB Members will receive the following information regarding their evaluation:*

> Attached to this message is your individual evaluation of performance as an IRB member. The evaluation was completed by the Chair of your IRB panel in collaboration with the staff HRPA. For attendance, we adopted an arbitrary standard of 80% or more attendance at your scheduled meetings being Good to Outstanding, and 50% to 79% as Satisfactory. We know there are good reasons for missing meetings, and we need to average better than 50% attendance to maintain quorum. The other measures clearly are more subjective. If you have questions, please contact your IRB chair or HRPA. Accelerated Advancement: As an aside, please be aware that your service with the IRB can qualify as exceptional performance when you are considered for advancement, per guidelines from the Provost. Among Examples of Exceptional Performance are: Sustained (3 years) and dedicated University service on a major campus committee such as CAP, IRB, CAR; or on a School’s admissions committee as appropriate. For more on Accelerated Advancement, see page 10 of the University Senate Handbook.

Thank you for your continued efforts at protecting research participants and facilitating ethical research at Roosevelt.

**Section 6: Review Outcomes**

6.1 IRB Review Outcomes

One of two general outcomes are possible following review: a) the investigators can begin the study without submitting additional information to the IRB or b) the investigators may not begin the study until additional information is provided and the IRB approves the response. A third but very rare outcome is that the study is disapproved and cannot be conducted. The IRB will apply one of the following outcomes to each submission based on the discussion during the review process.

- Straight Approval or Approval with Comments: Study can begin.
- Approved with Comments that Must Be Addressed: Study can begin.
- Revisions Requested: Study approved in concept but directed changes or concurrences requested before study can begin.
- Returned for Additional Information: To be reviewed again by Full Committee.
- Disapproved: Study cannot be conducted under aegis of Roosevelt.
- **Tabled** is another rare but possible outcome. This occurs when the criteria for a convened full board meeting are not met (e.g., loss of quorum, or a required member, such as the community
member representative or the nonscientist, are not present) and/or appropriate expertise for a particular study (e.g., pediatrician) is not available at the meeting. The study will be reviewed at the next available full board meeting.

6.2 IRB Full Committee Votes on Review Outcomes
The full committee takes a vote for all submissions requiring approval. The number of members voting for or against the outcome is recorded in the minutes. The names of those voting one way or the other are not recorded, except in the case of abstentions. Members may request that a secret ballot be used, though typically a vote is indicated orally or by raising hands. Dissenting members may write a minority report to be included in the minutes. Any member may abstain from voting if he or she desires and this decision will be recorded in the minutes. A member must abstain, leave the room before the final discussion, and vote if he or she is listed as an investigator on a study or has another conflict of interest.

6.3 Post-Approval Event Determinations
The committee occasionally is asked to make determinations on post-approval events, including internal adverse events or protocol violations and incidents. Here are the specific determinations (and accompanying definitions) the committee must make about these events:

- **An unanticipated problem** involving risk to participants or others is defined as: an unexpected, research-related event where the risk exceeds the nature, severity, or frequency described in the protocol, study consent form, Investigators Brochure or other study information previously reviewed and approved by the IRB.
- **Noncompliance** is defined as failure to follow state or federal regulation, or the University policies, or the requirements of the VHA Handbook 1200.5, or determinations of the IRB for the protections of the rights and welfare of study participants.
- **Serious Noncompliance** is defined as failure to follow state or federal regulations or University policies, or determinations of the IRB for the protection of the rights and welfare of study participants. In addition, it is defined by judgment of the IRB, results in, or indicates a potential for a) a significant risk to enrolled or potential participants or others, or b) compromises the integrity of the Roosevelt HRPP or the University.
- **Continuing Noncompliance** is defined as a pattern of noncompliance that continues to occur after a report of noncompliance and a corrective action plan have been reviewed and approved by the IRB. The Committee may request additional corrective action plans or request that the Quality Improvement Unit conduct a directed site visit [50]. The Committee may also suspend or terminate IRB approval.

6.4 Minutes
Minutes of the IRB meetings are prepared by HRPA after all of the stipulations and comments from the meeting have been sent. The minutes record the attendance and list the outcomes, regulatory determinations, and stipulations and comments for each submission reviewed. The minutes also summarize discussions of any controverted issues and/or other discussions as appropriate. The minutes also include a report of submissions that were reviewed under an expedited procedure.

Minutes are distributed via email to all members of that committee who attended the meeting. Only those members in attendance at the convened meeting may vote on the minutes. Members may request that changes be made in the minutes or they may request additional information about a study.
that was discussed. Approved minutes are maintained in IRB Manager and are available for review by auditors.

**Section 7: Policy, Guidelines, Regulations, and Ethical Principles**

7.1 Roosevelt Policy and Guidelines

All of the IRB forms and guidance can be found on the Roosevelt IRB website. All IRB policy is based on Roosevelt interpretation of federal regulations and state law and is included in the IRB website. Another source of IRB policy is the Roosevelt University Office of the Provost. New Roosevelt guidelines and policy typically are developed by the Policy and Compliance Committee, approved by the Executive Council, and then distributed to IRB members for comments and suggestions. The Roosevelt Institutional Official approves policy changes. While Roosevelt policy may be more restrictive than federal or state regulation or Office of the Provost policy, it may not be less restrictive.

7.2 Regulations and Ethical Principles

A comprehensive list of Federal Regulations, State Statutes and Guidance can be found on the IRB website. Below are some of the more commonly referenced items.

- The Nuremberg Code
- World Medical Associations *Declaration of Helsinki*
- The Belmont Report

7.3 Abbreviated Recruitment and Informed Consent Considerations for Members

As discussed above, the first Belmont principle is that of *respect for persons*. This principle requires that subjects give their free and informed consent to participate in research. As such, during its review of a study, the Committee must examine the study’s recruitment and consent process including recruitment materials and the consent form or information sheet to be used at the time of consent. Below are some points to consider when reviewing the recruitment and consent process. Please also utilize the IRB Reviewers Checklist, which includes regulatory issues related to these processes. The **Recruitment, Consent and HIPAA** section of the IRB website has additional information on acceptable recruitment strategies, consent guidance, and considerations for unique situations or when vulnerable populations are involved.

**Recruitment Considerations**

**How will subjects first be contacted?** Does the recruitment strategy emphasize the voluntary nature of participation? The application form should discuss how, where, when, and by whom prospective subjects will be contacted. In addition, the recruitment strategy should make clear that subjects are free to refuse to participate.

For studies where contact information on potential subjects is obtained from medical or other private records, the IRB generally recommends initial contact by letter rather than telephone. In addition, the IRB strongly suggests that subjects be approached by someone already involved in their care. For telephone recruitment or surveys, the IRB expects that subjects will have the study explained and will be
Roosevelt University
IRB Guidebook

asked explicitly whether they are willing to participate in the research study. The investigator should submit scripts or guides that will be used for recruitment interviews.

Advertisements and other recruitment materials also must be submitted (see below) and meet Roosevelt requirements.

How will the privacy of prospective subjects be respected? The study team should make efforts to respect the privacy of possible subjects. If a study is first explained to subjects in a group, the IRB usually asks that the actual consent process be done in private.

Is the person obtaining informed consent qualified to do so? It is important that the person obtaining the subjects consent be knowledgeable and appropriate.

General Considerations of Informed Consent (summarized from the federal regulations): Consent must obtained from subjects or representatives before enrollment (there are very rare exceptions). Consent must be obtained under circumstances that provide the subject or the representative sufficient opportunity to consider whether or not to participate. The possibility of coercion or undue influence must be minimized. Prospective subjects must be able to understand the information provided to them. Subjects or representatives who do not speak English must receive information in their own language. Review guidance on Consenting Non-English Speakers for details. No language may be used that makes subjects waive or appear to waive any rights. We will soon post a checklist of criteria required by federal regulation to approve informed consent. In the meantime, please review the criteria here.

Additional Forms: HIPAA Authorization and Experimental Subjects Bill of Rights
In addition to the consent form, subjects at Roosevelt may receive up to two additional documents during the consent process. These documents do not need to be submitted to the IRB for review. However, the Consent section of the consent document should specify that subjects will receive the additional documents.

1. HIPAA Authorization Form:

HIPAA applies to a research study if researchers access, use, create, or disclose the individual's protected health information (PHI) for research purposes. For example, HIPAA applies to a research study if researchers add research results to the subjects medical record. Abstract data (e.g. medical history, clinical test results, etc.) from the subjects health record for research purposes. Share/disclose the subjects PHI with the outside groups, such as the study sponsor. Create a medical record because subjects enroll in a study. At Roosevelt, the IRB is the HIPAA Privacy Board, which means the IRB makes HIPAA determinations for research projects. If HIPAA regulations apply to a research study, the IRB must determine the following: whether signed HIPAA authorization is required, or if a waiver of authorization can be granted. A waiver can be granted only if specific criteria apply. The IRB also can grant a waiver of authorization for recruitment purposes only. For example, researchers often want to screen medical records to identify potential subjects, but only obtain written authorization from subjects who enroll in the study. In such cases, the IRB can grant a waiver of authorization for recruitment purposes only. More information is available in the HIPAA section of the HRPP website.

Recruitment and Consent Materials to Review
The following items must be submitted as part of the initial application for IRB review. Any additions or changes to these documents must be submitted as formal modifications:
Letters to Subjects: All letters to subjects or their representatives, regardless of who signs the letters, including the PI, a primary care provider, or an organization the subject has joined.

Advertisements: All advertisements in all media, including flyers, posters, newspaper ads, radio or television announcements, and informational videos. The content of these ads must meet certain criteria.

Recruitment Scripts: All scripts or guides that will be used for in-person or telephone recruitment interviews.

Web Postings or Pages: Investigators should describe content and/or submit printouts of postings or pages used for direct recruitment. Informational descriptions posted on websites that have policies insuring that study descriptions are accurate and balanced (e.g. ClinicalTrials.gov) do not need to be submitted for review.

Consent Documents:
- Consent forms, including any parental consent forms
- Assent forms
- Information sheets and/or scripts
- VA-specific consent form

Investigators do not need to submit a copy of the HIPAA authorization form or the Experimental Subjects Bill of Rights.

Roosevelt Consent Form Templates: The HRPA has prepared several consent and assent form templates that investigators should use as models. Consent forms that follow these templates comply with all federal regulations, state laws, and Roosevelt institutional requirements. Therefore, investigators are strongly encouraged to use the formats, although it is not absolutely required. If another template is used, please refer to the Consent Form Checklist for Using a Non-Roosevelt Consent Form.

Source URL: ----new website address with link to handbook----

Links:

Human Subject Regulations Decision Charts
The Office for Human Research Protections (OHRP) provides the following graphic aids as a guide for institutional review boards (IRBs), investigators, and others who decide if an activity is research involving human subjects that must be reviewed by an IRB under the requirements of the U.S. Department of Health and Human Services (HHS) regulations at 45 CFR part 46. OHRP welcomes comment on these decision charts. The charts address decisions on the following:
- whether an activity is research that must be reviewed by an IRB
- whether the review may be performed by expedited procedures, and
- whether informed consent or its documentation may be waived.
Considerations
The charts are intended to assist IRBs, institutions, and investigators in their decision-making process and should not be used as substitutes for consulting the regulations. OHRP cautions that the full text of applicable regulatory provisions should be considered in making final decisions.

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

The charts do not address requirements that may be imposed by other organizations, such as the Food and Drug Administration, National Institutes of Health, other sponsors, or state or local governments.
Chart 1: Is an Activity Research Involving Human Subjects?

Start here. Is it research?

If the activity is a systematic investigation designed to develop or contribute to generalizable knowledge? [45 CFR 46.102(d)]

Activity is research. Does the research involve human subjects?

Does the research involve obtaining information about living individuals? [45 CFR 46.102(f)]

The research is not research involving human subjects, and 45 CFR part 46 does not apply.

Is the information individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information)? [45 CFR 46.102(f)(2)]

Activity is research involving human subjects. Is it covered by the regulations?

Is it conducted or supported by HHS? [45 CFR 46.101(a)(1)]

The research involving human subjects is covered by the regulations.

Does the institution hold an FWA under which it applies 45 CFR 46 to all of its human subjects research regardless of the source of support?

The research involving human subjects is NOT covered by the regulations.

Go to Chart 2 AND Other Federal, State and local laws and/or regulations may apply to the activity. [45 CFR 46.101(f)]

February 16, 2016

Activity is not research, so 45 CFR part 46 does not apply.
Chart 2: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.101(b)?

From Chart 1

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**

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

  - NO
    - If not exempt under (b)(1)
      - 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

        - NO
          - If not exempt under (b)(2) or (b)(3)
            - 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

              - NO
                - If not exempt under (b)(4)
                  - Research studying, evaluating, or examining public benefit or service programs?

                    - YES
                      - Exemption 45 CFR 46.101(b)(5) may apply.
                      - Go to Chart 6

                    - NO
                      - If not exempt under (b)(5)
                        - 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
                            - If not exempt under (b)(6)
                              - 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.

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

1. From Chart 2
   - Is the research only** conducted in established or commonly accepted educational settings? (Including but not limited to schools and colleges. May include other sites where educational activities regularly occur.)
   - **“Only” means that no non-exempt activities are involved. Research that includes exempt and non-exempt activities is not exempt.

2. NO
   - Research is not eligible for 45 CFR 46.101(b)(1) exemption.
   - Next

3. YES
   - Does the research study involve only normal education practices? (Such as research on regular and special education instructional strategies, or research on effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.)
   - NO
     - Return to Chart 2 and consider whether 45 CFR 46.101(b)(2) exemption applies.
   - YES
     - Research is eligible for 45 CFR 46.101(b)(1) exemption from 45 CFR part 46 requirements.
Chart 4: Does exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?

**“Only”** means that no non-exempt activities are involved. Research that includes exempt and non-exempt activities is **not** exempt.

- **Yes**: Does the research involve *only* the use of educational tests, survey procedures, interview procedures, or observation of public behavior?
  - **Yes**: Is the information obtained recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and could any disclosure of the human subjects' responses outside the research reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation?
  - **No**: Research is not eligible for exemption under 45 CFR 46.101(b)(3).
  - **Yes**: Research is eligible for exemption under 45 CFR 46.101(b)(3) from 45 CFR part 46 requirements.

- **No**: Does the research involve children to whom 45 CFR part 46, subpart D applies?
  - **Yes**: Only research involving *only* educational tests or observation of public behavior without participation by the investigator in the activities being observed is exempt under 45 CFR 46.101(b)(2).
  - **No**: Research is not eligible for exemption under 45 CFR 46.101(b)(2) or (b)(3).

- **No**: Research is not eligible for exemption under 45 CFR 46.101(b)(2) or (b)(3). Return to Chart 2 and consider whether 45 CFR 46.101(b)(4) exemption applies.

February 16, 2016
Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data, Documents, Records and Specimens) Apply?

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

From Chart 2

Does the research involve only** the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens? *

("Existing" means existing before the research is proposed to an institutional official or the IRB to determine whether the research is exempt.)

** "Only" means that no non-exempt activities are involved. Research that includes exempt and non-exempt activities is not exempt.

YES

Are these sources publicly available?

YES

Research is eligible for exemption under 45 CFR 46.101(b)(4) from 45 CFR part 46 requirements.

NO

Will information be recorded by the investigator in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects?

YES

Research is not eligible for exemption under 45 CFR 46.101(b)(4) from 45 CFR part 46 requirements.

NO

Return to Chart 2 and consider whether 45 CFR 46.101(b)(5) exemption applies.
Chart 6: Does Exemption 45 CFR 46.101(b)(5) (for Public Benefit or Service Programs) Apply?

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

- Is the research or demonstration project conducted or approved by the Department or Agency Head?
  - YES
    - Does the research or demonstration project involve only the study, evaluation, or examination of:
      - Public benefit or service programs;
        - YES
        - Research is eligible for exemption under 45 CFR 46.101(b)(5) from 45 CFR part 46 requirements.*
        - NO
      - Procedures for obtaining benefits or services under public benefit or service programs;
        - YES
        - Research is eligible for exemption under 45 CFR 46.101(b)(5) from 45 CFR part 46 requirements.*
        - NO
      - Possible changes in or alternatives to public benefit or service programs or to procedures for obtaining benefits or services under public benefit or service programs;
        - YES
        - Research is not eligible for exemption under 45 CFR 46.101(b)(5).
        - NO
      - Possible changes in methods or levels of payment for benefits or services under those public benefit or service programs?
        - YES
        - Research is not eligible for exemption under 45 CFR 46.101(b)(5).
        - NO
    - NO

**“Only”** means that no non-exempt activities are involved. Research that includes exempt and non-exempt activities is **not** exempt.

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

From Chart 2

Does the research involve only** a taste and food quality evaluation or a food consumer acceptance study?

** "Only" means that no non-exempt activities are involved. Research that includes exempt and non-exempt activities is **not** exempt.

YES

Are wholesome foods without additives consumed?

YES

Research is eligible for exemption under 45 CFR 46.101(b)(6) from 45 CFR part 46 requirements.

Other Federal, State, and local laws and/or regulations may apply to the activity. [45 CFR 46.101(f)]

NO

Is food consumed that contains a food ingredient, 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?

YES

NO

Research is not eligible for exemption under 45 CFR 46.101(b)(6).

Go to Chart 8

February 16, 2016
Chart 8: May the IRB Review Be Done by Expedited Procedures Under 45 CFR 46.110?*

From Chart 2, or 7

Has the research been previously reviewed and approved by the IRB?

YES

Is the review a continuing review? [45 CFR 46.109(d)]

NO

Does the research present no more than minimal risk to human subjects and does the research involve only procedures included in categories 1 through 7 on the list of categories of research that may be reviewed through an expedited review procedure? [45 CFR 46.110(b)(1)]

YES

Is the research classified? [Paragraph (D) of Categories of Research That May Be Reviewed By an IRB through an Expedited Review Procedure.]

NO

Could identification of subjects put them at risk of criminal or civil liability, or be socially or economically damaging? [Paragraph (C) of Categories.]

YES

Research is eligible for IRB review through expedited procedures. Agency head may restrict, suspend, terminate or choose not to authorize an institution’s or IRB’s use of the expedited review procedure. [45 CFR 46.110(d)]

NO

DOES THE REVIEW INVOLVE A MINOR CHANGE IN APPROVED RESEARCH DURING THE (ONE YEAR OR LESS) PERIOD OF APPROVAL? [45 CFR 46.110(b)(2)]

YES

Review by convened IRB is required.

NO

ARE MEASURES IN PLACE TO MAKE RISKS NO MORE THAN MINIMAL?

YES

Go to Chart 9

NO

Go to Chart 10

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

From Chart 8

Has the research been *previously reviewed* and approved by the IRB using *expedited* procedures?

- **YES**
  - Have conditions *changed* such that the research is *no longer eligible* for expedited review (e.g., protocol change, or experience shows research to be of greater than minimal risk)?
    - **YES**
      - Review by convened IRB is required.
    - **NO**
      - Go to Chart 10
  - **NO**

**Category 8**

- (a) For this site:
  - Is the research permanently closed to enrollment of new subjects?
  - Have all subjects completed all research-related interventions?
  - Does the research at this site remain active only for long-term follow-up of subjects?

- **YES**
- **NO**

- (b) Have no subjects been enrolled at this site?
  - **YES**
  - **NO**

**Category 9**

- Is the research conducted under an IND or IDE?
  - **YES**
  - **NO**

- (c) Are the remaining research activities at this site limited to data analysis?
  - **YES**
  - **NO**


February 16, 2016
Chart 10: Can Informed Consent Be Waived or Consent Elements Be Altered Under 45 CFR 46.116(c) or (d)**

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

- From Chart 8 or 9
  - Will the research or demonstration project be conducted by or subject to the approval of state or local government officials?
    - Yes: Is the project designed to study, evaluate, or otherwise examine: (i) Public benefit of service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs? (45 CFR 46.116(c)(1))
    - No: Will the research involve greater than minimal risk, as defined in Section 46.102(i)?
      - Yes: Is it practicable to conduct the research without the waiver or alteration? (45 CFR 46.116(d)(3))
        - Yes: No waiver of informed consent or alteration of consent elements is allowed.*
        - No: Will waiving or altering the informed consent adversely affect the subjects’ rights and welfare? (45 CFR 46.116(d)(2))
          - Yes: Go to Chart 11
          - No: Will pertinent information be provided to subjects later, if appropriate? (45 CFR 46.116(d)(4))
            - Yes: Waiver of informed consent or alteration of consent elements is allowed if IRB documents these findings and approves waiver or alteration.
            - No: If informed consent is not waived entirely

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

February 16, 2016
Chart 11: May Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?

From Chart 10

Would the consent document be the only record linking the subject and the research and would the principal risk be potential harm resulting from a breach of confidentiality? [45 CFR 46.117(c)(1)]

NO

Does the research present no more than minimal risk and involve no procedures for which written consent is normally required outside the research context? [45 CFR 46.117(c)(2)]

YES

IRB may waive the requirement for a signed consent form for some or all subjects.

AND

If IRB Allows Waiver of Documentation Under 45 CFR 46.117(c)(1)

Investigator will ask each subject if he or she wants documentation linking the subject with the research. [45 CFR 46.117(c)(1)]

Subject’s wishes will govern whether informed consent is documented. [45 CFR 46.117(c)(1)]

NO

IRB may NOT waive the requirement for a signed consent form for any subjects.

February 16, 2016
Appendix A: IRB Approval of Research Checklist

Project Number: Project Title:

Principal Investigator:

1. Participant risks are minimized

☐ Risks to participants are minimized by using procedures which are consistent with sound research design and which minimize exposing participants to risk.
   • Can alternative or fewer procedures answer the scientific question and reduce the likelihood or magnitude of harm?
   • Consider physical, psychological, social, legal, and economic risks.

☐ One of the following is true:

☐ The research involves no more than minimal risk.
☐ The research plan makes adequate provision for monitoring the data collected.
   • What and when will the data be monitored?
   • Who will be doing the monitoring?

2. Participant risks are reasonable

☐ Risks to participants are reasonable in relation to anticipated benefits.
   • Is the research likely to achieve its proposed aims?
   • Is the importance of the aims clear?
   • Consider physical, psychological, legal, social, and economic risks.
   • Consider direct potential benefits to participants, if any.

3. Participant selection

☐ Selection of participants is equitable
   • Consider inclusion and exclusion criteria.
   • Consider recruitment methods.
   • Consider the purpose of the research.
   • Consider the setting in which the research will be conducted.

4. Informed consent

☐ One of the following is true:

☐ Informed consent will be sought from each participant or an appropriate representative.
5. Informed consent documentation

☐ One of the following is true:

☐ The informed consent process will be waived.
☐ The requirement for written documentation will be waived.
☐ Informed consent will be documented in writing.

Anticipated elements:
- Purpose
- Number of participants
- Duration
- Description
- Additional cost
- Benefits
- Confidentiality
- Procedure
- Risk
- Contact person
- Voluntary nature

6. Data safety and monitoring

☐ There are adequate provisions to protect the confidentiality of the data.
- Restricted access (Encryption/locks/passwords)
- Certificates of confidentiality

7. Participant privacy

☐ One of the following is true:

☐ Participants will have no expectation of privacy.
  - Will participants think that the information sought is any of the researcher’s business?
  - Will participants be comfortable in the research setting?
☐ There are adequate provisions to protect the privacy of participants.
  - Do procedures for identifying participants minimize any invasion of privacy?

8. Vulnerable populations

☐ One of the following is true:
☐ None of the participants 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 participants likely to be vulnerable to coercion or undue influence.

This project qualifies as:
☐ Exempt
☐ Expedited
☐ In Need of Full Review by Board

 ____________________________________________  ______________________
 IRB Member Signature                        Date

 ____________________________________________  ______________________
 IRB Administrator/Office of the Provost      Date

References: Office of Human Research Protections, HHS, Roosevelt University, University of Indianapolis, University of California, San Francisco.