



INSTITUTIONAL REVIEW BOARD
THE UNIVERSITY OF UTAH

Board Member Manual

A basic training guide designed to support board members as they learn the IRB process



2017 Edition

Board Member Handbook: A Basic Training Guide to Assist New Board Members with the IRB Process

Provided by:

University of Utah Institutional Review Board
Research Administration Building
75 South 2000 East, Room 140
Salt Lake City, UT 84112
Phone: 801-581-3655
Email: irb@hsc.utah.edu
<http://irb.utah.edu/>

Compiled, updated and formatted by Lisa Rigtrup, IRB Operations Manager: July 2017.

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Welcome to the Institutional Review Board

Dear IRB Board Member,

The University of Utah Institutional Review Board is pleased to welcome you as you begin your service on the IRB. We hope that you will enjoy an interesting and fulfilling term with us.

The IRB prides itself on serving the University's research community through the application of the highest standards of intellectual integrity and careful attention to federal research regulations. We continually strive to provide investigators and study teams with competent and skilled staff and board members, as well as the best technology and resources in order to foster good research practices and protect human participants in research. We are eager to add your skill and expertise to our array of assets.

Once again, we would like to take this opportunity to wish you every success in your role here at the Institutional Review Board and to thank you for your commitment to this important responsibility.

Best Regards,

Jeffrey R. Botkin, M.D., M.P.H.

Professor of Pediatrics

Chief, Division of Medical Ethics and Humanities

Associate Vice President for Research

General Information

Background

The Institutional Review Board (IRB) is an independent committee comprised of at least five members from relevant academic disciplines, and at least one non-affiliated member. The members may include faculty, staff, students, as well as members from the local community. IRB members must have the necessary experience and expertise to evaluate proposed research projects. IRBs must be diverse in terms of race, gender, cultural backgrounds, and include members from the community.

The IRB functions as a type of “human subjects advocate” whose role is to protect subjects participating in research. The IRB committee reviews research projects submitted by researchers (students, faculty, or staff). The committee has the authority to approve, require changes, or disapprove proposed research projects.

The IRB is charged with reviewing all projects involving human subjects for compliance with institutional policies and state, local, and federal laws, as well as the ethical principles contained in the Belmont Report (i.e. respect for persons, beneficence, and justice). The IRB is part of a bigger system, The Human Research Protections Program (HRPP), charged with the protection of research subjects. At the University of Utah, the HRPP includes the IRB, the Office of Sponsored Projects (OSP), and other institutional officials and committees (e.g. the Radioactive Drug Research Committee).

The Common Rule

In 1981, the Department of Health and Human Services codified the Policy for the Protection of Human Subjects (Title 45, Part 46). Subpart A of these regulations, sometimes called the “Common Rule,” provides for the basic foundation of the Institutional Review Boards. This Federal Policy has been accepted by the federal agencies that conduct, support, or otherwise regulate human subjects research, hence the title “Common Rule.”

Additional subparts of Title 45, Part 46, provide protections to vulnerable populations such as pregnant women, fetuses, and neonates (Subpart B), prisoners (Subpart C), and children (Subpart D) involved in human subjects research. Many federal agencies and departments have not adopted subparts B, C, and D. Therefore only Subpart A is known as the “Common Rule.”

The IRB is charged with the responsibility of reviewing and overseeing human subject research. The IRB review process is designed to protect the rights and welfare of human subjects by ensuring equitable subject selection, assuring adequate informed consent, assessing and minimizing risks, and maintaining privacy and confidentiality. Human subject research projects cannot be conducted without the approval of the IRB.

It is important to note that officials at an institution (e.g. the Vice President for Research) may disapprove an IRB approved project. However, officials at the institution cannot approve a project that has been disapproved, suspended, or terminated by the IRB.

Once IRB approval is granted, the IRB must conduct a continuing review of the research at intervals appropriate to the degree of risk, and in accordance with IRB policy.

Panel Member Service

University of Utah panel members are appointed to serve for at least three years. There are seven panels here at Utah. Most panels convene once a month, generally on Wednesday or Thursday. Meetings are re-scheduled in special cases where they fall on or very near a holiday. You will be assigned to a specific panel, and will meet during a specific week each month. Each panel is assigned an IRB coordinator/administrator team, who will coordinate the monthly meeting and serve as your primary contacts to the IRB.

The IRB currently meets inside the Research Administration Building, usually in the first floor conference room (Room #111). Each member is required to attend at least 75% of their scheduled board meetings each year. Appointments to the IRB are year-long; nine month contracts do not preclude members from continuing to serve during the summer months.

We understand that the summertime and the winter holidays pose special circumstances of vacations and time off from the University setting. Keep in mind that research at the University of Utah continues unabated during these times, and the IRB mission continues throughout the entire year. We ask that you keep this in mind as you plan your vacations. Please keep your IRB coordinator informed if you must be absent from meetings.

Your coordinator will be contacting you each month via email to remind you of the board meeting and confirm your attendance. Please be sure that you respond to these requests promptly and keep your email address updated in the ERICA system. In order to meet regulatory requirements regarding panel representation, it is very important that we know who will be in attendance at each meeting.

Laptop Computers

Laptop computers can be made available at the board meetings for your use if needed. The machine will remain University property. It is preferable for members to use their department IT support for routine issues, but the IRB has computer professionals available if needed.

New Member Orientation

All new board members should meet with one of the IRB Administrators for a brief orientation first thing. The orientation will provide you with the “quick start” basics you’ll need to get started as a member of the IRB.

Human Subject Research Training

IRB member training involves several steps. First, members are required to complete and certify in an approved human subject research ethics course. Approved courses can be found on the IRB website under “Training”.

Second, the IRB provides an online training specific to new board members, as well as a live annual training session for all active members. All new board members must complete the online new

board member training during their first six months of service, and all active board members are required to attend an annual training session each year.

Orientation Board Meeting

If this is your first year serving on the University of Utah IRB, we require that you attend one board meeting prior to performing reviews at your panel's convened meeting. Please review your schedule and visit the IRB meeting schedule page on the IRB website (<http://irb.utah.edu/>) for a list of upcoming board meetings. Plan to attend at least one meeting for orientation, and contact the IRB Administrative Assistant to let us know which day you plan to attend. You can attend any of the panel meetings for this observation piece of your training.

New Board Member “To Do” Checklist

There are a number of administrative items that must be completed before the IRB can consider your service fully activated. Some of these items have already been covered in previous sections. All of the items on your “To Do” list are maintained by the IRB Administrative Assistant, who is ultimately responsible for adding you to the IRB’s official roster. Please ensure all of these items have been completed as soon as possible after notification of your appointment to the IRB.

1. Schedule and attend an in-person orientation with an IRB Administrator.
2. Successfully log into the ERICA system. If your university ID number (uNID) or password are not working, please either contact the Campus Helpdesk (801-581-4000), or contact one of the IRB’s computer professionals for assistance. Ensure that you have access to board member functions in ERICA (board member checklists, etc.).
3. Complete your Board Member Information profile in ERICA, including the Conflict of Interest Disclosure Section, and the Confidentiality Agreement. Make sure your email address is current and correct.
4. Email an electronic copy of your Curriculum Vitae (CV) or resume to the IRB, and/or ensure it is attached in your Board Member Information profile in ERICA.
5. Complete an accepted human subjects training course.
6. Attend at least one Board Meeting as an observer for orientation.
7. Complete the online New Board Member Training series. Follow the instructions on the IRB website to certify that you have completed the training.

Note: A tear-out version of this list can be found at the end of this manual.

AAHRPP Accreditation

As of June 2007, the University of Utah Institutional Review Board achieved full accreditation from the Association for the Accreditation of Human Research Protection Programs (AAHRPP). Full re-accreditation was awarded in 2011, and again in 2015. AAHRPP offers accreditation to research organization that “provide comprehensive protections to research participants” (<http://www.aahrpp.org>).

“Accreditation benefits research organizations, participants, and the research enterprise as a whole. The accreditation process requires organizations to take a comprehensive look at their human research protection programs (HRPPs)—to identify and address any weaknesses and to build upon their strengths. The result is a more cohesive HRPP, with the systems in place not only to protect research participants but also to advance research more efficiently and effectively” (<http://www.aahrpp.org>).

The accreditation process includes several steps, including application preparation, on-site evaluation, and council review, as well as annual reporting and site visits to maintain full accreditation status.

The Panel Member Review Schedule

Meetings begin at 12:00 Noon and generally run until about 3:00 PM. Please plan to attend the entire meeting. Visit the IRB website at <http://irb.utah.edu/> to get current meeting dates and applicable announcements.

The board member schedule is typically a five-week cycle that centers around the member’s board meeting.

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Week 1. The IRB Coordinator will send out an email to find out whether or not panel members will be able to attend the next Board Meeting for their Panel.						
Week 2. The IRB Coordinator will assign the agenda for this month. Reviews should be started during Week 2; the panel will have until the Board Meeting to complete them.						
Week 3. The Panel completes their assigned Board Reviewer Checklists.			Board Meeting 12:00 PM*	Week 3-4, Post-Board. Expedited approvals and tabled studies follow-up.		
Week 3-4, Post-Board (continued). Expedited approvals and tabled studies follow-up.						
Week 4-5. The IRB Coordinator may contact applicable panel members regarding any pending issues or tabled studies from the previous meeting.						

Panel meetings can be affected by government holidays.

- If a holiday falls on or very near the day of the board meeting, typically the IRB will cancel that panel’s meeting for the month, or move it to a few days prior. This most often occurs around Independence Day (July 4), Thanksgiving (fourth Thursday in November), and Christmas Day (December 25).

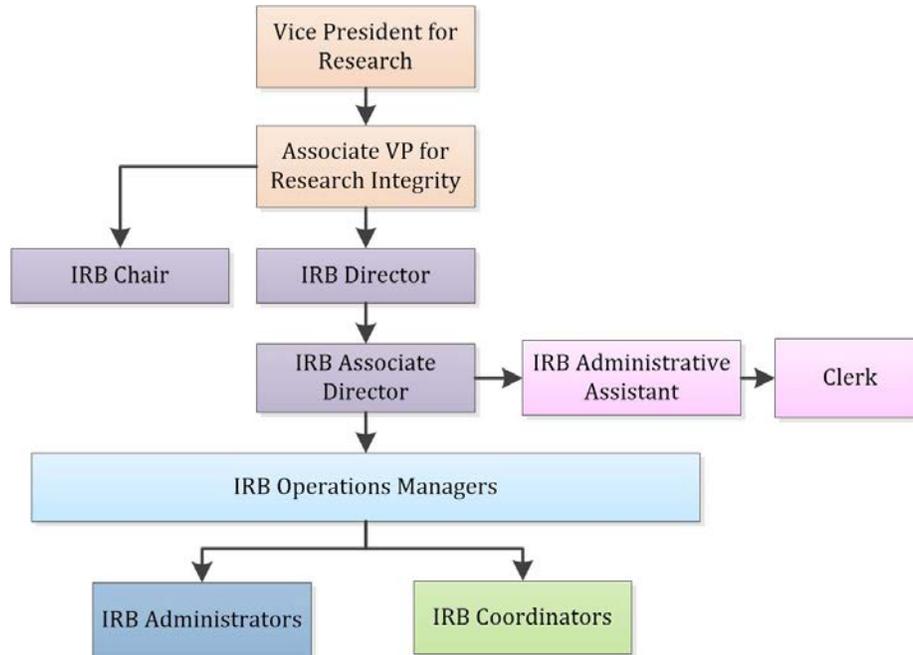
If you are unable to attend your board meeting for a given month, contact your IRB coordinator as soon as possible so arrangements can be made.

**Panel 6 meets on Thursday instead of Wednesday. Panel 7 doesn’t convene regularly. Make sure you check with your meeting coordinator if you have any questions about your panel schedule.*

Meet the IRB Staff

IRB Organizational Chart

A copy of the most current organizational chart for the IRB will be included in your onboarding materials. However, a general representation of the organization of the IRB office is included below:



Your panel meeting coordinator is your first contact for any questions you may have about anything related to the review process, regulations, IRB guidelines, etc. Feel free to contact your coordinator anytime during the review cycle if you have questions or concerns.

IRB Staff Contact Information

From the IRB website (www.irb.utah.edu), click on the “Contact Us” link at the top of the page. All of the IRB staff is listed on the Contact Us page.

Your IRB coordinator will be listed on the “IRB Coordinators” tab next to your panel number. Your assigned coordinator will be your primary point of contact at the IRB, however, you can always contact any member of the IRB staff if you need to.

The IRB Website

The IRB website (<http://irb.utah.edu/>) has been designed as a resource to assist board members and the research community as a whole with the IRB process. You are strongly encouraged to familiarize yourself with this resource. As a new board member, you will find an abundance of essential information that you will find yourself referring back to often during your tenure with the IRB.

- **A-Z Index:** The A-Z Index is an alphabetized list of a wide-variety of human subject research-related topics.
- **Board Member Resources:** This menu has been specifically designed with tools for board members and includes an electronic copy of this manual, copies of your review checklists, as well as several links to references and regulations that you will likely find helpful.
- **Training:** The University of Utah Human Research Protections Program (HRPP) offers several resources for investigators, staff, and board members who want to learn more about the ethical conduct of research and associated requirements at our institution. This page includes details about training courses offered.
- **Form Templates:** This page includes a comprehensive list of templates used by the IRB separated by Main Campus and Health Sciences locations.
- **Contact Us:** Current contact information for all of the IRB staff is housed on this page.

ERICA Basics

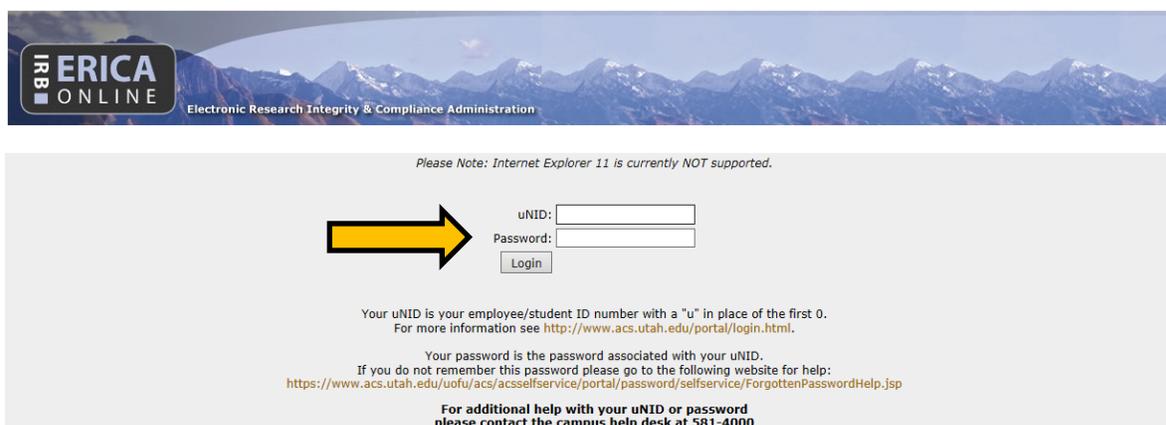
The **E**lectronic **R**esearch **I**ntegrity and **C**ompliance **A**dministration (ERICA) system is the primary electronic resource for the IRB review process. ERICA is used to enter, submit, track, review, and approve all studies submitted to the IRB.

Logging into ERICA



The screenshot shows the homepage of the Institutional Review Board. In the left sidebar, there is a menu with the following items: Submitting an Application or Report, Forms & Templates, Fees, Training, Research Participant Resources, Guidelines & Policies, and About the IRB. A yellow arrow points to the 'ERICA ONLINE' icon at the top of this menu. Below the menu is a large banner image of a mountain landscape with a video player overlay. Below the banner, there are sections for 'News & Announcements' and 'Other Resources'.

- Go to <http://irb.utah.edu/>.
- Click on the “ERICA IRB ONLINE” icon.



The screenshot shows the ERICA ONLINE login page. At the top left is the ERICA ONLINE logo with the tagline 'Electronic Research Integrity & Compliance Administration'. Below the logo is a navigation bar with a 'Please Note: Internet Explorer 11 is currently NOT supported.' message. The main content area contains a login form with fields for 'uNID:' and 'Password:', and a 'Login' button. A yellow arrow points to the 'Login' button. Below the form, there is explanatory text: 'Your uNID is your employee/student ID number with a "u" in place of the first 0. For more information see <http://www.acs.utah.edu/portal/login.html>. Your password is the password associated with your uNID. If you do not remember this password please go to the following website for help: <https://www.acs.utah.edu/uofu/acs/acselfservice/portal/password/selfservice/ForgottenPasswordHelp.jsp>. For additional help with your uNID or password please contact the campus help desk at 581-4000'.

- Log into ERICA using your University uNID (e.g., u0123456) and University network password. This is the same password you use to log into the Campus Information System (CIS) or Kronos.
- For additional assistance logging in, contact the Campus Help Desk (801-581-4000).

Completing Your Board Member Information File in ERICA

The IRB uses the ERICA system to maintain a record of all board member information required to meet regulatory standards. As a board member, you will need to maintain and update your Board Member Information File in ERICA throughout your term on the board. There are several sections that will need to be completed in the Board Member Information File. You can complete each of these sections progressively using the ERICA system.



- Log into ERICA using your username and password.
- Click on “My Profile” on the red menu bar at the top of the screen.
- Click on your name under the “My Profile” tab.
- Click “Continue” through each page as you complete the profile. Make sure each required section is thoroughly completed:
 - IRB Member Recusal Agreement
 - Confidentiality Agreement
 - Earned Degrees & Professional Certificates
 - Affiliation
 - Relationship to the HRPP
 - Anticipated Contribution to the IRB
 - Vulnerable Populations
 - Conflict of Interest
 - Board Composition
- Click “Submit” under “My Activities” when you are finished.

Profiles are used by the IRB and OHRP to verify that each panel has appropriate representational capacity to review studies. It also assists the IRB staff when deciding who to assign studies to for review. Board members are required to update or verify their profiles annually. You will receive an email reminder from the ERICA system if your profile has not been updated within the year. Email reminders will contain a link directly to the profile.

You can update your profile at any time by following the instructions above. To begin editing the profile, click “Make Editable” under “My Activities” before click the “Edit Profile” button. Board members are encouraged to update their profile as soon as possible if their affiliation or conflict(s) of interest have changed. ERICA will send an email reminder every 20 days while the profile is left in the Editable state. Remember to click “Submit” when you are finished. Please contact your IRB coordinator if you have any questions about how to complete your profile.

MY HOME in ERICA

IRB Member

Folder for New Board Member

My Roles

IRB Member

Board Meetings

Meeting

- 7/11/2007 - Panel 2
- 7/18/2007 - Panel 3
- 7/25/2007 - Panel 4
- 8/1/2007 - Panel 1
- 8/8/2007 - Panel 2
- 8/15/2007 - Panel 3
- 8/22/2007 - Panel 4
- 9/5/2007 - Panel 1

New Reviews
Revision Reviews

New Studies

<input type="checkbox"/>	ID	Name	PI	Review
<input type="checkbox"/>	IRB_00012345	Title Goes Here		Convened Board Review
<input type="checkbox"/>	IRB_00023456	Another Title Goes Here		Convened Board Review

Amendments

Name	PI	IRB#	Title	Review
There are no items to display				

Renewals

<input type="checkbox"/>	Name	PI	IRB#	Title	Review
<input type="checkbox"/>	RE_6/8/2007 9:35 AM		IRB_00034567	And Yet Another Title	Convened Board Review
<input type="checkbox"/>	RE_6/1/2007 9:35 AM		IRB_00045678	Yup, You Guessed It - Another Title	Convened Board Review
<input type="checkbox"/>	RE_5/29/2007 12:32 PM		IRB_00056789	This is the Last Title	Convened Board Review

- Log in to ERICA using your uNID and password.
- Click on “My Home” in the top right corner of the screen.
- A tab titled, “My Reviews” will generate as the default view.
- New Studies, Amendments, and Continuing Reviews will be separated by study type on the screen.
- Click on the study you wish to review.
- You can always return to this screen by clicking on “My Home” at the top of the screen.

- The “My Home” screen shows studies you have been assigned to review for the current meeting, as well as links to current and past meeting agendas and minutes.
- ERICA will also send you an email notification when the IRB Coordinator has assigned you to review something. The notification will contain a link which will allow you to access the study’s working page in ERICA.
- Please feel free to contact the Principal Investigator (PI) directly if you have any questions or concerns during your review. **However, make sure you keep your IRB coordinator informed if you decide to require any changes that will need to be implemented into the application or study documents.**

Reviewing Studies in ERICA

IRB Studies > Title Goes Here

Full Board Review

IRB_00012345 **Current Status:** Full Board Review

PI: **Meeting Date:** 7/25/2007

Title: Title Goes Here

Assigned Administrator: Your IRB Administrator **Risk Assessment:** Minimal

Assigned Coordinator: Your IRB Coordinator **Risk Assessment:**

Primary Reviewer: New Board Member

Secondary Reviewer: Another New Board Member

My Activities

Board Comments

Board Review | Correspondence | View Documents | Minutes

Primary Reviewer: New Board Member

Secondary Reviewer: Another New Board Member

Final Board Decision:

Begin a New Checklist

Board Reviewer Checklist

Name	Date Created	Date Modified	Owner	State
Board Reviewer Checklist	7/19/2007 5:20 PM	7/19/2007 6:12 PM	New Board Member	Submitted
Board Reviewer Checklist	7/19/2007 10:11 AM	7/22/2007 2:47 PM	Another New Board Member	Submitted

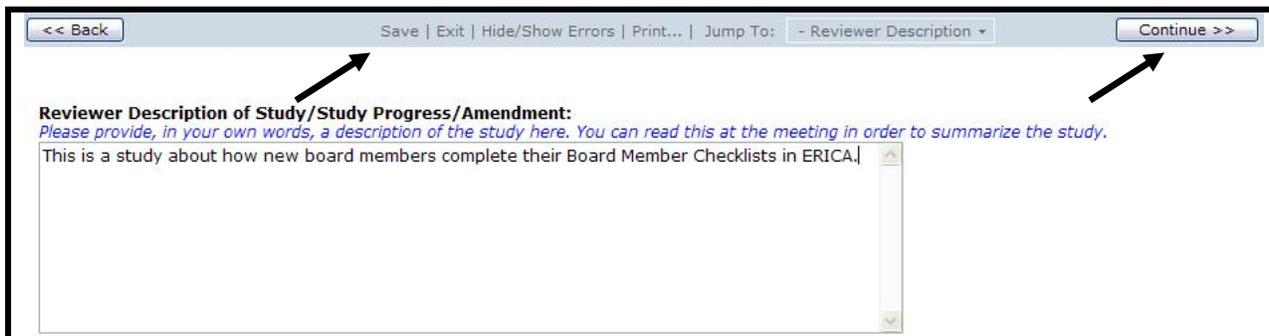
Board Comments

The query produced no results.

- From your “My Home” page, click on the study you wish to review.
- Right-click on “Print View” and select “Open Link in New Window”.
- The complete study application will display, including links to attached documents.
- Attached Documents can be opened for review by clicking on the title of the document.
- Return to the main working page of the study by closing the Print View browser.
- Click on “Begin a New Checklist.”

- **Please remember to save often.**
- Studies with Vulnerable Populations require additional considerations while reviewing. Such “Additional Checklists” include the Children Checklist, the Pregnancy Checklist, the Prisoner Checklist, and the Device Checklist. If you are reviewing a study that includes a Vulnerable Population, make sure you complete the required checklist. These checklists will automatically populate based on your answers at the beginning of the checklist.

Reviewing Studies in ERICA (Continued)



Reviewer Description of Study/Study Progress/Amendment:
Please provide, in your own words, a description of the study here. You can read this at the meeting in order to summarize the study.

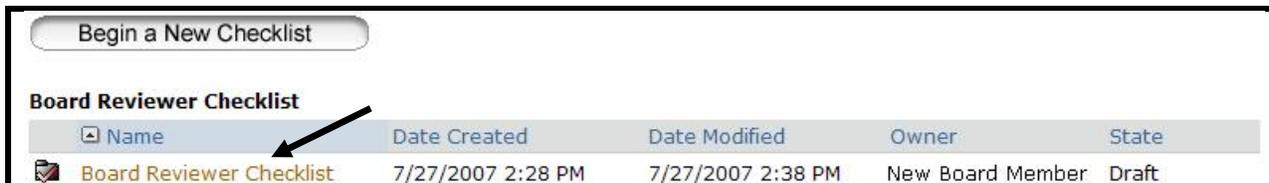
This is a study about how new board members complete their Board Member Checklists in ERICA.

- Fill out all of the required sections in your Board Member Checklist. **Remember to press “Save” or “Continue” often to save your work.**

- At the end of the checklist, you can add any final comments or concerns.
- You may also attach documents to the last page.
- Press “Finish” to save your final page.

Edit or Withdraw a Board Reviewer Checklist

If you find you need to leave your checklist and come back later, you will be able to save your progress and come back later using the “Edit Checklist” activity in ERICA. If you decide to completely withdraw your Board Reviewer Checklist, you may do so using the “Withdraw Reviewer Checklist” activity.

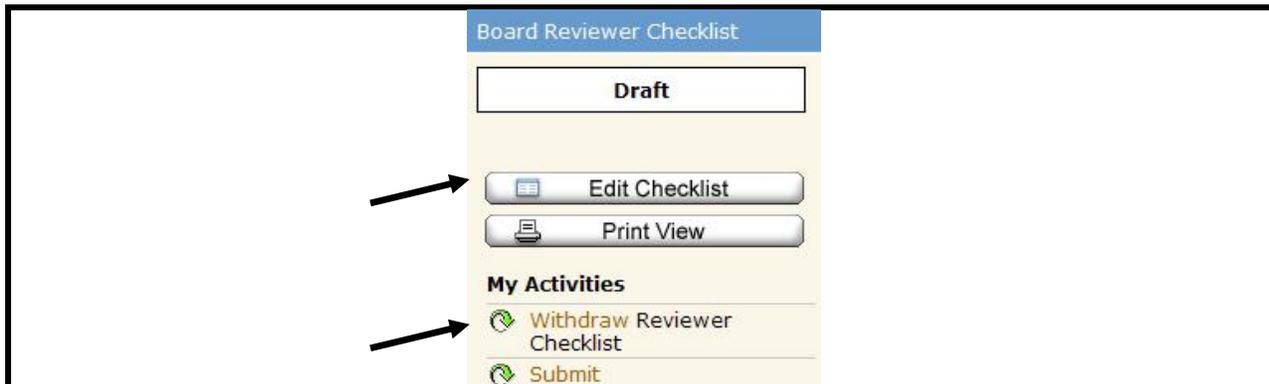


Begin a New Checklist

Board Reviewer Checklist

Name	Date Created	Date Modified	Owner	State
Board Reviewer Checklist	7/27/2007 2:28 PM	7/27/2007 2:38 PM	New Board Member	Draft

- Click on the checklist you have already created.



Board Reviewer Checklist

Draft

Edit Checklist

Print View

My Activities

Withdraw Reviewer Checklist

Submit

- To **Edit** the checklist, click on “Edit Checklist.” You will be allowed to jump to different sections of the checklist by using the “Jump To” option at the top of the screen.
- To **Withdraw** the checklist, click on “Withdraw Reviewer Checklist.”

Completing Reviews

There are three main types of studies you will review as a board member for the IRB: New Studies, Amendments, and Continuing Reviews (also known as “Renewals”). Each study that is submitted to the IRB receives an internal pre-review from a member of the IRB staff before the panel ever sees it. During the pre-review, the staff assigns the study an initial risk level, and determines whether the study should receive a convened board review, or whether it should be expedited.

The staff may also determine that the research is exempt from IRB review or that the project does not meet the definition of human subject research. There is a different process for review and approval based on the risk level and type of application. The general procedure for each type of review process is detailed later in this chapter.

Risk Levels

The risk level of a study depends on a number of different factors that are taken into account by the IRB staff during the pre-review process. Such considerations include (but are not limited to): the type of procedures involved in the study, the type of participant data that is collected, whether participants will or will not be contacted, the level of informed consent that is warranted, and whether participant Protected Health Information (PHI) is collected and/or stored or sent to sites outside the institution.

There are three risk levels that the University of Utah IRB recognizes:

- Exempt
- Minimal (both expedited and those reviewed by the convened board)
- Greater than minimal risk

Note: Although the IRB staff makes a preliminary determination regarding the risk level of a particular study, if during the review process a board member disagrees with the staff determination, the board may decide to agree with or overrule the staff’s determination.

Exempt Studies

Exempt research is research with human subjects that is “exempt” from the provisions stated in Title 45, Part 46, Subpart A, the Common Rule. An Exempt research project does not require an ongoing review from the IRB unless the project is amended in such a way that it no longer meets the exemption criteria. The IRB is required to determine if a research project falls under one of the six Exempt Categories listed in the federal regulations (45 CFR 46.101(b)). See the IRB website for a list of the Exempt Categories.

Minimal Risk Studies

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

After the pre-review, minimal risk studies are either submitted for Expedited review, or sent to the convened board for full discussion, depending on the type of study, and whether or not the procedures fit into one the Expedited Categories.

Discussed minimal risk studies can be assigned one *or* two reviewers depending on the age range of the participants. When children are part of the research objective(s) and/or procedures, the study requires two reviewers. When the study only includes adults (18 years and up), it is assigned only one reviewer. The reviewer(s) is responsible to assess the risk/benefit ratio and provide an overall review of the study.

Greater than Minimal Risk Studies

Greater than minimal risk studies are those that are considered to include procedures that constitute more than minimal risk to the participants (see above definition).

Greater than minimal risk studies require review by the full board at initial review. However, a study that is determined to be greater than minimal risk at initial review may still be expedited at continuing review in certain specific cases.

Types of Applications

The IRB handles a number of different types of applications, including:

- New Studies;
- Amendments;
- Continuing Reviews;
- Report Forms, which include Adverse Events, Protocol Deviations, reports of Non-Compliance, and Unanticipated Problems; and
- Final Project Reports

As an IRB panel member, you will generally only deal with the first four types of applications.

New Studies

A new study is one that is being considered for initial review and approval. All greater than minimal risk new studies are discussed by a convened panel. New studies that appear to be minimal risk, but do not fit into any of the approved expedited categories (see later section) are also discussed by the convened panel. If a new study is sent to the convened board for review, it will usually require two reviewers to complete the review. A primary reviewer is assigned to review the protocol and consent process, and a secondary reviewer is assigned to review the consent process again and in more detail.

Amendments

Any change to the currently-approved protocol and/or consent process requires an Amendment application. These are only considered after a study has received initial review and approval as a new study. Most amendments do not require full board review and are handled by the IRB Chair and an IRB coordinator. However, when it appears that the risk:benefit ratio may be changed by a proposed request, or there are considerable changes to the approved protocol that cannot be adequately assessed by the IRB staff, the amendment will be forwarded to a convened panel for discussion.

Continuing Reviews

Continuing Reviews are also referred to as “Renewals.” Federal regulations require that studies are reviewed at least annually, so research that is initiated, funded, or supported by the U.S. Government is reviewed on at least an annual basis. In addition, the IRB reviews all research that is greater than minimal risk at least annually.

Other research may be eligible for a longer approval period. IRB policy allows research that is minimal risk and not initiated, funded, or supported by the U.S. Government to be approved for up to two years. The IRB staff will recommend an appropriate approval period during the pre-review of the application, but the board ultimately determines the period of approval.

Continuing Review applications will have information regarding the number of participants that have been enrolled and/or withdrawn, any unexpected problems that have been identified, any changes (amendments) that have been implemented since the last approval, and any preliminary or final results that have been obtained. These applications reflect studies that are still enrolling subjects and/or have not completed all research-related interventions.

Continuing Reviews are discussed by the convened board unless the study is minimal risk and fits into an expedited review category, **or** in the following instances:

- Continuing review of research previously approved by the convened IRB where all research-related interventions have been completed, the study is only open for long-term follow-up and data analysis, and where the study is permanently closed to enrollment;
- Continuing review of research previously approved by the convened IRB where no participants have been enrolled and no additional risks have been identified;
- Continuing review of research not conducted under an investigational new drug application or investigational device exemption and the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risks.

Report Forms

- Report forms will be discussed in detail later in this manual.

Review Types

Research projects are reviewed at three different levels:

1. Exempt;
2. Expedited; and
3. Convened or “Full” Board

In most cases, minimal risk or less than minimal risk projects fall under the review categories of “Exempt” or “Expedited” review.

With few exceptions, studies that are deemed *greater than minimal* risk require a full board review. An explanation of each type of review is found below. Student investigators are advised to consult with the IRB or their faculty advisor if they are unsure of which review applies to their study.

Exempt Review

After the IRB staff has completed the pre-review process, Exempt studies assigned to an IRB administrator for review and determination of exemption. Exempt studies do not require annual review or continued oversight by the IRB.

Expedited Review

Expedited studies meet certain federal regulations and do not require full board discussion, unless an internal reviewer (staff) or board member has significant concerns regarding the study and

would like the full panel to address them. If you are assigned an expedited review and you feel full board discussion is needed on an expedited study you are reviewing, please contact your IRB coordinator prior to the meeting. These usually include any minimal risk studies that were initially approved through an expedited review process, but could include greater than minimal risk studies that qualify for expedited review in the specific cases noted above. Disapprovals cannot be conducted through expedited review. If while reviewing an expedited study, a board member feels that the application should be disapproved, this will likely need to be brought before the full board for discussion.

Convened Board

Convened Board or “Full Board” studies are discussed and voted upon by the convened panel. Any type of application can be reviewed by the convened board. Convened Board studies usually involve greater than minimal risk procedures or interventions that raise significant concerns about participant safety or privacy.

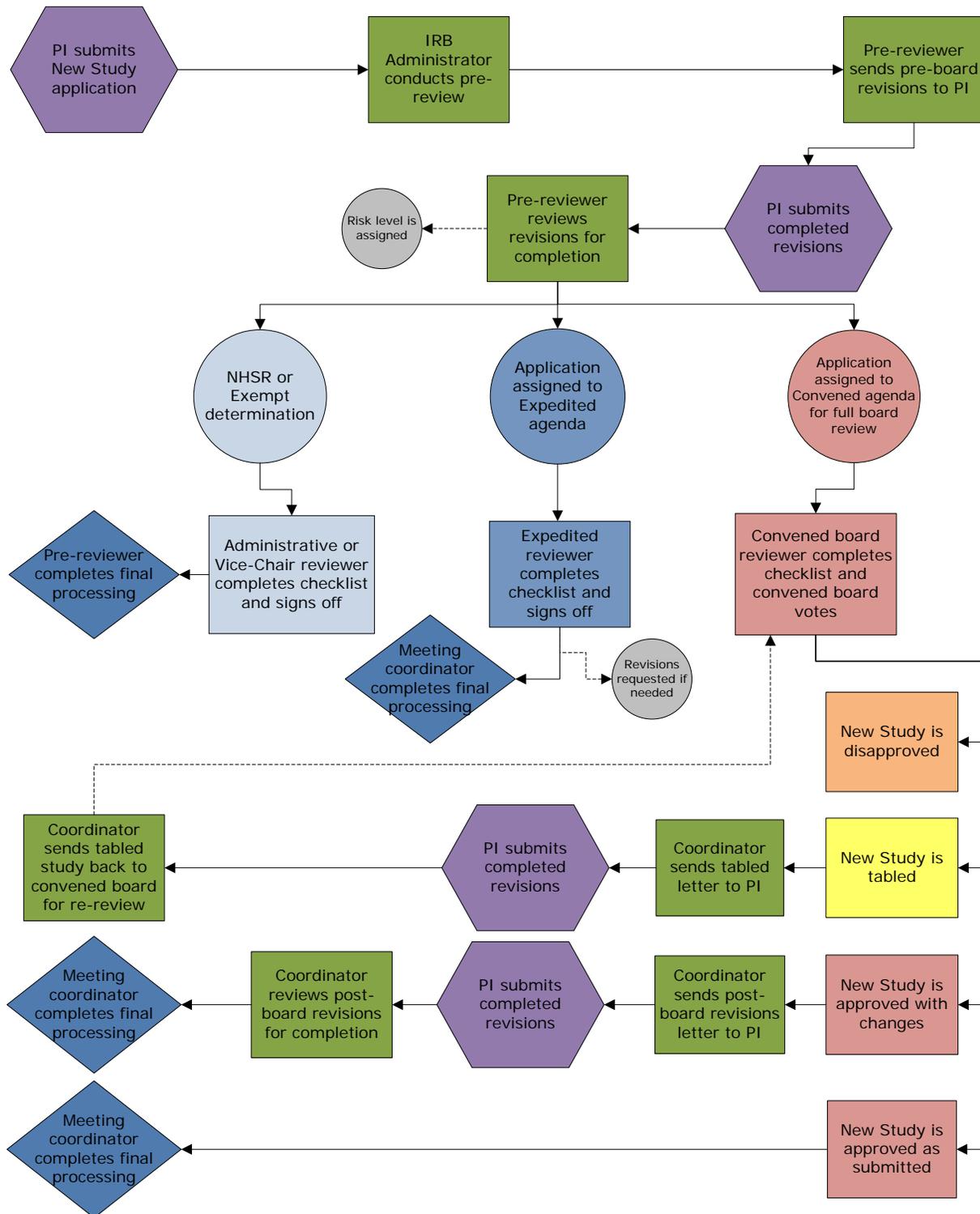
Occasionally, the IRB staff will send a minimal risk study to the convened board for discussion because the study does not fall into one of the Expedited Categories, because it involves unusual procedures, or because the design, consent process, etc. are not typical of studies usually reviewed by the IRB. After being reviewed by the convened board, the panel may vote to “expedite” the minimal risk study in the future under Expedited Category #9.

Review Summary Table

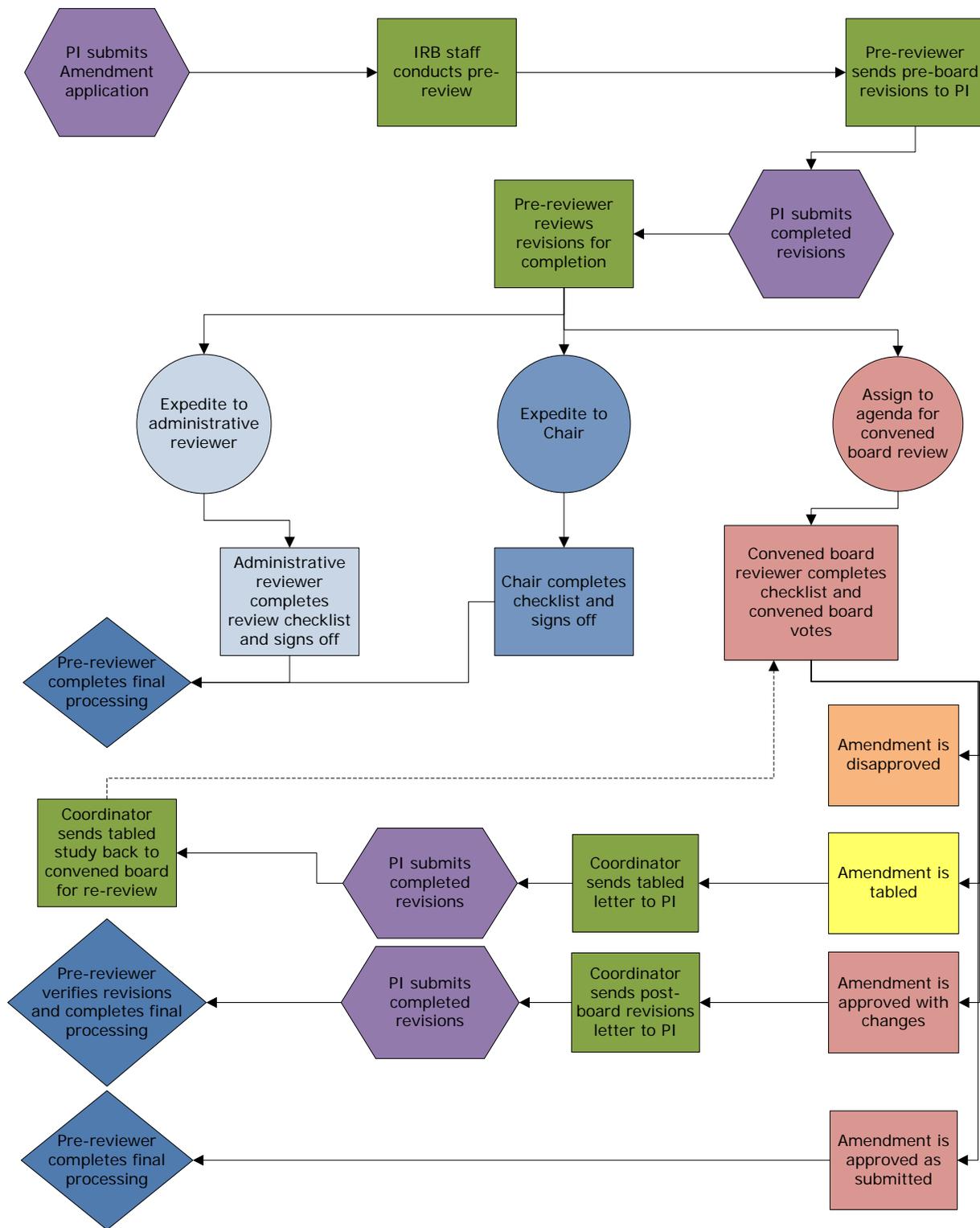
Type of Review	Exempt	Expedited	Convened Board
Risk Level	Exempt	<ul style="list-style-type: none"> Minimal GTM* Risk studies (under expedited category #8) 	Any level can be discussed at the board, but typically: <ul style="list-style-type: none"> Minimal-discussed GTM risk
Type of Application(s)	<ul style="list-style-type: none"> New Studies Amendments 	<ul style="list-style-type: none"> New Studies Amendments (if the requested change does not affect the study's risk/benefit ratio) Continuing Reviews 	<ul style="list-style-type: none"> New Studies Amendments Continuing Reviews Report Forms
Frequency of Review	If a study is determined to be "exempt" from IRB review, it is not subject to annual review.	At least annually if federally funded, up to two years otherwise	Most GTM risk studies will require review at least annually by the convened board, unless the board determines the study should be reviewed more often.
Reviewed By	IRB Administrator	Designated Expedited Reviewer	Convened Board Reviewer

**GTM: Greater than minimal risk.*

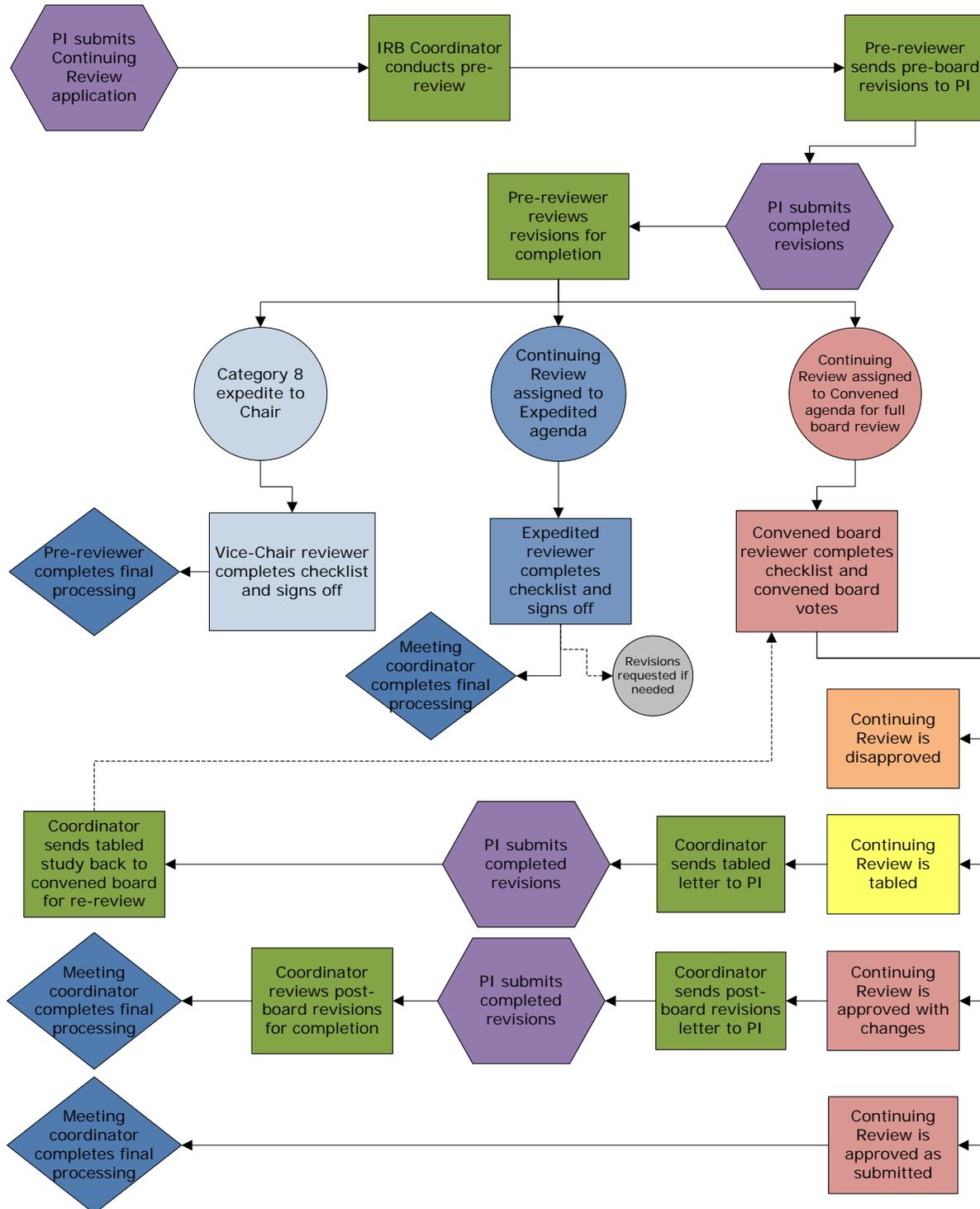
The New Study Application Review Process



The Amendment Application Review Process



The Continuing Review Application Review Process



Expedited Studies

After a few months of reviewing studies for discussion at board meetings, your IRB coordinator may notify you that you have been officially designated as an “experienced, Expedited Reviewer.” This will mean that you may be assigned to review expedited studies along with your discussed studies each month.

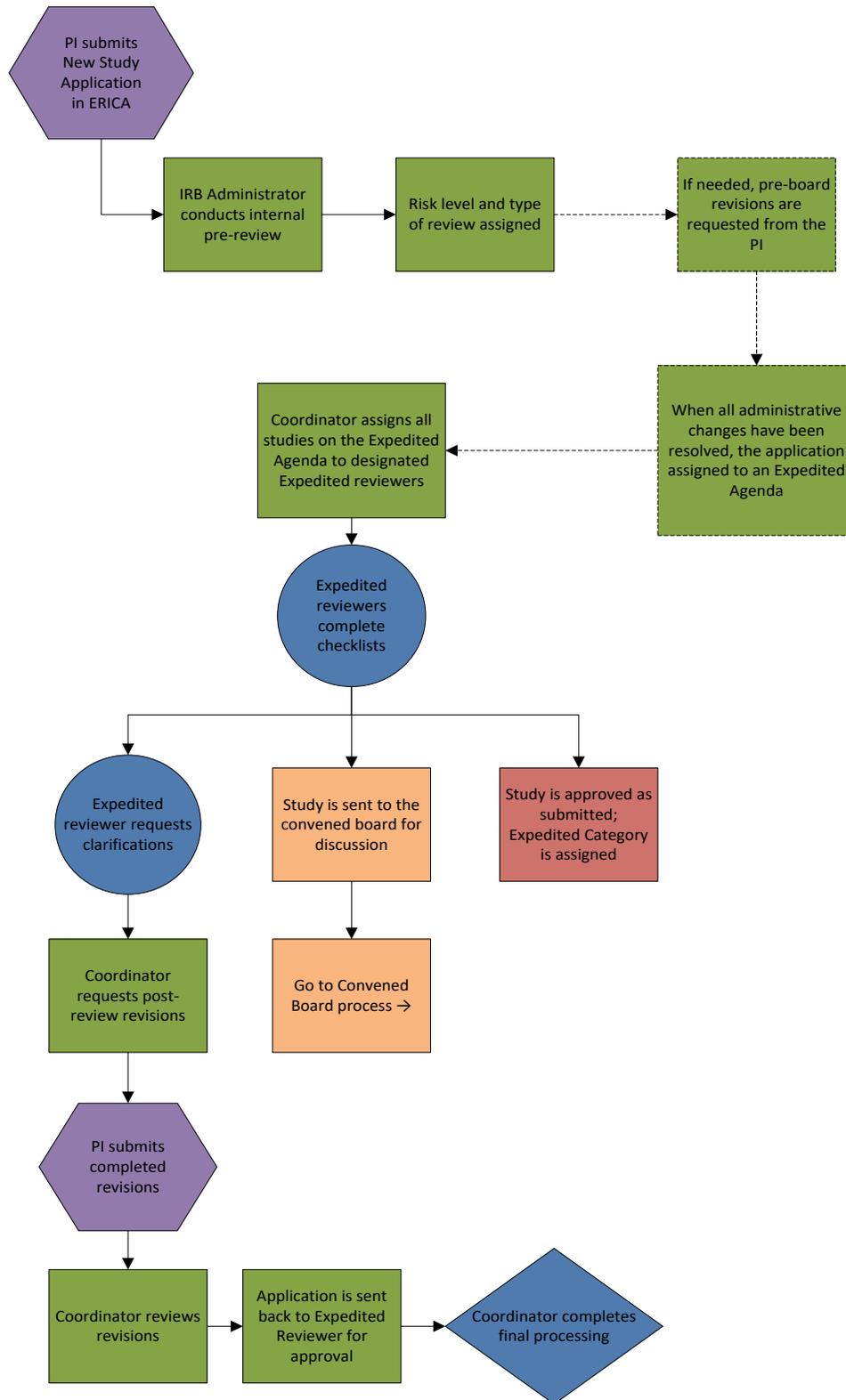
Please note that the term “expedited” has been known to be a bit confusing. The term is not intended to relate to the amount of time it takes to gain approval – sometimes, Expedited studies take *longer* to gain approval than discussed studies do – but, IRB coordinators do their best to make this the exception and not the rule. “Expedited” actually refers to the fact that the review type only requires one board reviewer to approve it, instead of a vote of approval by a convened panel of board members.

Because expedited studies are not discussed at the convened board meetings, more communication with your IRB coordinator is required for the expedited review process to be successful. After the expedited study is assigned to you, you should complete your Board Reviewer Checklist review by the day of the board meeting. Contact your IRB coordinator if you are unable to complete your checklist by the end of the board meeting so arrangements can be made, if necessary.

The IRB coordinator will contact you if clarifications or revisions are required for the study. Once the PI submits any required revisions, the expedited study is sent back to you to approve. There is an “Approve” activity in ERICA that will allow you to do this. Then, the study will go into the “Final Processing” state, and the IRB coordinator will finish the approval process.

Tip: If the IRB coordinator notifies you that the study is ready for you to click “Approve”, but no “Approve” button is available, contact your coordinator as soon as possible; this problem is usually easily remedied.

Expedited Study Application Process



Expedited Review of Research

Research activities may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110.

All of the following must be true in order for the application to be eligible for expedited review:

1. The research falls into one or more of the expedited categories.
2. The research or remaining research involves no more than minimal risk to the participants or the research falls into category 8(b) outlined below.
3. The research or the remaining research procedures do not involve procedures where the identification of the subjects or their responses will place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal or the research falls into category 8(b) outlined below.
4. The research is not classified (i.e. research is not subject to government secrecy laws).

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Note: The activities listed in the Expedited Categories should not be deemed to be of minimal risk simply because they are listed. Inclusion on the list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

Expedited Review Categories

1. **Clinical studies of drugs and medical devices only when condition (a) or (b) is met:**
 - a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
 - b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. **Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:**
 - c. From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml [37 Tbsp] in an 8 week period and collection may not occur more frequently than 2 times per week; or
 - d. From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml [3.4 Tbsp] or 3 ml per kg [0.28 tsp per lb] in an 8 week period and collection may not occur more frequently than 2 times per week.
3. **Prospective collection of biological specimens for research purposes by noninvasive means. Examples:**
 - e. Hair and nail clippings in a non-disfiguring manner;
 - f. Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
 - g. Permanent teeth if routine patient care indicates a need for extraction;
 - h. Excreta and external secretions (including sweat);
 - i. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue;
 - j. Placenta removed at delivery;
 - k. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
 - l. Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
 - m. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
 - n. Sputum collected after saline mist nebulization.
4. **Collection of data through noninvasive procedures** (not involving general anesthesia or sedation) **routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.** Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) **Examples:**

- o. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
 - p. Weighing or testing sensory acuity;
 - q. Magnetic resonance imaging;
 - r. Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
 - s. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
5. **Research involving materials** (data, documents, records, or specimens) **that have been collected, or will be collected solely for nonresearch purposes** (such as medical treatment or diagnosis).
6. **Collection of data from voice, video, digital, or image recordings made for research purposes.**
7. **Research on individual or group characteristics or behavior** (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) **or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.**
8. **Continuing review of research previously approved by the convened IRB as follows:**
- t. Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
 - u. Where no subjects have been enrolled and no additional risks have been identified; or
 - v. Where the remaining research activities are limited to data analysis.
9. **Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.**

Waivers

Regulations and Overview

Federal regulations require both an informed consent process and documentation of informed consent. 45 CFR 46.116 outlines the general requirements for informed consent. The regulations allow for a waiver or alteration of some or all of the elements of informed consent. The regulations also allow for a waiver of documentation of informed consent in some cases.

The IRB application allows for investigators to request such waivers. In turn, the IRB will evaluate each request on a case-by-case basis and may grant the waiver(s). The IRB or designated reviewer must make the required findings according to the regulations (§46.116(c)(d)) in order to grant the waiver or alteration. The findings are documented in the board reviewer checklist or during the board discussion.

Consent Verses Authorization

When considering waivers, it is important to understand the difference between *consent* and *authorization*. When a participant signs a consent document, they are affirming that they have read the information presented in the consent document, and they are voluntarily agreeing to take part in the research study.

Certain studies that include Protected Health Information (PHI) require additional agreement from the participant to “authorize” the researchers to use and disclose health information about the participant for the study (see “Health Insurance Portability and Accountability Act of 1996 (HIPAA)” in the Glossary for more information).

Most Main Campus studies do not require that the researchers obtain authorization for the use of PHI, because they often do not use or record participant health information as a part of the research. Research that takes place within the Covered Entity (e.g. medical research) usually involves PHI, and so authorization is generally required. The “Authorization for Use of Protected Health Information” section of the consent document template (available on the IRB website) includes the language required to obtain authorization from patients.

Waivers Quick Reference

The following is a brief overview of the types of waivers that may be requested, where in the application they are requested, and common examples of situations where it may be appropriate to grant the waiver(s).

Waiver of Informed Consent:

Description: No contact with participants and no documentation of consent.

Example: Chart or archived record review.

New Study Application:

1. **Study Information Page #5, How will consent be obtained?:** Select “Waiver or Alteration of Informed Consent”.
2. **Request for Waiver or Alteration of Consent Page:** Select “Waiver of

<p>Informed Consent” under “Type of Request” and complete the rest of the page.</p>
<p>Alteration of Informed Consent: <i>Description:</i> Specific elements of informed consent are removed or altered. A consent document is still used. <i>Example:</i> When a study uses deception, the researcher may need to remove or alter an element of consent (e.g. the actual purpose of the research).</p> <p>New Study Application:</p> <ol style="list-style-type: none"> 1. Study Information Page #5, How will consent be obtained?: Select “Consent Document” and “Waiver or Alteration of Informed Consent”. 2. Request for Waiver or Alteration of Consent Page: Select “Alteration of Informed Consent” under “Type of Request” and complete the rest of the page. 3. Consent Process Page: Complete this page entirely. 4. Documents and Attachments Page: Attach a consent document altered as requested in the waiver. 5. Documents and Attachments Page: If applicable, attach a debriefing form in addition to the consent document.
<p>Waiver of Documentation of Consent: <i>Description:</i> Consent is obtained, but no documentation of consent (i.e. signature) is required. <i>Example:</i> A questionnaire cover letter or web-based consent with no signature block where submitting the completed questionnaire constitutes consent to participate in the research.</p> <p>New Study Application:</p> <ol style="list-style-type: none"> 1. Study Information Page #5, How will consent be obtained?: Select “Consent Document”. 2. Consent Process Page #8, Waiver of Documentation of Consent: Select “Yes” and complete Sections 8a and 8b. 3. Documents and Attachments Page: Attach a consent document with the signature block omitted as requested in the waiver.
<p>Waiver of Authorization: <i>Description:</i> Waives the requirement for authorization for all uses of Protected Health Information (PHI) for a particular study, or a particular aspect of a study. This waiver is only applicable if the study involves PHI. <i>Example:</i> Investigator uses medical records for screening or recruitment purposes, or to identify potential eligible participants to invite them to participate. Also commonly requested for chart or medical record reviews where there is no prospective contact with participants.</p> <p>New Study Application:</p> <ol style="list-style-type: none"> 1. HIPAA and the Covered Entity Page, #1a, Authorization: Select “Waiver of Authorization”. 2. Request for Waiver of Authorization Page: Complete this page entirely. 3. Documents and Attachments Page: If participants will be contacted for participation in research, attach the appropriate consent document(s).

If you need assistance determining which consent process is appropriate for a study, please contact the IRB staff.

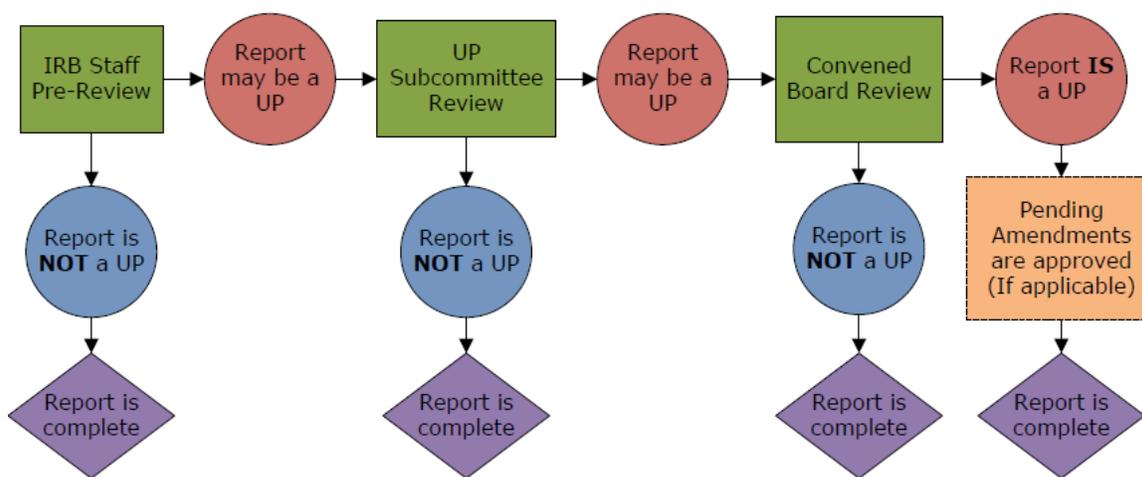
Report Forms

The Report Form (RF) application is used to submit problems, events, or information to the IRB for review. The convened board is the only body that can conclusively determine that an event is an Unanticipated Problem (UP), or that a report of non-compliance represents serious or continuing non-compliance. If the RF is determined to be a UP or a significant compliance issue, corrective actions/sanctions will be imposed and any required Amendments will be requested.

Level of Review

First, the report is reviewed at the **administrative level**. The IRB staff may determine that the report is NOT a UP, but cannot determine that the report IS a UP. If the member of the IRB staff believes the report may be a UP, the report is forwarded to the UP Subcommittee.

Next, the **Subcommittee** member reviews the report and may determine that the report is NOT a UP, but cannot determine that the report IS a UP. If the member of the UP Subcommittee believes the report may be a UP, the report is forwarded to the Convened Board for a final determination.



Convened Report Forms

When the Report Form has been assigned to the board reviewer, a Reviewer Checklist is completed for the form, and determinations must be made:

Unanticipated Problem Assessment:

- The problem, event or information described in this report **[is/is not] expected** (by the researcher or the research participant) given the research procedures and the subject population being studied.
- The problem, event or information described in this report **[is/is not] related** or probably related to participation in the research or the problem probably or definitely affects the safety, rights and welfare of current participants.
- The problem, event or information described in this report **[does/does not]** suggest that the research places subjects or others at a **greater risk of harm** (including physical, psychological, economic or social harm) than was previously known or recognized.

Item “a” must be “is not”, “b” must be “is”, and “c” must be “does” in order for the Report to be considered a UP.

Non-Compliance Assessment: The board reviewer must describe the justification that the report does or does not represent serious or continuing non-compliance.

Note: It is important to note that the board does not vote to *approve* the Report Form. Rather a *determination* is made regarding whether or not the RF represents a UP or serious non-compliance issue. Any documents that are attached to the RF will not be approved by the IRB (e.g. protocol summary, consent documents, etc.). If the study team needs a revised document approved as a result of the reported event, they must submit an Amendment application and link the Amendment to the RF.

Non-UP Determination Notification

If the board determines that the RF is NOT a UP or does NOT represent serious or continuing non-compliance, then a simple notification is sent to the study team and no further action is required.

	<p>The report, [name of report], has been reviewed by the [IRB staff/subcommittee/convened board] and has determined that it does not represent an unanticipated problem involving risks to participants or others. Please note that you must still provide a description of this problem, event or information in your next application for continuing review.</p>	
<ul style="list-style-type: none"> ▪ This is the notification the study team will receive if the RF is determined to NOT represent a UP or significant non-compliance issue. 		

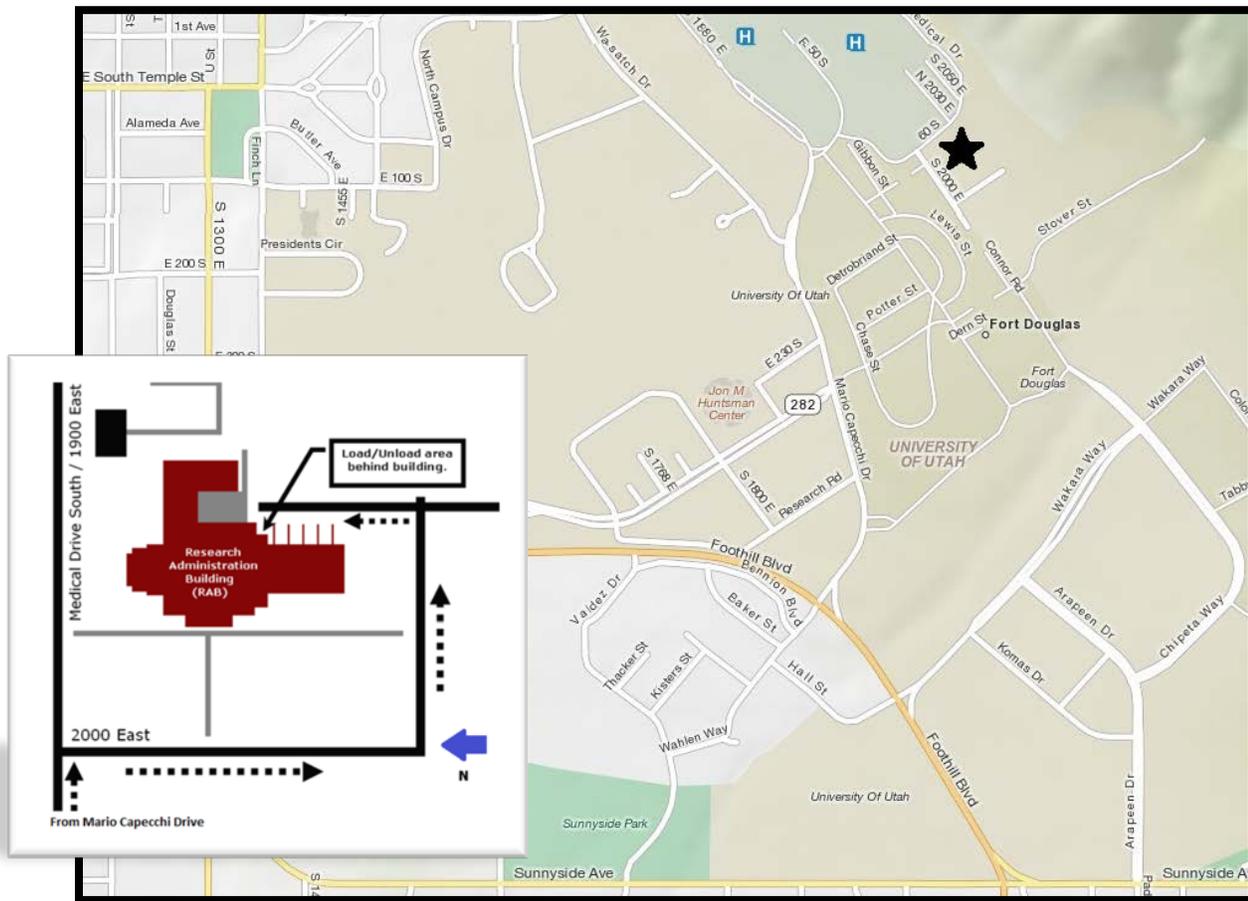
UP Determination Notification

If the panel finds that the report is a UP, the study team, OHRP, the FDA, the study sponsor, etc., are notified as applicable. If the panel required changes to the protocol as a result of the UP, the study team will be notified that they are required to file the appropriate Amendment Application. If the study team has already filed an Amendment as a result of the report, the Amendment will be linked to the report in ERICA, but the Amendment will be approved separately (i.e. two votes will be required).

Whenever possible, any amendments that are filed as a result of the UP determination will be reviewed by the same panel that reviewed the Report Form.

The Board Meeting

Map to the IRB



Call: (801) 581-3655 for assistance or additional directions.

Visit: <http://www.map.utah.edu/index.jsp> for the University of Utah interactive campus map.

Visitor Parking

Research Administration Building

75 South 2000 East

- The corner of South Medical Drive and 2000 East (the Northwest corner of the RAB)



Continue on South Medical Drive up the hill.

- The RAB will be on your right.
- You will be able to see the multi-level parking terrace coming up on your left.



Turn left onto 2030 East.



Enter the Health Science Parking Center (HSCPT) from the ground level.

- Get an entrance ticket on your way through the gate.
- The IRB will provide you with hourly validations as needed.



Research Administration Bldg.
75 South 2000 East



Health Science Parking Center
55 South 2030 East

Parking

There is limited parking around the RAB for employees with current University of Utah “A” permits. There is also a visitor parking terrace across the street from the IRB building and the IRB provides parking validations for board members for the duration of the meeting. Don’t forget to keep track of your arrival time; request a parking validation sticker from the IRB Coordinator at the end of the meeting for each hour you are parked in a pay lot.

Lunch

Lunch is provided at the monthly board meetings. If you have specific dietary preferences or food allergies, please inform your IRB Coordinator so arrangements can be made.

Board Room Layout



When you enter through the front doors of the Research Administration Building, the board meeting will be in Conference Room 111 straight ahead. Tables on the right as you enter the board room will have the lunch spread for the meeting ready; help yourself at your leisure.

Feel free to sit anywhere on the south, west, or north sides of the room. The table on the east side of the room will have 3 chairs set up; one for the IRB coordinator, one for the IRB administrator, and one for the IRB chair. These seats, as well as any others reserved for guests or other individuals, will be designated with tent card nameplates. Your IRB coordinator will have a nameplate ready for you; don’t forget to pick yours up on the way into the room; it will help your fellow board members learn who you are.

No paper materials are typically used in IRB Board Meetings. Most board members will bring their laptop computers and read their reviews directly from their summary in the Board Reviewer Checklist in ERICA. There are electrical outlets provided on the tables for your laptop computer. If you need paper copies of any of your review materials, your IRB Coordinator can arrange to have them printed or copied for you.



What to Do if You Have a Conflict of Interest

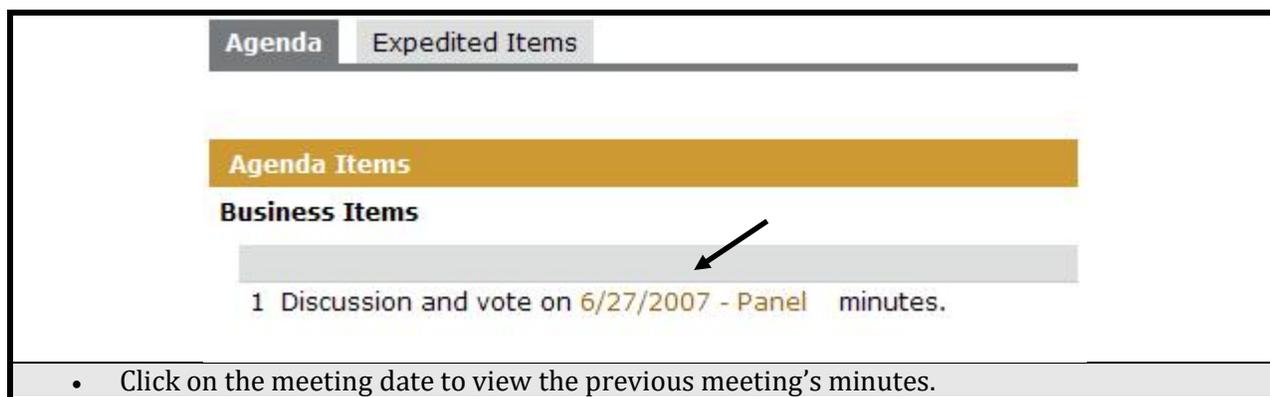
After the IRB chair calls the meeting to order, s/he will remind the Board Members to declare any potential conflicts of interest they may have with research that is about to be reviewed at the meeting. It is important to review the agenda for any conflicts (including financial conflicts of interest with sponsors, or if you are a member of the study team). If you have a potential or perceived conflict of interest with research specifically assigned to you for review, please contact your IRB coordinator before the meeting so the item can be re-assigned to another member of the panel. Once the item comes up for discussion at the meeting, inform the IRB chair that you are stepping out of the room because you have a conflict of interest. You will be asked to excuse yourself during the discussion and vote of the affected research. Once the vote has concluded for that item, you will be asked to come back into the room.

The Agenda

The agenda for your board meeting can be accessed when you log into the ERICA system. You should find a list of Board Meeting dates on the left side, on your “MY HOME” screen. By clicking on the appropriate meeting date, an agenda will populate that lists all of the items up for review at your particular meeting.

How to Read the Agenda

The first section of the Agenda will list all of the business items that require discussion and/or a vote. Typically, the minutes from the previous month’s meeting will be listed here.



Note: Each panel member should carefully review the minutes for studies that were assigned to them during the previous month. Any omissions or corrections should be forwarded to your IRB Coordinator prior to the board meeting or requested during the discussion. The minutes are considered the official documentation of the meeting, and each section must accurately reflect the discussion that occurred.

The IRB chair will call for a motion to approve the minutes. Once the minutes are approved, the discussion will move on to the discussed studies. It is appropriate to abstain during the vote to approve the minutes if you did not attend the meeting that the minutes discuss.

Order of Discussion

It is recommended that board members browse through the entire discussed agenda before the meeting to get an idea of the issues that will be discussed. Any pertinent comments can be posted in ERICA by using the “Board Member Comments” activity on the study page.

The order of discussion typically begins with New Studies, then Continuing Reviews and Amendments.

Typical Agenda Order:

- Minutes from last month's meeting
- Tabled New Studies (if applicable)
- New Studies
- Tabled Continuing Reviews (if applicable)
- Continuing Reviews
- Report Forms
- Tabled Amendments (if applicable)
- Amendments
- Any Expedited studies that require discussion

New Studies require more detailed reviews and usually entail more complicated discussion, so be prepared to discuss these first when you are assigned as the reviewer. Also, New Studies will have a "secondary reviewer", usually a citizen representative assigned to review the consent documents for readability and clarity. The primary reviewer will also need to review the consent documents for content and consistency, but be aware that the secondary reviewers' comments will be included in the discussion, as well.

Continuing Reviews are continuing reviews of studies previously-approved by the IRB, and are usually less complex to review, unless significant changes have been made to the protocol, study procedures, or consent documents. The board will look at how enrollment has been progressing, any results that have come from the research, and adverse events that have been reported, and any amendments to the study that are submitted with the Continuing Review.

If there are any **Report Forms** to be discussed, a member of the panel that is trained to review this type of application will present it. Report Forms are discussed in more detail earlier in this book.

Amendments are discussed last, and can be simple or complex depending on the study and the type of change being requested.

After all of the discussed items have been covered, the IRB Chair will ask if there are any issues with the **Expedited Agenda** that need discussion. If no issues exist regarding Expedited studies, the meeting is adjourned until the next month.

Writing a Review Summary

Description

This document includes descriptions of the information that should be included in a review summary. Board members should use this guidance and their reviewer checklists as a guide when preparing their review summaries. This document addresses the following types of reviews:

- New studies
- Continuing reviews
- Reports
- Amendments

A review summary should take 1 – 2 minutes to present to the Board. Additional discussion from board members may occur after the summary is presented. At the end of each review presented to the Board, the board reviewer must make a recommendation regarding approval or other determination for the study.

New Studies

Main Summary:

- Summarize the purpose, design, and procedures of the study (typically 1 – 3 paragraphs).
- Summarize any significant risks.
- Summarize recruitment procedures (typically 1 – 3 sentences).
- Summarize consent process and documentation (typically 1 – 3 sentences).
 - Discuss unique consent processes.
 - Always state how consent will be obtained.
- Mention plans for data and safety monitoring, when applicable.
- Mention extra precautions to protect privacy and confidentiality.
 - Mention when there is an increased risk to privacy and confidentiality compared to a normal study.
- Summarize any concerns about the study or topics that need board discussion and provide specific revisions that are necessary.

Vulnerable Populations:

Describe any vulnerable populations which are involved. Additional points that may need to be mentioned include:

- Children:
 - What ages are included?
 - What is the assent process?
- Cognitively Impaired Adults:
 - What are the circumstances or nature of the impairment (e.g. coma, permanent mental impairment, sedation, etc.)?
 - What is the consent/assent process?
- Pregnant Women:
 - How long will they be enrolled (e.g. the entire pregnancy, portion of the pregnancy, after the birth, etc)?
 - Is the research studying the woman or the pregnancy?

Continuing Reviews

Main Summary:

- Summarize the purpose of the study (1 – 3 sentences).
- Summarize the study's enrollment status:
 - Open, closed, suspended, over- or under-accrued
- Summarize the event/problem reports.
 - Have any of these events/problems been significant?
 - State whether or not these events/problems have been reviewed by the IRB
- Mention any DSMB findings in the last year, if applicable.
- Amendments with the continuing review:
 - Give a *short* summary of the amendment and if the change is appropriate
 - State whether or not the risk:benefit ratio has changed.

Reports

Main Summary:

- Summarize the purpose of the study (1 – 3 sentences).
- Describe the problem or event.
- Mention if an amendment has been submitted in conjunction with the report.
- Describe any corrective actions the investigator has implemented in response to the problem.
- State if any corrective actions need to be requested.
- Give the problem assessment, based on the checklist:
 - Does this problem or event represent an unanticipated problem involving risks to participants or others?
 - Does this problem represent serious or continuing non-compliance?

Amendments

Main Summary:

- Summarize the purpose of the study (1 – 3 sentences).
- Describe the changes that are being made.
- State whether or not the risk:benefit ratio has changed.
- State whether or not the changes are acceptable.

References & Links

*For more information regarding reviewer presentations, please refer to the **Institutional Review Board Member Handbook** by Robert Amdur, MD.*

Criteria for Approval

In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

- 1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- 2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
- 3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
- 4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116.
- 5) Informed consent will be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117.
- 6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- 7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- 8) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

Tabled Studies

A tabled study is an application that has been recently reviewed by one of the four IRB panels, but the panel felt that further information or clarification was required before a determination could be made about the study. If the tabled study is up for discussion again, this means that the PI and study team has made revisions or clarifications to the application, and now believes the study is ready for a follow-up review.

Any type of application that is discussed by the convened board may be tabled for any number of reasons, and the IRB coordinator will follow-up with the board reviewers and the study team throughout the tabled period in an attempt to correct the application and get it ready for board again as soon as possible. Except in special circumstances, a tabled study must be reviewed again by the same panel and same board reviewer that originally reviewed it.

The regulations specify criteria for approval. If there is something missing or unclear in the application that does not allow the board to make a definitive decision regarding any of the criteria for approval, the study should be tabled. Board reviewers make the initial motion to table a study, and the convened board will discuss the motion and vote.

See the section titled "Examples of Reasons to Table a Study" for a list of several issues that commonly result in the tabling of application. **Please note that the section is not meant to be all-inclusive.** There are other problems that may warrant tabling a study. Contact your IRB coordinator if, after contacting the study team to try and resolve the application deficiency, you still believe a study should be tabled.

Requesting Revisions

Clarifications should be made to be as specific as possible. Revisions that begin with, "Please clarify..." or "Explain in the application..." are usually too broad for someone to determine whether or not the change provided is one that the IRB wanted. If you anticipate tabling a study application, please be prepared to make specific revision requests that will result in an approvable application. Also, be prepared to review the revisions before the next time the study is discussed at the convened board.

Example 1:

- "Please describe the mechanism for ensuring that women are not pregnant when they are enrolled."

This is an example of a vague revision request where the IRB must be more specific. If the investigator responds, "I will ask potential participants if they think they might be pregnant," this would raise more questions, such as:

- Would the IRB find this response acceptable?
- Are urine pregnancy tests acceptable?
- Are blood tests required?

The answers could be affirmative or negative, depending on study procedures, budgetary concerns, study staffing concerns, etc. A more specific revision request follows:

- *"Please indicate that a negative urine pregnancy test at the time of enrollment is required to participate."* or *"Please indicate that women must state that they are not pregnant as a condition of participation."*

Example 2:

- "Please explain how long specimens will be kept and what type of tests might be conducted on them."

If the IRB does not know this information, then the protocol should come back to the convened IRB. If the IRB knows this information, then the board reviewer should read this information into the minutes.

A more specific revision request follows:

- *"Describe how the samples will be handled as indicated on page 7 of the Protocol Summary, how long the samples will be retained as indicated on page 5 of the Protocol, and what will happen to the samples after the study is completed as indicated on page 9 of the Protocol."*

Examples of Reasons to Table a Study

General Problems	Basis for Tabling the Study
Recruitment materials not attached to the application, and/or the Administrative Responsibilities section in the Protocol Summary does not describe the recruitment procedures (e.g. what materials will be used, how potential participants will be contacted, etc.).	The board cannot determine whether the selection of subjects is equitable. The IRB does not know whether the circumstances minimize the possibility of coercion and undue influence.
Significant revisions required in the Consent, Parental Permission, or Assent Documents.	The board cannot determine that the requirements of informed consent are met.
Consent procedures involved in the study are not described (e.g. when and where consent is obtained, who is available for questions, etc.).	The board cannot determine how consent will be obtained and if it will be documented appropriately.
The study requires that a DSMB be in place, and no DSMB is discussed in the Protocol Summary.	The board cannot determine that adequate provisions are made for monitoring the data collected to ensure the safety of subjects.
The risk-benefit ratio cannot be adequately determined with the information provided in the application and documents.	The board cannot determine that risks to subjects are minimized and that the risks are reasonable in relation to benefits.
Clarification regarding the design of the study, or the participant inclusion/exclusion criteria is needed.	The board cannot determine that risks to subjects are minimized if the design is unclear. The board cannot determine whether the selection of subjects is equitable.

Ancillary Committees

In order to receive IRB approval, it may be necessary to provide information to and/or receive ancillary approval from one of the entities below. Please see http://www.research.utah.edu/irb/submissions/ancillary_req.html for a links to all of the ancillary committees.

Huntsman Cancer Institute Project Review & Monitoring Committee (HCI PRMC)

The PRMC was established to provide scientific review for all cancer trials as required by National Cancer Institute (NCI) Cancer Center Support Grant (CCSG) guidelines. All clinical trials at the University of Utah that involve cancer patients or subjects at risk for cancer (screening or prevention studies) must undergo an initial review by the PRMC. Two reviewers with no involvement in the trial under review, a biostatistician, a research pharmacist, a research nurse, and a patient advocate provide written reviews. (Source: <https://healthcare.utah.edu/huntsmancancerinstitute/clinical-trials/clinical-research-committee.php>).

Radioactive Drug Research Committee – Human Use Subcommittee (RDRC-HUS)

The following is an excerpt from RPR 48: *Radioactive Drug Research Committee and Human Use Subcommittee of the Radiation Safety Committee* (Version 3/2002):

In accordance with **Food and Drug Administration (FDA)** regulations, the **Radioactive Drug Research Committee (RDRC)** is empowered and required to evaluate and to approve or disapprove all research and developmental uses of radioisotopes on or in humans. The **RDRC** also serves as the **Human Use Subcommittee of the Radiation Safety Subcommittee (HUS)**. As required by **Utah Division of Radiation Control**, the **HUS** evaluates and approves or disproves all proposed uses of ionizing radiation sources on or in humans for investigational or non-routine clinical procedures.

All research applications for use of ionizing radiation sources in human research studies submitted to the **RDRC-HUS** also shall be submitted to, evaluated by, and approved or disapproved by the **Institutional Review Board (IRB)**. Human research studies involving ionizing radiation sources shall not begin until approval of the **IRB** and **RDRC-HUS** is obtained.

(Source: <http://www.rso.utah.edu/>).

Approval by the RDRC ancillary committee is required before final IRB approval. RDRC Approval may not be received prior to IRB Board Review. If it is not, and if RDRC requests changes to the Protocol Summary and/or Consent Form, the changes will have to be re-reviewed by the convened board prior to final IRB Approval.

The RDRC reviews studies using X-rays, CT (computed tomography) and CAT (computed axial tomography) scans, bone density scanning (also called dual-energy x-ray absorptiometry [DXA or DEXA scans]), MUGA scans, PET scans, skeletal surveys, Fluoroscopy, Iodine 131 Bexxar, mammograms, computed tomography coronary angiography (CTCA) scans, and any other procedures that involve radiation or radioactive substances (e.g., MRI with contrast agents).

Approval Requirements

The RDRC's approval process is built into ERICA. This means that once they have approved the study, the approval will be recorded in ERICA. If the RDRC requires changes to the study's consent documents, the IRB must review the changes. The RDRC will review and approve or exempt all new studies prior to the pre-review conducted by the IRB.

Resource for Genetic and Epidemiologic Research Committee (RGE)

The Resource for Genetic and Epidemiologic Research (RGE) governs access to certain data and research resources provided to the University of Utah for use in biomedical research. One set of data, the [Utah Population Database \(UPDB\)](#), includes family history records, vital records, cancer registry records, driver license records, and others. These records are linked together to form multi-generational pedigrees as well as longitudinal person-level data. Another set of data includes specimens and family and medical data from individuals enrolled in the High Risk Cancer Clinics (HRCC) at the Huntsman Cancer Institute at the University of Utah.

Access to these research resources requires review and approval by the RGE Review Committee and by the IRB. RGE approval is required before final IRB approval. (Source: <http://www.research.utah.edu/rge/>).

Approval Requirements

The RGE's approval processes for New Studies, Continuing Reviews, and Amendments are built into ERICA. This means that once they have approved the study, the approval will be recorded in ERICA. The RGE will review and approval all new studies, amendments, and continuing reviews prior to the pre-review conducted by the IRB.

Institutional Biosafety Committee (IBC)

Research proposals involving the deliberate transfer of recombinant DNA (r-DNA) or RNA derived from recombinant DNA into human subjects (human gene transfer) will be considered through a review process involving the University of Utah Institutional Review Board (IRB) and Institutional Biosafety Committee (IBC), as well as the NIH Office of Biotechnology Activities (OBA) and the Recombinant DNA Advisory Committee (RAC). (Source: <http://www.utahehs.org/index.php?tier=4&id=291>).

Veteran Affairs Salt Lake City Health Care System (VASLCHCS)

If a study includes patients and/or staff members as subjects as well as resources and time at the VA, there are specific requirements that must be met before applications will be approved. A complete list of all of the requirements is available on the IRB Website, but in general, VA studies require additional paperwork or verbiage in the application related to information security, and the VA requires that researchers use the VA's consent template for participants recruited at the VA. The VA also has specific training requirements for their researchers. The VA Research Compliance Officer will ensure that all of the VA requirements are met before issuing their ancillary approval in ERICA.

Primary Children's Hospital Privacy Board

Primary Children's Hospital (PCH) has an agreement with the University of Utah allowing the U of U IRB to review and approve clinical projects that take place at PCH. Patients treated at PCH are both Intermountain Healthcare (IHC) and U of U Department of Pediatrics patients. IHC does not recognize any external entity's authority to make a ruling on the adequacy of protections of Intermountain data, so IHC requires a Privacy Board review outside of U of U IRB review. The PCMC Privacy board will complete their review of an application before issuing their ancillary approval in ERICA. After the Privacy Board has issued its ancillary approval in ERICA, the application is forwarded to the IRB for review.

Vulnerable Populations

The IRB makes additional considerations when a study involves a vulnerable population. Members of the IRB who are experienced in working with these populations should be assigned to review studies which involve vulnerable populations.

Children

Approval Criteria for Research Involving Children

The IRB must make specific findings when approving research involving children. Children are defined by the federal regulations as persons who have not attained the legal age for consent to treatment or procedures involved in the research, as determined under the applicable law of the jurisdiction in which the research will be conducted. In Utah, unmarried individuals under the age of 18 are considered children as defined by DHHS and FDA regulations unless one of the exceptions listed below applies. In Utah, a person under the age of 18 is no longer considered a child as defined by DHHS and FDA regulations and Subpart D (21 CFR 50 and 45 CFR 46) does not apply if he or she is:

- Married;
- A member of the armed forces of the United States;
- “Emancipated,” a finding typically made by a court;
- Seeking treatment for one of the following conditions (provided that the research is directly related to one of these conditions):
 - A sexually transmitted disease (Utah Code 26-6-18);
 - Pregnancy or childbirth (Utah Code 78-14-5).

The IRB reviewer will use the reviewer checklist to document the required findings. The University of Utah IRB has categorized these findings as follows:

Category #1: Research not involving greater than minimal risk.	45 CFR 46.404 21 CFR 50.51
Category #2: Research involves greater than minimal risk but presents the prospect of direct benefit to the individual participants.	45 CFR 46.405 21 CFR 50.52
Category #3: Research involving greater than minimal risk and no prospect of direct benefit to the individual participants, but likely to yield generalizable knowledge about the participant's disorder or condition.	45 CFR 46.406 21 CFR 50.53
Category #4: Research not otherwise approvable, but which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. PLEASE NOTE: Research in this category can ONLY be approved if the Secretary of DHHS and the Commissioner of the FDA also review and approve the research.	45 CFR 46.407 21 CFR 50.54

Child Category 3

The Following must be true to approve a study under Child Category 3:

1. More than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual participant, or by a monitoring procedure, which is not likely to contribute to the well-being of the participant.
 - o The risk to the participant represents no more than a minor increase over minimal risk (for EACH procedure performed).
2. The intervention or procedure presents experiences to participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations.
3. The participants have a disorder or condition.
4. The intervention or procedure is likely to yield generalizable knowledge about the participants' disorder or condition which is of vital importance for the understanding or amelioration of the participants' disorder or condition.
5. The research does NOT involve wards of the State or any other agency, institution, or entity **OR** The research meets the criteria for involvement of wards of the State or any other agency, institution, or entity.

Pregnant Women, Human Fetuses, and Neonates

45 CFR part 46, Subpart B provides regulations for the additional protection for pregnant women, human fetuses, and neonates involved in research. Additional consideration is given to studies that include these populations, because of the inherent dangers to fetuses of some research procedures. The IRB reviewer uses the reviewer checklist to document findings when a study involves pregnant women, fetuses and neonates.

Prisoners

"HHS regulations at 45 CFR part 46, subpart C provide additional protections pertaining to biomedical and behavioral research involving prisoners as subjects... 'Prisoner' is defined by HHS regulations at 45 CFR part 46.303(c) as 'any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing'" (*OHRP Guidance on the Involvement of Prisoners in Research, 2003*).

When the IRB reviews a protocol involving prisoners as a vulnerable population, "at least one member of the IRB must be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity" (45 CFR 46.304(a) and (b)).

The IRB reviewer uses the reviewer checklist to document findings when a study involves prisoners.

(Source: <http://www.hhs.gov/ohrp/humansubjects/guidance/prisoner.htm>).

Mentally Disabled Persons or Participants with Diminished or Impaired Decision-Making Capacity

Current federal regulations have not been adopted by either the FDA or DHHS for studies involving adult subjects who have diminished decision-making capacity. However, the University of Utah Institutional Review Board has written policy regarding this vulnerable population as detailed below.

Research involving persons with impaired decision-making capability may be approved when the IRB finds:

- The investigator demonstrated that there is a compelling reason to include incompetent individuals or persons with impaired decision-making capacity as subjects;
- The proposed research entails no significant risks, or if the research presents some probability of harm, there must be at least a greater probability of direct benefit to the participant. (Incompetent people or persons with impaired decision making capacity are not to be subjects of research that imposes risk of injury, unless the research is intended to benefit the subject and the probability of benefit is greater than the probability of harm.); and
- Procedures have been devised to ensure that the participant's representatives are well informed regarding their roles and obligations to protect incompetent subjects or persons with impaired decision-making capacity.

Additionally, the board should consider if the following points should be required for approval of the study:

- The IRB should consider whether obtaining assent and informed consent from an authorized representative should be required, and whether periodic re-consenting is appropriate to ensure that a subject's continued involvement is voluntary.
- The IRB should consider whether reassessment of decision-making capacity is necessary.

Research involving mentally disabled who are less than 18 years of age is treated as other research with children as subjects. Other mentally disabled subjects must give informed consent, or assent if possible. If informed consent is not possible, mentally disabled subjects must have permission from parents or guardians. Where parents or guardians are unavailable, there will be an official court designated representative for the disabled subject.

All individuals with mental illnesses who have been determined to lack capacity to consent to participate in a research study must be notified of that determination before permission may be sought from his/her legally authorized representative (LAR) to enroll that person in the study. If permission is given to enroll such a person in the study, the potential subject must then be notified. Should the person object to participating, the participant's wishes will govern.

Legally Authorized Representatives (LAR)

In the event that the research involves adults unable to provide consent, a legally authorized representative (LAR) may be used. *Legally authorized representative* means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. *The IRB will accept consent from an LAR given that the PI has established that the consenting individual has legal authority to do so.* More information about using LARs in research can be found in the Investigator Guidance Series (IGS) which can be accessed on the IRB website.

Placebo Guidelines

If a placebo is part of the design of a study, the investigator must provide additional information to the IRB. The board members will use the information to determine whether the research is approvable considering the University of Utah Placebo Guidelines.

When the protocol is reviewed, the reviewer will use the reviewer checklist to document which situation the protocol fits under. When a study includes a placebo, the board reviewer is responsible for proposing to the board which of the accepted placebo guidelines the study may be approved under. Coordinators must document any additional discussion regarding placebo in the minutes.

The University of Utah IRB may accept placebo comparator under **any of the** following situations:

1. There are no established effective therapies for the population and for the indication under study; **
2. Existing evidence raises substantial doubt regarding the net therapeutic benefit of available therapies;
3. Participant(s) is/are refractory to the available therapies by virtue of their past treatment history of known medical history;
4. The study involves adding a new investigational therapy to an established effective therapy (established effective therapy + new therapy vs. established effective therapy + placebo);
5. Participants have determined that the response to the established effective therapies for their condition is unsatisfactory to them; or
6. Participants have previously refused established effective therapies for their conditions.
7. Minor health problems (This includes conditions for which both informed participants and their physicians might reasonably elect to withhold treatment (e.g., baldness, tension headache, allergic rhinitis).
8. Placebo cross-over designs will be evaluated on a study by study process.
9. The proposed placebo exposure is of a specified duration such that evidence supports the exposure as no more than minimal risk. Such cases will be reviewed by the IRB on a case by case basis.

** As determined by the Board

Frequently-Asked Questions from Board Members

- **What Departments are inside the Covered Entity?**
 - See: <http://privacy.utah.edu/intranet/internal/admin/coveredentity.html>.
- **How many reviews will I have to complete each month?**
 - Typically, board members will receive 6 reviews or less per month. This is usually a mix of New Studies, Continuing Reviews, Report Forms and Amendments, some of which will be expedited reviews (if you are a designated Expedited Reviewer). During peak months where applications are heavier (usually mid-summer and December), you may be assigned more studies, but your IRB coordinator will do everything possible to prevent this.
- **What should I do if I would like to contact the PI or study team but I don't want my identity known?**
 - Your IRB coordinator is happy to act as a “go-between” in cases like this. Coordinators assume you wish to be kept anonymous when contacting PI's about other issues, and only refer to “the Board Reviewer” or “the Board” when discussing issues or decisions made regarding their applications. If you would like to remain anonymous, please make this clear to your coordinator.
- **How many meetings am I able to miss per calendar year?**
 - The IRB asks that you miss no more than 3 meetings per year.
- **If I am unable to attend my board meeting during a given month, will I still be assigned to review studies that month?**
 - If you are unable to attend your panel's meeting during a given month, you may arrange to attend another panel's meeting during another week, or, if you are a designated Expedited reviewer, you may be assigned to only review Expedited studies that month.
- **The PI for the study I'm reviewing is a co-worker of mine. Can I still review the study?**
 - Yes, if you are not a part of the study team, and you feel you can review the study objectively, you can still review the application.
- **What are the Placebo Guidelines? What are the Genetic and Tissue Banking Guidelines?**
 - All of the guidelines are posted on the IRB website at: <http://irb.utah.edu/guidelines/investigator.php>. If you have specific questions relating to an application you are reviewing, contact your IRB Coordinator for guidance.
- **How long will I have to complete my reviews?**
 - Your IRB Coordinator will assign the studies at least one week before the meeting. You are encouraged to complete your reviews early so you have time to work out any problems with the study team prior to the meeting to help prevent tabling the study.
- **What do I do if I find a significant problem in a study I am reviewing?**
 - Contact your IRB coordinator immediately. You can work with the coordinator and the PI to get a solution to the problem before the meeting. If the problem cannot be addressed before the meeting, prepare a list of direct questions and/or actions that need to be addressed by the PI.

- **What should I do if I cannot attend my board meeting during a specific month?**
 - Inform your IRB coordinator that you will be absent.
- **What should I do if I will be late to a board meeting, or if I need to leave the meeting early?**
 - Contact your IRB coordinator and let him/her know what time you will be at the meeting. The coordinator will arrange for your studies to be discussed during the time you are at the meeting.
- **What should I do if there isn't an "Approve" button when I try to approve an Expedited study?**
 - Email or call your IRB coordinator and give him/her the IRB number of the study you are trying to approve. The coordinator will make the necessary adjustments to the Internal Checklist so that the "Approve" activity will appear.
- **What should I do if I do not feel I have the appropriate expertise to review a study that is assigned to me?**
 - Contact your IRB coordinator. The coordinator will re-assign the study to another reviewer.

As always, never hesitate to contact the IRB Staff – we are here to assist you!

Glossary

A more comprehensive version of this Glossary can be found at the IRB website: <http://irb.utah.edu/glossary.php>

45 CFR 46. Title 45, Part 46 of the Code of Federal Regulations, Protection of Human Subjects. Most recently updated in June 1991 (Subpart B in 2002), these regulations govern human subjects research conducted by all federal agencies. Together, this body of regulations governs the conduct of human subjects research today.

Belmont Report. A statement of basic ethical principles governing research involving human subjects issued by the National Commission for the Protection of Human Subjects in 1978.

Certificate of Confidentiality. A document that provides additional protection of data from legal subpoena. The Certificate provides protection against compelled disclosure of identifying information or other identifying characteristics of a research participant enrolled in biomedical, behavioral, clinical, and other forms of sensitive research.

Clinical Cancer Investigation Committee (CCIC). Reviews cancer-related protocols for scientific merit and progress, including participant accrual. It also prioritizes cancer protocols that may compete for the same patient population. Its function is complementary to that of the Institutional Review Board, which focuses on the protection of human subjects. All cancer-related studies require CCIC approval before final IRB approval.

Clinical Trial. A prospective study involving human subjects designed to answer specific questions about the effects or impact of particular biomedical or behavioral interventions; these may include drugs, treatments, surgical procedures, devices behavioral or nutritional strategies (Note that not all human research studies are clinical trials-see human subjects research).

Phase 1 Trial. Includes the initial introduction of an investigational new drug into humans. These studies are typically conducted with healthy volunteers. Phase 1 trials are designed to determine the metabolic and pharmacological actions of the drug in humans, the side effects associated with increasing doses (to establish a safe dose range), and, if possible, to gain early evidence of effectiveness. The ultimate goal of Phase 1 trials is to obtain sufficient information about the drug's pharmacokinetics and pharmacological effects to permit the design of well-controlled, sufficiently valid Phase 2 studies. Other examples of Phase 1 studies include studies of drug metabolism, structure-activity relationships, and mechanisms of actions in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes.

Phase 2 Trial. Includes controlled clinical studies conducted to evaluate the drug's effectiveness for a particular indication in patients with the disease or condition under study, and to determine the common short-term side effects and risks associated with the drug. These studies are typically well controlled, closely monitored, and conducted with a relatively small number of patients, usually involving no more than several hundred subjects.

Phase 3 Trial. Involves the administration of a new drug to a larger number of patients in different clinical settings to determine its safety, efficacy, and appropriate dosage. They are performed after preliminary evidence of effectiveness has been obtained, and are intended to gather necessary additional information about effectiveness and safety for evaluating the overall benefit-risk relationship of the drug, and to provide an adequate basis for physician labeling. In Phase 3 studies, the drug is used the way it would be administered when marketed. When these studies are completed and the sponsor believes that the drug is safe and effective under specific conditions, the sponsor applies to the FDA for approval to market the drug. Phase 3 trials usually involve several hundred to several thousand patient-subjects.

Code of Federal Regulations (CFR). The Code of Federal Regulations is an annual codification of the general and permanent rules published in the Federal Register by the executive departments and agencies of the Federal Government. The CFR is divided into 50 titles representing broad areas subject to Federal regulation. Each Title is divided into chapters that are assigned to agencies issuing regulations pertaining to that broad subject area. Each chapter is divided into parts and each part is then divided into sections -- the basic unit of the CFR. The purpose of the CFR is to present the official and complete text of agency regulations in one organized publication and to provide a comprehensive and convenient reference for all those who may need to know the text of general and permanent Federal regulations (National Archives).

Collaborative IRB Training Initiative (CITI). An internet-based set of educational modules on the protection of human participants in research. It is sponsored by a consortium of IRB professionals and researchers from universities and medical schools across the country and is administered by the University of Miami.

Company Protocol: This is the study plan provided by a sponsor of a study. Not all studies will include a protocol, but studies that involve investigational drugs; investigational devices will always have this document. Other privately-sponsored studies may also include these.

Conflict of Interest. The real or apparent interference of one person's interests with the interests of another person, where potential bias may occur due to prior or existing personal or professional relationships.

Consent Document(s). Commonly referred to as “ICF, or Informed Consent Form.” These are the documents presented to a subject or parent guardian prior to beginning a study. Most studies will have this document submitted with the proposal, unless requesting a Waiver (see below). The IRB has provided a template on the web site for investigators to prepare their documents.

Adult Informed Consent. This is required when subjects are 18 years and older. This should be written to the subject using appropriate language (“you”).

Parental Permission Document. This is required when subjects are 17 years and younger. This should be written to the parent/guardian using appropriate language (“your child”).

Assent Document. Assent is an agreement by an individual not competent to give legally valid informed consent (*e.g.*, a child aged 7+ or cognitively-impaired person) to participate in research. This is required for children enrolled in studies that are 7-17 years of age. If the board deems appropriate, this can be requested for younger children.

Data and Safety Monitoring Board (DSMB). A committee of scientists, physicians, statisticians, and others that collects and analyzes data during the course of a clinical trial to monitor for adverse effects and other trends (such as an indication that one treatment is significantly better than another, particularly when one arm of the trial involves a placebo control) that would warrant modification or termination of the trial or notification of subjects about new information that might affect their willingness to continue in the trial.

Expedited review. Review of proposed research by the IRB Chairperson or a designated voting member or group of voting members rather than by the entire IRB. Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research.

Final Project Reports: Once a study is completed, this form is submitted to close out the study.

Health Insurance Portability and Accountability Act of 1996 (HIPAA). To improve the efficiency and effectiveness of the health care system, the Health Insurance Portability and Accountability Act (HIPAA) of 1996, Public Law 104-191, included “Administrative Simplification” provisions that required HHS to adopt national standards for electronic health care transactions. At the same time, Congress recognized that advances in electronic technology could erode the privacy of health information. Consequently, Congress incorporated into HIPAA provisions that mandated the adoption of Federal privacy protections for individually identifiable health information.

HIPAA TERMINOLOGY:

Authorization. Permission from individuals to use or disclose their *Protected Health Information*; generally required for research involving *PHI*. Certain statements are required; similar to but in addition to the Common Rule’s informed consent; can be added to a consent form. (45 CFR 164.508)

Covered Entity. Defined as health care providers who conduct certain financial and administrative transactions electronically, such as billing and fund transfers; also, all health plans and health care clearinghouses. (45 CFR 160.103) Covered Entities must comply with HIPAA.

The University of Utah’s *Covered Entity* includes nearly all parts of the University of Utah Health Sciences Center. Contact the HIPAA Regulatory Office (587-9241) or go to <http://www.compliance.utah.edu/privacy/index.html> for information on the University offices that are inside or outside the *Covered Entity*.

Disclosure. The release, transfer, provision of access to, or divulging in any other manner of information outside the *Covered Entity* holding the information. (45 CFR 164.501)

Protected Health Information (PHI). Information about the past, present, or future physical or mental health of an individual that identifies or could be used to identify the individual and is created or received by a *Covered Entity*. (45 CFR 160.301, 164.501; information about the provision of health care and payment for health care is included; some educational and employment records are excluded.)

Humanitarian Use Device (HUD). An FDA regulated medical device intended to benefit patients in the treatment or diagnosis of a disease or condition, but not yet approved for unrestricted use. The use of a HUD is subject to IRB oversight.

Human Participants Research. This term applies to federally regulated research in which human participants (see definition above), their data, tissue, genetic material or other is investigated in a systematic fashion. It includes clinical trials, retrospective studies (subject to IRB oversight or exempt from continuing IRB oversight), outcome studies, surveys, etc.

Informed Consent. A process by which a subject voluntarily confirms his or her willingness to participate in a particular research project, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed, and dated informed consent form unless such documentation is waived by the IRB (ICH Guidelines 45 CFR 46).

A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence [Federal Policy §116; 21 CFR 50.20 and 50.25] (OHRP).

Institutional Review Board (IRB). A specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research.

Investigational New Drug (IND) or Device (IDE). A drug or device permitted by FDA to be tested in humans but not yet determined to be safe and effective for a particular use in the general population and not yet licensed for marketing.

Legally Authorized Representative (LAR). An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. There are several considerations that must be addressed when the inclusion of an LAR is proposed, such as, whether periodic re-consenting is warranted, and whether the probability of benefit is greater than the probability of harm.

Office for Human Research Protections (OHRP). The office under the Department of Health and Human Services responsible for implementing DHHS regulations (45 CFR 46) governing biomedical and behavioral/social science research involving human subjects.

Protocol Summary. This document is completed by the PI and includes a summary of the protocol or can be the study plan for the entire study. The IRB announced in late 2011 that the information collected in the Protocol/Research Summary forms was being integrated into the ERICA application, such that the Protocol/Research Summary would no longer be required as of early 2012.

Radioactive Drug Research Committee (RDRC). The University of Utah's radiation safety program is designed to prevent unnecessary radiation exposures, and to control those that are necessary. An ancillary committee to the University of Utah Institutional Review Board, which is responsible for the review and approval of research protocols involving human participants and radiation exposure, and the administration or use of radioactive drugs. Clinical investigations that include exposing human participants to radiation (x-rays, etc.) require RDRC approval before IRB approval may be granted.

Risk Determinations. Determinations are usually made by an administrator and a coordinator prior to board review. These can include:

Greater than Minimal Risk. The subject will undergo procedures that will increase their risks above those normally encountered in daily life. These can include but are not limited to clinical drug trials, device trials, genetic studies, risks that include insurability and employability.

Minimal Risk. The subject will undergo procedures that do not appear to increase the risks above those normally encountered in daily life. These can include but are not limited to studies that involve survey, questionnaire, interview, medical records review, observation of behaviors, drawing a small amount of blood from a healthy individual, etc.

Exempt. These studies are not usually reviewed by board members, but are reviewed by the chairman. These have been determined to fit certain federal regulations as exempt from IRB review.

Short Form Consent Document. The Short Form was created in an effort to increase the University's compliance with regard to non-English speaking participants. The regulations state that informed consent information should be presented "in a language understandable to the subject", and in most situations, that informed consent be documented in writing. This means that participants who do not speak English should be presented with a consent document written in a language understandable to them. Any time a study proposes to use the Short Form as an alternative consent process, the form and the process must be approved by the convened board. The Board should determine whether or not the process is adequate and appropriate for the study, or if a fully-translated consent document should be required.

Unanticipated Problem (UP). Any incident, experience, or outcome that meets all of the following criteria: 1) The event is not expected by the researcher or the research participant given the research procedures and the subject population being studied; 2) The event is related or probably related to participation in the research or if the event or problem probably or definitely affects the safety, rights, and welfare of current participants; and 3) The event suggests that the participants or others are placed at a greater risk of harm (including physical, psychological, economic, or social harm) by the research than was previously known or recognized.

Vulnerable Participants. Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.

Waiver of Authorization. In some situations, the IRB can waive the requirement that research subjects sign an Authorization Form. To qualify for a Waiver of Authorization, the research use of the health information should not represent more than a minimal risk to privacy, and the researcher should indicate that the research could not be done without the requested health information, that it would not be practical to obtain signed authorizations from the research subjects, and that the specific elements of health information that are requested are not more than the minimum necessary to accomplish the goals of the study.

Waiver of Consent. Occasionally there are reasons to waive written consent or to alter the requirements of consent. Only the IRB can make the determination to waive some (written) or all (written and verbal) consent requirements. In order to qualify for a Waiver of Consent, the following conditions should be met: 1) that the research pose no more than minimal risk to subjects; 2) no adverse effects as a result of the waiver or alteration; 3) without the waiver or alteration the research in question could not be carried out; and 4) information will be provided after participation is completed, if appropriate.

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Tear-Out Information Sheet & Checklist

Instructions: Please complete this information sheet and deliver it to your IRB Coordinator as soon as possible. You are free to skip any questions you do not wish to answer.

Your Name: _____

Your Panel: _____

1. Do you have any food allergies or dietary restrictions?

2. Are there any specific kinds of protocols you would be interested in reviewing, or are there any kinds of protocols you would prefer not to be assigned?:

New Board Member “To Do” Checklist

- Attended an in-person orientation with an IRB staff member.
- Successfully logged into the ERICA system.
- Completed my Board Member Information file in ERICA, including the Conflict of Interest Disclosure Section, and the Confidentiality Agreement. I have verified that my profile email address is correct.
- Attached an electronic copy of my Curriculum Vitae (CV) to my ERICA profile.
- Completed the biomedical and social/behavioral human subjects research training course, as well as a GCP course.
- Attended at least one convened board meeting as an observer for orientation.
- Completed the online New Board Member Training series and sent my completion certification to the IRB.

