This manual is a useful training tool and a reference designed to improve the IRB member experience. Please direct any and all questions to the IRB Operations Team at hrpo@med.cornell.edu.

Once comfortable with this information, it is recommended that the readers of this guide explore the following websites:

Institutional Review Board:
https://research.weill.cornell.edu/irb

Federal Office for Human Research Protections:
http://www.hhs.gov/ohrp/

Food and Drug Administration:
http://www.fda.gov/

These websites provide extensive resources and information on human subjects protections.
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SECTION 1: General Information

The Weill Cornell Medicine Institutional Review Board (WCM IRB) is an appropriately constituted group whose primary responsibility is to ensure that the rights and welfare of human subjects in research are protected. In accordance with the Common Rule and FDA regulations, the IRB has the responsibility of approving, modifying, and/or disapproving human subject research. The IRB has the responsibility to monitor active human research. The IRB also has the authority to suspend or terminate research in order to protect research subjects and for non-compliance with applicable rules and regulations.

The WCM IRB spans across 6 committees that review different areas of research and submission types:

- **General Expedited IRB**, which reviews expedited and exempt submissions for General/Non-cancer research
- **General IRBs 1 and 2**, both of which review greater than minimal risk general/non-cancer research
- **Cancer IRBs 1 and 2**, both of which review all Cancer research, including exempt, minimal risk, and greater than minimal risk research.
- **Executive IRB**, which reviews reportable events and urgent submissions, with membership composed of only the Chairs and Vice Chairs of all other boards.

The WCM IRB is registered with the Office for Human Research Protections (OHRP) under federal wide assurance number FWA00000093.

### 1.1 Current Member and Staff Lists

#### 1.1.1. Committee Member Lists

The WCM IRB does not make its member lists publicly available to protect the confidentiality of the individual team members. If you need information about your fellow IRB members, please contact the IRB office with your request.

#### 1.1.2. Staff List

The most up-to-date staff listing can be found on our [website](http://www.med.cornell.edu), under “Contact Us”

#### 1.1.3. General Information

- General Office Telephone: (646) 962-8200
- Email: irb@med.cornell.edu

### 1.2 IRB Meeting Dates and Locations

All IRB meetings are conducted via Zoom. IRB Members will receive calendar invitations with appropriate links to the IRB meetings in advance of each meeting. It is essential that IRB members communicate their attendance to meetings so that staff can ensure that we have appropriate representation and necessary numbers to conduct business. The IRB Staff will solicit feedback regarding meeting attendance and availability for reviews monthly using a Qualtrics survey.
Meeting attendance is considered satisfactory if the IRB member has attended 75% of convened IRB meetings for which he/she/they serve as a prime member in the last year (excluding extraordinary meetings). The same criterion applies for those members serving only as an alternate IRB member.

The most current list of WCM IRB meeting dates can be found on our website.

1.3 Resources

The following resources are available to WCM-IRB members:

1.3.1. WCM IRB Website

The IRB website is the primary source of information for the WCM research community, staff members, and IRB members. The website houses a trove of resources, including recent news, announcements, policy, as well as links to various outside resources (e.g., federal agency websites).

1.3.2. Member Checklists and Guides

The WCM IRB provides checklists to assist our members in their reviews. These checklists are meant to familiarize IRB members with the pertinent information necessary to conduct reviews and are useful as a reference tool during reviews. Please note:

- Checklists used for expedited/exempt reviews must be retained by the IRB Office as part of HRC records.
- Checklists for all other reviews (i.e., Full Board) must be purged once the review is completed.

1.3.3. Monthly Newsletters

Major changes or updates to policies or federal/state regulations will be announced in the WCM IRB monthly newsletter. Changes in procedure, updates to application forms, and other items that affect human research will be included in this newsletter, as well as educational programs and upcoming seminars. The newsletter will be posted on our website under News and Announcements and distributed electronically to all active members on the Research Coordinator Network (RCN) and ALLPROTOCOLS listservs.

1.3.4. Institutional Review Board: Member Handbook

Each new IRB member receives an electronic copy of Institutional Review Board: Member Handbook by Robert Amdur and Elizabeth A. Bankert. This book provides members with important information needed in order to help them in the collaborative effort to protect the rights and welfare of research subjects. Topic-specific chapters list the criteria IRB members should use to determine how to vote on specific kinds of studies and offer practical advice on what IRB members should do before and during committee meetings.

1.3.5 IRB Policies and Procedures

IRBs are expected to follow federal, state, and local laws, as well as regulatory and institutional policies. In addition to these requirements, IRBs examine ethical issues when reviewing research projects. For the WCM IRB, a comprehensive set of policies and procedures can be found on our website.
IRB members should familiarize themselves with these policies and procedures and refer to them when completing reviews.

SECTION 2: Introduction to the HRPP and IRB

This section provides basic information for those interested in serving as a member on an IRB and is designed to answer common questions. For more detailed information on the institution’s HRPP, please visit our website.

2.1 Defining Human Subjects Research

Federal regulations charge IRBs with the responsibility of reviewing human subjects research. Any study that meets the definition of “human subjects research” falls under the purview of the IRB. Federal regulations define “human subject” and “research” in a way that differs from common use of those terms. In order to assess whether a study qualify as human subjects research, the activity must first meet the definition of “research,” then “human subject”, which are defined below. Staff make the determination about whether an activity is human research before it is sent to a reviewer.

2.1.1 What is Research?

Per the definition put forth by the Office for Human Research Protections (OHRP) at the Department of Health and Human Services (DHHS):

Research is the systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to general knowledge.

Note: This is distinct from a quality improvement or quality assurance project, or a program evaluation – something that is intended to solely improve practice in a particular institution (e.g., improving medication adherence to a small set of WCM patients and investigating how we can do this ONLY to this group of patients).

Also, publication/dissemination is not a determining factor as to whether an activity is human research requiring review and approval by the WCM IRB.

The U.S. Food and Drug Administration (FDA) uses the term clinical investigation and defines it as:

A clinical investigation is defined as an experiment in which a drug is administered or dispensed to, or used, involving one or more human subjects.

Note: if a clinical drug is used as part of a clinical practice (e.g., Paxil is prescribed to a patient to alleviate symptoms of anxiety), this would not be a clinical investigation.

2.1.2 What is a Human Subject?

The OHRP defines a human subject as a living individual about whom an investigator obtains:
• Information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens, OR
• Identifiable private information or identifiable biospecimens and uses, studies, or analyzes this information.

The FDA states that a human subject is a living individual who participates in an investigation:

• Either as a recipient of an investigational new drug or as a control OR either as an individual on whom or on whose specimen an investigational device is used or as a control.

2.2 The Human Research Protection Program (HRPP)

WCM fosters a research environment that promotes the ethical conduct of research. A Human Research Protection Program (HRPP) is fundamental to promoting ethical research. The responsibility for protecting the rights and welfare of research participants is not the sole responsibility of a single office or of the IRB, rather, this responsibility falls to multiple entities, including: WCM administrators, offices/departments, and committees whose roles/responsibilities directly or indirectly involve human research (e.g. Conflict of Interest Committee, Radiation Safety Committee, Institutional Biosafety Committee, etc.), Principal Investigators, faculty advisors, student researchers, and members of the research team. These entities collectively comprise the HRPP.

2.3 The Institutional Review Boards (IRBs)

The IRB must be, and must be perceived to be, fair and impartial, immune from pressure from either the institution’s administration, the Investigators whose protocols are brought before it, and/or other professional or non-professional sources. IRB members can be faculty, staff, or students from the institution, and members from the local community.

Under the terms of the Common Rule, the IRB must:

• Have at least five members, at least one whose primary concerns are scientific and one whose primary concerns are nonscientific
• Include individuals from academic disciplines relevant to the research being reviewed
• Include at least one non-affiliated member
• Be diverse in terms of race, gender, and cultural background
• Have the necessary experience and expertise to fairly evaluate the proposed research.

The following are some of the IRB’s authorities.

• Approve, require modifications to secure approval, or disapprove all research activities overseen and conducted at WCM, regardless of location of the research activities;
• Require that informed consent be obtained and documented in accordance with regulatory requirements unless the criteria for the waiver or alteration of such requirements has been satisfied and approved by the IRB. The IRB may require that information, in addition to that specifically mentioned in the regulations, be given to the subjects when in the IRB’s judgment the information would meaningfully add to the protection of the rights and welfare of subjects;
• Monitor active research to ensure appropriate and ethical conduct of research;
• Suspend or terminate approval of research not being conducted in accordance with the IRB’s requirements or that has been associated with unexpected serious harm to subjects;
• Observe, or have a third party observe, the consent process and the conduct of the research; and
• Determine whether data or information gathered without IRB approval or in association with serious non-compliance may be published or used for research purposes.

2.4 IRB Staff

WCM IRB staff are employed by the institution and comprise the IRB office. Their duties include preparing agendas, conducting initial regulatory screening of protocols, compiling correspondence, taking minutes, providing support for investigators and researchers, and arranging IRB meetings. Each study or protocol that is submitted for IRB review is assigned to a staff reviewer to begin the process. This person is responsible for screening the protocol and solving as many issues as possible before the study is reviewed by an IRB member. These may include obtaining missing documents, getting answers to regulatory and administrative questions, or addressing problems that will delay IRB approval.

Staff members know a great deal about the regulations governing research. WCM IRB staff often have backgrounds in research, including research administration, clinical research, the medical and legal fields, and the social sciences. They come to the process with a strong knowledge of the regulations, and the institutional culture. As a result, they are a great help to community members, IRB reviewers, and the research team—and a wonderful resource to call on when you have questions or want help.

Section 3: IRB Member Roles and Responsibilities

As an IRB member, you are a key component of the HRPP. The role of the IRB member is to protect research participants by determining whether Human Research submitted for review meets, or continues to meet, the criteria for approval. This means that you may play a significant role in reviewing new projects, continuing reviews, amendments, as well as in reviewing events (e.g., unanticipated problem involving risk to participants or others). For WCM faculty and staff, this is a voluntary unpaid position; community members will be compensated for their time. You have been formally appointed to serve as an IRB member because you are in a position to make a valuable contribution to the IRB’s mission, whether due to your subject matter expertise or your experience with particular participant.

3.1 What is expected of an IRB Member?

A considerable time commitment is required when serving as an IRB member. IRB members need to set aside blocks of time to review IRB applications and protocols, attend meetings, and avail themselves to educational opportunities. The amount of time needed will gradually lessen as the process becomes familiar. Keep in mind - some studies are so technical, complex, and dense, that other IRB members or consultants will need to review the most technical sections in addition to your review.

It is important that the IRB Member understands that serving on the IRB is not to rush the approval of research, but to serve as a link between the investigator and the research subjects. In order to fulfill one’s duties, all IRB
Members are expected to be knowledgeable of the regulations governing human subject protections, biomedical and behavioral research ethics, and the policies of WCM germane to human subjects research.

3.1.1 WCM-IRB Member Appointment

Potential IRB Members may self-nominate or be nominated by a colleague/department head to serve on the IRB. Once the potential member’s qualifications to serve on a particular Board are verified, the onboarding process begins, starting with an Appointment Letter signed by the IO. The Human Research Protection and Compliance (HRC) Executive Director, in consultation with the Chairs and the Institutional Official, makes the final decision in appointing new members.

Newly appointed IRB Members must complete the following action items upon appointment to the WCM IRB:

- Ensure current resume, CV, or summary of experience has been submitted to the IRB office.
- Satisfy training and education requirements for IRB Members
  - Completion of the relevant CITI IRB Members course
    - IRB Chairs and Vice Chairs must complete the IRB Chairs course as well.
  - Complete the New IRB Member Orientation and Training course on Canvas
- Schedule a New IRB Member Orientation with a member of the Human Research Compliance Operations Team. This orientation session includes an overview of IRB Member functions and expectations, IRB processes, regulations, IRB Member tools, and training on the Weill Research Gateway – Human Subjects (WRG-HS; the electronic submission platform system utilized by the WCM-IRB).
- Review, sign, and submit the IRB Member/IRB Community Member Confidentiality and Conflicts of Interest Agreement
- Attend three convened IRB meetings as an observer, A signed IRB Guest Confidentiality Form must be submitted prior to your attendance

Only once the above is completed will new IRB members will be considered fully onboarded.

3.1.2 Member Evaluations

The HRC Executive Director and Chairs will periodically review the membership of the IRB and recommend re-appointments or additions as necessary to ensure adequate review of research and regulatory compliance.

IRB members will be evaluated annually to ensure that member expectations are being met as defined on the “Guidance on Interpretation of Criteria for Assessment IRB Members” document.

The following will be completed at the end of each calendar year:

<table>
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<th>Evaluation Form</th>
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<tr>
<td>IRB Member Self-Evaluation Form</td>
<td>IRB Member</td>
</tr>
<tr>
<td>IRB Chair/Vice-Chair Self-Evaluation Form</td>
<td>IRB Chair/Vice-Chair</td>
</tr>
<tr>
<td>IRB Chair Evaluation Form</td>
<td>IRB Members</td>
</tr>
<tr>
<td>IRB Member Evaluation Form</td>
<td>IRB Chair</td>
</tr>
<tr>
<td>IRB Member and Chair/Vice-Chair Evaluation Form</td>
<td>IRB Staff</td>
</tr>
</tbody>
</table>
Throughout the year, attendance and completion of assigned reviews will be documented monthly.

All IRB members, Chairs, and Vice-Chairs will be given the results of their evaluations. Any noted areas of improvement will be discussed with the HRC Executive Director or designee. Additional training/education may be assigned or, in circumstances where evaluations reveal poor performance in a number of areas, the member may be removed.

3.1.3 IRB Member Removal

In the unlikely event that a member of the IRB should conduct themselves in a manner contrary to the policies and ethical and professional responsibilities of the IRB, such member can be removed from the board at any time by the IRB Executive Board.

3.1.4 Term of Service

Members are appointed for three-year terms, with renewal occurring annually and based on the member evaluation. The appointment may be evaluated periodically by the Chair, the Executive Director, or the IO, with input from the IRB staff.

3.1.5 IRB Member Expectations

<table>
<thead>
<tr>
<th>Evaluation Criteria</th>
<th>Interpretation of Criteria</th>
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| Attendance at IRB Meetings                  | - Attendance at IRB meetings can be deemed satisfactory if the IRB member has attended 75% of convened IRB meetings* for which he/she/they serve as a prime member in the last year (excluding extraordinary meetings).<br>- The same criterion applies for those members serving only as an alternate IRB member.  
- All IRB members must regularly report availability and notify IRB staff immediately if unable to attend a meeting to which they had previously committed.  
  *i.e., the IRB Full Board member has missed no more than 6 out of 24 IRB meetings in the last year. |
| Meeting Participation                       | IRB members must actively participate in meeting discussions with respectful communication. Albeit subjective, this is demonstrated by a general willingness to disagree with consensus or majority opinion, active listening, openness to alternative views, comfort in sharing opinions and interpretations, willingness to ask questions as needed, and/or willingness to take direction from other members, Chair, and/or IRB staff. |
| Knowledge and Application of Federal Requirements, Ethical Principles, and Institutional Policies | IRB members are expected to have a working knowledge of Federal regulations, ethical principles, and institutional policies specific to human subjects research, as evidenced by frequent appropriate application of the above in all reviews and meeting discussions. |
### Fulfillment of Training Requirements

Fulfillment of training requirements are deemed satisfactory if the IRB member has:
- Taken required CITI IRB member training courses
- Completed the New IRB Member Orientation and Training Course on Canvas
- Attended a New IRB Member Orientation or equivalent
- Completed all other assigned continuing education training throughout the past year

### Conflict of Interest Requirements

The IRB member must
- consistently remove oneself as a reviewer or absent oneself during convened meetings if any financial or non-financial conflict of interest exists
- complete the required Conflict of Interest Statement annually or at the time of a change

### Timeliness of Reviews

Timeliness of reviews can be deemed satisfactory if the IRB has provided his/her/their review by the prescribed deadline (5 days in advance of the scheduled meeting, except for Expedited Board members, who must complete their review by the agenda date) 75% of the time in the last year.

Note, IRB Members are expected to review meeting minutes from previous meetings.

### Quality of Reviews

Quality of reviews can be deemed satisfactory if the IRB member, a majority of the time, provides sufficient detail in his/her/their reviews, completes reviewer checklists such that the IRB staff is able to document determinations required by the regulations and institutional policies in IRB letters and/or IRB meeting minutes.

### Communication

IRB Members must treat IRB Staff, researchers, colleagues, and others with respect during and outside of meetings.

### Confidentiality

IRB Members must maintain confidentiality for all discussions, reviews, meeting minutes, and proprietary information encountered as an IRB Member, including shredding/deleting IRB documents from personal paper and electronic files.

### Additional Chair/Vice-Chair Evaluation Criteria

<table>
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<tr>
<th>Interpretation of Criteria</th>
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<tr>
<td><strong>Directs Proceedings and Discussions</strong></td>
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<tr>
<td>The chair/vice-chair must effectively direct the proceedings and discussions at IRB meetings in such a way as to encourage active participation of members, facilitate IRB determinations that are fair, impartial, and appropriate, ensure there are clear and</td>
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## Human Research Compliance

### Member Handbook Ver. 040422

<table>
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<tr>
<th>Attendance</th>
<th>In addition to scheduled meeting attendance requirements above, the chair must attend 75% of all pre-meetings. The vice-chair must attend pre-meetings as needed.</th>
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<tbody>
<tr>
<td>Meeting Management/Time Management</td>
<td>The chair/vice-chair must demonstrate good time management skills during IRB meetings by managing the agenda well, facilitating meaningful discussion, and summarizing main points as needed. He/she/they must also maintain meeting organization.</td>
</tr>
<tr>
<td>Preparedness</td>
<td>The chair/vice-chair must be prepared for each meeting by conducting a thorough review of all meeting materials, demonstrating a knowledge of all agenda items, identifying ad-hoc consultants as needed prior to the meeting, and communicating with relevant parties when additional information is needed.</td>
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<tr>
<td>Collaboration</td>
<td>The chair/vice-chair must collaborate with IRB Staff, regularly communicating and providing updates as necessary regarding IRB related topics.</td>
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### 3.1.6 Roles of IRB Chair and Vice Chair

**IRB Chair:** In addition to the expectations listed in section 3.1.4 above, the Chair must:

- Be available to assist the IRB office with any needs.
- Ensure that the IRB carries out its responsibilities as required by federal regulations, ethical principles, state laws, and university policy.
- Provide support and expertise as needed with respect to investigation of complaints or allegations of non-compliance.
- Serve as an expedited reviewer when needed.
- Contribute to continuing education when asked.
- Contribute to the routine evaluation of IRB members’ performance and assist with member performance management as needed.
- Support WCM’s research and education mission by meeting with researchers as needed.

**IRB Vice Chair:** The Vice Chair serves as the Chair of the Board in the absence of the designated Chair:

- When the IRB Chair is recused from an individual protocol review due to a conflict of interest, the Vice Chair automatically assumes the responsibility of Chair for that particular review.
- If both the Chair and Vice Chair are absent or recused due to conflicts of interest, the acting IRB Chair must appoint an experienced IRB Member to act as IRB Chair for the duration of the Chair or Vice Chair’s absence.
The IRB Chair may delegate to the IRB Vice Chair or to an experienced IRB Member to assist or act on behalf of the IRB Chair in particular IRB matters and at IRB meetings, either as a general procedure, or on a case-by-case basis.

3.2 IRB Member or Consultant Conflict of Interest

It is the policy of the WCM IRB that all conflicting interests of an IRB committee member, including alternates, or consultants, regardless of voting privileges, be declared before review of any research under IRB jurisdiction. IRB committee members, alternates, and consultants with a conflicting interest may not participate in any portion of the review of research activities except to provide information requested by the IRB and must recuse themselves from the meeting during the IRB’s deliberative discussion and vote on the affected research. The term “conflict of interest in research” refers to situations in which financial or other personal considerations may compromise, or have the appearance of compromising, a member’s professional judgment in reviewing or evaluating a research project.

All members and alternate members of the IRB, as members of the WCM research community, complete an annual Conflicts Survey (administered by the Conflict of Interests Office) and when their circumstances change. Nonaffiliated community members must complete an IRB Community Member Confidentiality and Conflicts of Interest Agreement upon joining the IRB. The Conflicts Survey, which is available through WRG-HS, is submitted to the COI Office annually; they then review the disclosure and determines if a COI exists. To protect the privacy of members, the specific details of the conflict will not be given to IRB staff or other members; however, the type of research where a COI exists will be provided (e.g., studies from X sponsor; studies using X device/drug; studies involving X investigator) to the Assistant Director, IRB Operations, on an annual basis or as new members join the IRB. The IRB staff, in turn, ensures based on this information that IRB members and alternates are not assigned to conduct reviews of studies for which the member has a conflict and reminds members of conflicts at convened meetings as needed to ensure recusal. IRB staff may consult with the COI Office to clarify whether a specific study involves a member COI.

IRB Members are responsible for making known any conflicts of interest concerning projects reviewed by the IRB. Complete the COI survey at the beginning of each calendar year and any time there are updates.

<table>
<thead>
<tr>
<th>Common Reasons for a Conflict</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Principal Investigator or key personnel</td>
</tr>
<tr>
<td>• Receiving funding from the research (listed in the budget)</td>
</tr>
<tr>
<td>• Any other reason for which you believe that you cannot provide an independent review</td>
</tr>
<tr>
<td>• Family member of PI (spouse or child)</td>
</tr>
<tr>
<td>• In a supervisory role over the PI of the project</td>
</tr>
</tbody>
</table>

If you have a conflict, please do the following:

- If you are assigned a submission to review and you have a conflict, tell the IRB staff immediately so that submission can be reassigned.
- For convened meetings, review the agenda before the meeting and tell the IRB staff if you have a conflict with an item on the agenda.
- At the start of a convened meeting, identify any COIs relating to any submission on the agenda.
- Recuse yourself during discussion and vote of that item.
Section 4: Types of Submissions and Reviews

4.1 Types of IRB Submissions

4.1.1 New Protocols (Initial Submissions)

All new studies involving human subjects research (per OHRP and FDA definitions) must receive IRB approval before they can begin.

4.1.2 Continuing Review

Continuing review involves reviewing the progress of a study to determine whether any new information is available that would change initial determinations and that the study continues to meet the criteria for approval. The frequency and extent of continuing review for each study is based upon the nature of the study, the degree of risk involved, the novelty of the research procedures, and the vulnerability of the study’s subject population. Greater than minimal risk and full board studies are assigned an expiration date and continuing review must occur at an interval set by the IRB but not less than once a year. Minimal risk research which received initial approval on or after 1/21/2019 does not have a requirement for continuing review and are assigned a PAM-AR. Reviewers can decide that a minimal risk study needs continuing review, but this decision must be justified. Each investigator must abide by the approval period imposed by the IRB at the time of the most recent IRB approval. If a project with an expiration date passed that date without continuing review, research activities (recruit, enroll, treat subjects, store or analyze data) must stop, except where doing so would cause harm to the subjects. It is the investigator’s responsibility to ensure that approval for an active protocol remains current. The IRB expiration date can be found on the protocol summary view in the WRG system. The investigator must submit a continuing review through WRG prior to expiration in order to renew the approval period.

1. Continuing review is ALWAYS required for studies regulated by the FDA/DOJ or as a term of a grant or contract
2. Failure to submit a continuing review application before the study expiration date will be recorded as non-compliance (see Section 8.3, Expiration of Approval Period) and will require the submission of a Corrective and Preventive Action (CAPA).
3. For studies regulated under 45 CFR 46 (The Common Rule):
   a. Continuing review is ALWAYS required for studies initially approved before 1/21/2019 (pre-2018 Common Rule)
   b. Continuing review is NOT required for minimal risk studies initially approved on or after 1/21/2019 (the date of the 2018 Common Rule). Study teams will be advised in their initial approval letter whether their study qualifies for an annual progress report (PAM-AR) submission. PAM-AR includes disclosure of any adverse events and/or whether any changes to research activities have been conducted without prior IRB approval.
   c. However, the IRB reviewer has the discretion to require continuing review as deemed necessary. Some examples are provided below:
I. The research involves topics, or procedures, or data that may be considered sensitive or controversial.

II. The research involves particularly vulnerable subjects or circumstances that increase subjects’ vulnerability

III. The investigator has minimal experience in research or the research type, topic, or procedures

IV. The investigator has a history of non-compliance

V. Other situations may arise, but the reviewer is required to document these reasons.

4.1.3 Amendment

All changes to a study must be approved by the IRB before they can be implemented, except when necessary to eliminate apparent immediate hazards to the subjects (these would still require reporting to the IRB). This includes minor changes that a research team may not consider consequential (e.g., screening criteria, procedures, recruitment methods or materials, consent form language, questionnaire items, etc). Amendment submissions can be reviewed administratively, using expedited procedures, or require review by the fully convened IRB depending on the study and types of changes. Investigators submit via WRG an amendment form and revised documents either by using Word’s “Tracked Changes” function, or by highlighting the changes (as long as they are clearly delineated) from the original document(s). In reviewing amendments, the IRB analyzes whether the changes pose additional risks to subjects or represents a significant change in study procedures and verifies whether existing determinations still apply or if new determinations need to be made.

4.1.4 Reportable Event*

*Including but not limited to Adverse Events, Protocol Violations, and/or Non-compliance

Federal regulations require investigators to report any post-approval research-related event or information that may meet definitions of unanticipated problems involving risk to participants or others, non-compliance, serious non-compliance, or continuous non-compliance (definitions for terms are provided under “Glossary” on our website).

4.1.5 Study Closure Reports

This is required for ALL types of studies to update the IRB on the conduct and outcomes of the study, including any problems that may have arisen since the study was approved or the last continuing review was submitted (if applicable) that may need to be disclosed to stakeholders. A research project is closed when subject accrual, subject follow-up, identifiable data analysis, and storage of identifiable research data are completed. Once a study is closed, no further research activity, including data analysis, may occur, unless the data to be analyzed is determined to be unidentifiable. Researchers should be strongly encouraged to speak with an IRB staff member before closing their studies to ensure that any identifiable information has been removed from their data and they are, in fact, unidentifiable.

Once the study is closed in WRG, the study is no longer under the purview of the IRB and the researcher can no longer conduct research under that protocol. If investigators wish to enroll new subjects for a closed study, they must reactivate the protocol with the IRB within 6 months of closure or submit a new
application. There are limited instances when the IRB will close a study for which the researcher retains identifiable data. These instances are situational and must be discussed and arranged with the IRB first. Additional research projects using data acquired in an approved study may constitute new human subjects research studies subject to separate IRB review.

4.1.6 Expanded Access to and Emergency Use of Experimental Drugs and Devices

Per FDA Guidance:

**Expanded Access** is a potential pathway for patients with a serious or life-threatening disease or condition to access an investigational medical device that has not been approved or cleared by the FDA for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available through one of three mechanisms: (1) Emergency Use, (2) Compassionate Use (or Individual Patient/Small Group Access), (3) Treatment Investigational Device Exemption (IDE)

The Emergency Use Authorization (EUA) authority under section 564 allows FDA to facilitate availability and unapproved uses of MCMs needed to prepare for and respond to CBRN emergency. The EUA authority is separate and distinct from use of a medical project under an investigational application (i.e., Investigational new Drug Application (IND) or Investigational Device Exemption (IDE)).

Most administration/use of unapproved devices, drugs or biologics is part of a systematic clinical trial. All clinical investigations, including pilot studies, require prior IRB review and approval.

4.1.7 Single IRB (sIRB)

Studies ceded out to external IRBs following execution of applicable reliance agreements; All federally funded multi-site research requires use of a sIRB. WCM IRB may serve as a sIRB. When we do, both the applicable IRB board and PRMC will review the research with all our regular procedures and expectations. We will be provided local context from the relying sites that we will need to be incorporated into the review. WCM IRB staff will work closely with you when reviewing research as a sIRB.

4.2 Types of IRB Review

There are five types of review: exempt, expedited, full board, administrative, and non-compliance review.¹

4.2.1 Exempt Review:

Certain categories of human research can be determined to be exempt from some of the provisions of the Code of Federal Regulations as long as they meet prescribed ethical criteria including the requirement for informed consent, minimal risk procedures, and considerations for participant privacy and data confidentiality. Any significant changes to an exempt project will need to be submitted to the IRB to ensure that the exempt determination still applies. This is a determination made by the IRB; researchers are not authorized to make exempt determinations.

¹ Note that not all research using human subjects require IRB review. Studies that do not meet the regulatory definitions of “human subject” or “research” are relegated to a category the WCM IRB calls Not Human Subjects Research (NHSR).
Examples of exempt projects include online anonymous surveys, classroom curriculum evaluations, interviews, topics, review of existing academic, medical, or other records without recording identifiers, etc.

4.2.2 Expedited Review

Certain research that involves no greater than minimal risk and only includes procedures listed in the Federal Register expedited review categories can undergo expedited review. This is a determination made by the IRB upon review of the project. Expedited review procedures allow an individual IRB member to review and approve projects on behalf of the full IRB. Projects that qualify for expedited review are reviewed on a rolling basis and are not confined to the convened meeting schedule.

Examples of expedited projects include research collecting biological specimens by noninvasive means such as saliva, research using MRIs or other noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, etc. Some full board projects may eventually qualify for expedited review, for example, once the project is limited to data analysis. Similarly, some amendments to full board projects may be reviewed using expedited procedures, for example, minor amendments that do not significantly impact the criteria for approval.

4.2.3 Full Board Review

Projects that do not qualify for any of the above and/or present greater than minimal risk to participants must be reviewed at a fully convened IRB meeting, a.k.a. full board meeting. WCM holds IRB meetings regularly and has one set of boards for cancer research and one set of boards for all other, non-cancer, research. Due to the frequency of full board meetings, there are deadlines for submission in order for items to be on the meeting agenda. Submissions that complete pre-review after the deadline will be reviewed at the next available meeting. A majority of the board and at least one non-scientific member must be present at the meeting in order for quorum to be established. If protocols include research with prisoners, then an IRB member with that expertise must be present in full board meetings that review such research.

Examples of full board projects include research in prisons, projects administering drugs or alcohol, research involving invasive interventions (e.g., biopsies), or high risk or vulnerable populations (e.g., maximal aerobic capacity testing on frail populations), etc.

4.2.4 Administrative Review

There are situations where administrative review is conducted, such as for SIRB, some reportable events, human research determinations, administrative amendments, closures, etc. These are conducted by staff and members would only be informed should it be necessary.

4.2.5 Non-Compliance Review

As discussed above, the IRB has a responsibility to monitor active research. There are times that through monitoring, IRB staff identify issues that will require non-compliance review. For example, issues identified through reportable events, participant complaints, and audits, are often brought to the IRB for a non-compliance determination. IRB staff and Chair(s) will collect information pertaining to any issues and present that along with corrective actions to the IRB for consideration.
The WCM IRB office uses an initial pre-review screening process, during which an IRB analyst reviews each submission for completeness and compliance. During this stage, the analyst may ask the PI to make changes to the submission or provide necessary documents. When the submission is complete (meeting basic submission standards such as inclusion of funding protocol, drug brochure, recruitment, or consent documents, et al.), the analyst will assign the submission to the appropriate IRB Member(s) for review. The IRB Member may also ask for changes and/or clarifications, which the IRB analyst will communicate to the Investigator after IRB review.

*Note: It is expected that all IRB Members review the entire protocol before the meeting so that they may contribute to and/or raise any items for discussion during the convened meeting.*

5.1 What Documents Should I Review?

For submissions reviewed at a convened meeting, all IRB members attending the meeting are expected to review the documents for each submission on the agenda, regardless of whether you are assigned as reviewer or not. Note that members who review submissions outside of the meeting are the only ones reviewing that submission.

The table below includes which documents should be reviewed for certain types of submissions.

<table>
<thead>
<tr>
<th>Submission Type</th>
<th>Documents To Be Reviewed</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Application Form</td>
</tr>
<tr>
<td>Initial Submission</td>
<td>✓</td>
</tr>
<tr>
<td>Continuing Reviews</td>
<td>✓</td>
</tr>
<tr>
<td>Amendments</td>
<td>Any/all modified documents</td>
</tr>
</tbody>
</table>

5.1.1 Review Process by Submission Type

<table>
<thead>
<tr>
<th>Submission Type</th>
<th>Review Process</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>New Protocol (Initial Submission)</strong> (has not been reviewed before)</td>
<td></td>
</tr>
<tr>
<td>1. Review the pre-review checklist</td>
<td></td>
</tr>
<tr>
<td>2. Read the consent document, this should give you a good basic introduction to the protocol</td>
<td></td>
</tr>
<tr>
<td>3. Read the full protocol and supporting material carefully, taking notes as needed</td>
<td></td>
</tr>
<tr>
<td>4. Re-read the consent document and other submitted documents and make suggestions for changes or corrections</td>
<td></td>
</tr>
<tr>
<td>5. Any changes should be focused on approval criteria</td>
<td></td>
</tr>
<tr>
<td>6. Record modifications on the Reviewer comments document/section in WRG, written in the manner you would like it presented to the researcher</td>
<td></td>
</tr>
</tbody>
</table>
| Amendment (changes to an already approved project) | 1. Read the pre-review  
2. Read the Amendment Application to understand the proposed changes  
3. Determine if the amendment changes risks for participants  
4. Determine if changes have been made in all appropriate documents (e.g., protocol, consent, recruitment, etc.)  
5. Determine if participants should be re-consented  
6. Determine whether existing determinations should be changed based on the changes to the research and ensure .111 criteria are still met |

| Continuing Review (re-review of the project) | 1. Read the pre-review  
2. Determine if the project is open or closed to enrollment, and enrollment numbers  
3. Review the protocol and consent form to ensure IRB determinations are correct  
4. Determine if the project is progressing as planned  
5. Determine if unexpected events or new information have occurred that may indicate a need for modification(s)  
6. Determine if there have been complaints and whether they impact the continuation of the project |

5.2 Conducting and Documenting an IRB Review

5.2.1 Full Board Reviews

When assigned to review full board submissions, a review includes reading project documents, making determinations (see Section 6 for types of determinations), completing checklists, and presenting the submission and determinations at a full board meeting. Members must also review submission, even if they are not the assigned reviewer. Members discuss each submission, the assigned reviewer typically recommends an action (see section 7 for more on this), and then members vote. The discussion and vote are documented in the minutes of that meeting and staff communicate IRB decisions to researchers. IRB Members are expected to review assigned studies completely and in depth so that they can provide a summary to fellow Members if needed.

Assignments for board meetings are typically done 10 to 14 days prior to the board meeting. Reviewer checklists have been created to help identify regulatory requirements and to note the ethical expectations that must be met. Work with IRB analysts to work through the review process and answer any questions.

5.2.2 Expedited Reviews

 Expedited review is similar to full board review, except that there is no meeting. This means that one member on behalf of the full board makes determinations. The completed checklist is key for documenting the review. Remarks/observations/concerns may be documented in ‘Reviewer Comments’ field in the Review section in WRG-HS. Researchers are unable to view your review/comments. Members conducting expedited reviews should work very closely with their IRB staff to complete reviews.
5.3 Tips for Reviewing:

1. Establish a review routine by using a systematic approach to review each new protocol in the same way.
2. Read the consent document to understand the important aspects of the study. The consent document should serve as a good introduction to the study protocol. It should also orient you to the overall design of the study.
3. Read the abstract in the IRB application, which provides key aspects of the study.
4. Read the full protocol and supporting materials carefully. The investigator provides the IRB with detailed information such as the study background and rationale, methodology, inclusion/exclusion criteria for subject enrollment, and other documents. Funding documents provide additional information. Take notes as needed.
5. Reread the consent document. Record suggested corrections or questions for the investigator and ensure that the consent form adequately describes the actual study design and procedures in a language that can be understood by the subject.
6. Contact the IRB analyst anytime you need help with the review, whether it’s project documents, reviewer checklists, or navigating WRG.
7. Once a review is complete and a meeting is ended, remember to delete/shred any review documents.

5.4 Reviewing Research Documents

Being mindful of certain requirements will help you identify ethical and regulatory issues while reviewing the IRB application.

5.4.1 General Considerations when Reviewing

- Apply the criteria required by federal regulations for IRB approval of a human research study and the appropriate regulatory determinations.
  - e.g., for inclusion of children, pregnant women, neonates, fetuses, and prisoners in research, criteria for waiving and/or altering consent, criteria for making non-significant risk determinations for devices.
- Be familiar with the funding agency documents to ensure that appropriate regulations are applied.
- Record your comments in WRG Member Comment section. See our website for more details about this process.
- What are the subjects required to do? Will they take a drug, fill out a survey, or be interviewed about criminal activity? Are the research activities potentially harmful or embarrassing?
- Would you participate in this study, or would you want your parents, children, spouse, or other family members to participate?
- Does the study make sense as written? Is it overwhelming with too much jargon or too many details?
- Is the informed consent document easy to understand and an accurate reflection of the study procedures?
- Who are the subjects and are they vulnerable in some way?
- If identifying information is collected, is there a mechanism in place to protect the subjects’ identities or other private information? If so, is it adequate?
• Is it necessary to keep the identifying information? Is more information being requested than is needed?
  o If identifying information is collected, is there a mechanism in place to protect the subjects’ identities or other private information? If so, is it adequate?
• Is the information provided in the protocol, consent, and recruitment materials consistent?
• Are there adequate safeguards to protect the subjects should something go wrong? Does the researcher have a plan and is that plan appropriate?
• If the intervention/treatment proves beneficial, will those subjects not in the intervention/treatment group (i.e. control group) be able to partake in the intervention or receive the treatment once the study has been concluded?
• What “gut” feelings do you get after reading the protocol? Sometimes, something about the study seems questionable and may make you feel uneasy. Express this unease and attempt to get the issue resolved, or vote “no” when the vote is taken.

5.4.2 Reviewing the Protocol

What you see:
• The past – variables of interest, previous literature that influenced the development of the project methods and aims
• The present – current project methods (recruitment, consent, data collection, etc.)
• The future - plan to manage, analyze, and store the data obtained from the research
• The protocol and project documents are used to make determinations

Things to consider:
• Does the researcher provide adequate and reasonable information for you to assess?
  o Risk/benefit
  o Privacy & data confidentiality
  o Consent process & documentation
  o Recruitment & screening

5.4.3 Reviewing the Consent Document

What you see:
• Document must contain the required elements of consent
• Project involves research, how long it will take to participate, what will happen to the participant in the study
• Who can the participant contact about the research, their rights, and if they get injured as a result of the project?
• Participation is voluntary, whether the participant can refuse or withdraw at any time without penalty or loss
• Other elements as applicable

Things to consider:
• Consent is required unless protocol specific findings justify waiver
• All required elements and any additional elements must be stated/described as appropriate for the audience
• Alteration of informed consent may be granted if justified by protocol specific findings
• Process can be done orally, electronically, or in writing
• Documentation is required unless protocol specific findings justify waiver of consent documentation (e.g., online survey)

5.4.4 Reviewing the Recruitment Materials

What you see:
• Documents used to inform potential participants about the research (variety of modalities)
• Recruitment Database
• Advertisements (paper, online)
• Letter, emails, social media posts (investigator or colleague)
• Participants unknown to researcher (snowball sampling)
• Records screening

Things to consider:
• Should not be misleading
• Benefits or compensation should not ‘stand out’
• Compensation should not be so much as to cause undue influence to participate
• Should clearly state ‘Research’ or ‘Investigation’
• Should include contact information
• May give brief eligibility criteria
• May give brief procedural information

Section 6: Review Considerations

This section covers regulatory and policy elements to keep in mind while reviewing a submission. Members are encouraged to reach out to chairs, members, and staff to ask questions, discuss controverted issues, receive guidance, obtain expert opinions, etc.

6.1 Determining Risk

Assessing risk of harm to individuals who participate in research is one of the IRB’s primary responsibilities. Federal regulations define minimal risk as the “probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests” (45 CRF 46.102(j) and 21 CFR 56.102(i)). Risks (physical, psychological, social, legal, or economic) occur as a result of participation in research. Both the probability and magnitude (severity) of a possible harm may vary from minimal to significant. The magnitude of potential harm is the summative measure of its severity, duration, and reversibility. A research protocol with a low probability of harm occurring, but a high magnitude of harm if it occurs, may be determined to be greater than a minimal risk (e.g., a severe allergic reaction to a new medication, or stigmatization from unintentionally
releasing participants’ HIV status). Alternatively, a protocol with a high probability of harm occurring, but a low magnitude of harm may be minimal risk for participants (e.g., distress related to answering sensitive, personal questions). The overall project risk is determined by the risk to the most vulnerable known members of the group.

If a study has even a single greater than minimal risk component, even if it has multiple minimal risk components, the study is determined to be greater than minimal risk.

The first step in a review is to determine the risk associated with the individual research procedures as well as the overall risk of the project (minimal or greater than minimal risk). A minimal risk project can be reviewed at a minimal risk review meeting. A greater than minimal risk project must be reviewed at a convened meeting. Reviewers then determine whether the anticipated risks to participants are reasonable in relation to the anticipated benefits to participants, if any, and the importance of the knowledge that may reasonably be expected to result. Risks should be considered along with the expected benefits, and these should be acceptable. A high-risk project may be approvable if there is a chance for direct benefit; a high-risk project is NOT approvable if the chance for benefits is low.

6.2 Criteria for Approval

For a project to be approved, it must meet the Criteria for Approval or 111 Criteria (45 CFR 46.111, 21 CFR 56.111). These criteria were developed from principles for ethical human research (see the Belmont Report).

<table>
<thead>
<tr>
<th>Criteria for IRB Approval Review Considerations</th>
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<tbody>
<tr>
<td><strong>Criterion</strong></td>
</tr>
<tr>
<td>------------------------------------------------</td>
</tr>
<tr>
<td>Risks to participants are minimized by using procedures which are consistent with sound research design and do not involve unnecessarily risks or by using procedures already being performed for diagnostic/treatment purposes.</td>
</tr>
<tr>
<td>Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.</td>
</tr>
<tr>
<td>Selection of participants is equitable.</td>
</tr>
<tr>
<td>When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.</td>
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</tbody>
</table>
When appropriate, there are adequate provisions to protect the privacy of participants.

Privacy relates to the person (not the data about the person).
Is there an expectation of privacy?
What is being done to protect privacy? Are the provisions adequate?
- In recruitment and consenting processes
- During study conduct
- In follow-up contact

When appropriate, there are adequate provisions to maintain the confidentiality of data.

Confidentiality refers to data about a person.
Is there risk of harm should there be a breach of confidentiality?
Is a Certificate of Confidentiality needed?
What protections are in place to secure data during collection and storage?
- Coded data
- Restricted access
- Encrypted data/equipment

If needed, there are additional protections for vulnerable populations.

Are special/different procedures needed to protect vulnerable populations?
Is research participant payment appropriate?
Is consent from a legally authorized representative (LAR) needed in situations where subjects are unable to provide independent informed consent?
Some vulnerable populations: children, prisoners, pregnant women in certain studies, persons who are unable to consent, or persons with economically/educational challenges that may intersect with participation in the research.

**Informed Consent Criteria**

| Informed consent will be sought and appropriately documented from each prospective participant or the participant’s legally authorized representative. | Does consent:
| | • Provide sufficient opportunity for consideration?
| | • Minimize the possibility of coercion or undue influence?
| | • Provide information in understandable language?
| | • Exclude exculpatory language?
| | Is the process for conducting consent discussions adequate?
| | Will there be an opportunity for participants to ask questions?
| | Will the participants or LAR sign and date the document?
| | Will a copy be given to the person signing the document?
| | Is child assent and/or parent permission needed?
| | Is the researcher requesting a waiver? If so, are criteria for waivers met? |

**6.3 Informed Consent**

*Informed consent is a process, a conversation, documented with a form that participants sign.* It is essential that informed consent discussions are conducted, and documents are written in plain language that participants can understand. The consent document(s) should always be revised if there are changes in the project that might affect the participant or when additional information will improve the consent process. If appropriate, participants who have previously provided informed consent may need to be notified of changes in the protocol and/or consent document(s). The consent form(s) should not contain any exculpatory language. That is, participants should not be asked to waive (or appear to waive) any of their legal rights, nor should they be asked to release the researcher, sponsor, or institution (or its agents) from liability for negligence. Federal regulations and institutional policy also require that researchers seek informed consent only under circumstances that provide the prospective participant (or representative) sufficient opportunity to consider whether to participate and that
minimize the possibility of coercion or undue influence, defined as any act of persuasion that overcomes the free will and judgement of another.

6.3.1 Informed Consent Not Needed for Screening

An IRB may approve a research proposal in which a researcher will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective participants without the informed consent of the prospective participant (or LAR), if either of the following conditions are met:
1) The researcher will obtain information through oral or written communication with the prospective participant or LAR, or
2) The researcher will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

6.3.2 Informed Consent and Documentation Waivers

An IRB may waive the requirement to obtain informed consent or approve a consent procedure which does not include, or which alters, some or all the elements of informed consent. In most cases, this occurs when the participant is not directly involved in the research procedures (e.g., record review, secondary data analysis) provided the researcher justifies and the IRB finds and documents that:

1) The research involves no more than minimal risk to the participants;
2) The research could not practicably be carried out without the requested waiver or alteration;
3) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
4) The waiver or alteration will not adversely affect the rights and welfare of the participants; and
5) Whenever appropriate, the participants or legally authorized representatives will be provided with additional pertinent information after participation.

In most cases, informed consent must be documented (obtain signature and date from participant). However, in some cases, waiver of documentation of consent (no signature) is appropriate and allowed. For the IRB to waive the requirement of a participant’s signature, one of the following conditions must be justified in the IRB protocol:

1) That the only record linking the participant and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant (or LAR) will be asked whether the participant wants documentation linking the participant with the research, and the participant’s wishes will govern; OR
2) That the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context; OR
3) If the participants or LARs are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to participants and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

If the documentation requirement is waived, the IRB may require the researcher to provide participants with a written statement regarding the research (i.e., a consent form with no signature lines). Note: If
requesting any type of waiver from the IRB, justifications must be provided in the IRB Protocol with direct reference to the criteria listed above.

6.4 Participant Compensation

The IRB will review the amount and schedule of incentives and compensation to assess the appearance or fact of undue influence or coercion for participants. All information concerning participant compensation should be included in the IRB protocol and informed consent document(s), including amount, method, and timing of disbursement. If compensation is mentioned in recruitment materials, the recruitment materials must also include a brief description of project procedures. Compensation cannot be contingent on completion of the project.

For researchers who would like to offer course credit or extra credit to the project population, they must also offer a non-research activity that is equivalent in effort and time/duration to project participation. Research lotteries and raffles can be utilized under certain specific conditions. For raffles and lotteries, participants must be over the age of 18, the study must be minimal risk, total cash value cannot exceed $5,000, there are no second chance drawings, and the consent form must disclose when and where the drawing will occur, the odds of winning, and how the winner will be notified. Please note that studies that receive federal funding may have additional requirements associated with compensation.

6.5 Research Data Security

Each member of the campus community is responsible for the security and protection of information resources over which they control. All researchers must be familiar with information security policies and procedures of their department or unit, WCM, the New York State and Federal privacy laws (e.g., HIPAA, FERPA, FOIA, New York IPRA, Certificates of Confidentiality, as well as the data confidentiality requirements associated with sponsor funding such as NIH, DOJ, etc.)

If there is a breach or loss of human research data, an event report must be submitted to the IRB within 7 days of the discovery of the occurrence. Additional reporting may be required to the institution and sponsor. To initiate sponsor related reporting, contact WCM Office of Sponsored Research Administration (OSRA).

6.5.1 HIPAA

The Health Insurance Portability and Accountability Act (HIPAA) protects Personal Health Information (PHI) collected in covered entities (e.g., clinics or departments that provide services which meet the definition of health care provider, health plan, or health care clearinghouse and bills patients/subjects electronically). The Office of Research Dean hosts a webpage specifically on HIPAA in Research, providing documentation and helpful links to resources with which members should familiarize themselves before reviewing projects invoking HIPAA.
When planning projects that invoke HIPAA, the researcher makes a preliminary determination as to whether HIPAA applies. They will either include required HIPAA authorization language in their informed consent document or as a standalone document. If they think that a HIPAA authorization waiver is appropriate, they will complete and submit a HIPAA authorization waiver form.

WCM IRB staff will verify if the research is regulated by HIPAA, that all elements of HIPAA signed authorization are included, or that waiver justification is provided. IRB members then review the material to ensure that all elements are included or that the justification provided for the waiver is appropriate.

Waiver of authorization can be justified in the following circumstances:

1. The use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
   - an adequate plan to protect the identifiers from improper use and disclosure;
   - an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
   - adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;

2. The research could not practicably be conducted without the waiver or alteration; and

3. The research could not practicably be conducted without access to and use of the PHI.

6.5.2 FERPA

The Family Educational Rights and Privacy Act (FERPA) regulates the disclosure of personally identifiable information from education records in all public elementary and secondary schools, school districts, intermediate education agencies and state education agencies, and any public or private agency or institution that uses funds from the U.S. Department of Education. The purpose of FERPA is to protect all student and parent information maintained in an Education Record (ER). Education records include but are not limited to course grades and graded documents, transcripts, class lists, student course schedules, health records, student financial information and student discipline files. For a researcher to access ER, signed permission from the parent or eligible student (18+ years old or attends a postsecondary institution) is required. Within the consent form the researcher must share what specific records will be accessed, the purpose of the disclosure and to whom the information will be disclosed.

Access to ER without permission (FERPA exception) can be granted under the following circumstances:
• The information is considered directory information as determined by the educational agency.
• If the school district or school official with legitimate access (and not on the study team) strips the information of identifiers prior to disseminating to the researcher.
• If the researcher has been hired by the educational agency to develop or validate educational tests, administer student aid programs, or improve instruction.
• Obtain an exception letter from the School Superintendent or University Registrar (this should be included in the IRB submission). The letter should contain the following information:
  o The determination of the exception;
  o Purpose, scope, and duration of the study;
  o Information to be disclosed;
  o That the information will only be used for the research purpose stated;
  o That protected information will not be released outside of the study team;
  o Whether the information is to be destroyed or returned to the educational agency upon completion of study; and
  o The timeframe in which the information is to be destroyed or returned.

6.6 Legally Authorized Representative

Legally Authorized Representatives (LARs) are used when participants are unable to consent for themselves. An LAR is an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective participant to the participant's participation in the procedures involved in the research.

6.7 Research with Pregnant Women

Federally funded research that includes pregnant women or fetuses must meet additional regulatory criteria (45 CFR 46 subpart B). Minimal risk research that includes but does not target pregnant women is not subject to the requirements of Subpart B, rather the protections under the 111 criteria are sufficient. For greater than minimal risk research, Subpart B regulations will apply with the exception of the requirement that the research develop “important biomedical knowledge”.

6.8 Research with Prisoners

Federally funded research that includes prisoners must meet additional regulatory criteria (45 CFR 46 subpart C) and be certified with OHRP. Persons in transitional custody are not considered to meet the federal definition of prisoner and the 111 criteria are sufficient protections for these participants.

6.9 Research with Children

Federally funded research that includes children must meet additional regulatory criteria (45 CFR 46 subpart D), including provisions for parental permission and assent (or determine that permission/assent need not be obtained). Additionally, requirements of 45 CFR 46.407 must be handled through the secretary of HHS.
6.10 Parent Permission and Child Assent

New York State law requires that if an individual is under eighteen years of age, parental permission be obtained for that child to participate in research, unless married or emancipated by court order. Parental permission must be documented in writing unless waived by the IRB. Parental permission may be waived by the IRB if it is not a reasonable requirement to protect the participants (for example, neglected or abused children). However, the PI requesting the waiver must provide a justification for this waiver and propose an alternative mechanism for protecting the children who will be participating in the project. In most cases, when a project involves minimal risk or involves greater than minimal risk but presents the possibility of direct benefit to the child, one parent or guardian’s permission is sufficient.

**Assent** means that a child has given affirmative agreement to participate in research. In determining whether children are capable of assenting, the IRB considers the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. In all instances where children are capable of providing assent, the researcher should develop a separate assent form written in the language appropriate to the educational level of the child. As a general guideline, children aged seven and older are considered capable of providing assent. Waiver of assent and documentation of assent follow the consent waiver criteria.

6.11 Period of Continuing Review (CR)

Federally funded projects reviewed by the full board are subject to continuing review and have a 1-year or less approval period. Minimal risk research is not required to have an expiration date for IRB approval. A reviewer may determine that a project should be eligible for continuing review depending on the research. The reviewer must justify why continuing review is needed. Projects that may be appropriate for CR include ones that involve: subparts/vulnerable populations; criminal behavior; substance use/mental health data; external sites; complex research procedures; use of devices; or other issues, which must be detailed in the justification.

6.12 FDA vs. HHS

Federally funded research invokes HHS regulations. Some research may also invoke FDA regulations (even if not federally funded). FDA regulations apply to research that meets the definition of clinical investigation and human research. There are some differences between HHS and FDA regulations.

<table>
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<tr>
<th><strong>HHS</strong></th>
<th><strong>FDA</strong></th>
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<tr>
<td><strong>Scope:</strong> All research involving humans conducted or supported by HHS.</td>
<td><strong>Scope:</strong> IRBs that review clinical investigations regulated by the FDA under sections 505(i), 507(d), and 520(g) of the act, and that support applications for research or marketing permits for products regulated by the FDA.</td>
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Research: Systematic investigation, including research development, testing and evaluation, designed to contribute to generalizable knowledge

Clinical Investigation: Any experiment that involves a test article and one or more human participants

Human Participant: A living individual about whom a researcher obtains data through interaction or intervention or private identifiable information

Human Participant: Any individual who is or becomes a participant in research, either as a recipient of the test article or the control – either healthy or a patient.

Participants are allowed to withdraw data if the project allows (noted in ICF)

Participants can’t withdraw data that has already been collected

Consent does not need to be dated

Consent must be signed and dated.

6.13 Research with Devices

When reviewing research with an investigational device, the IRB should determine if it is exempt from Investigational Device Exemption (IDE) or if an IDE is required. Device determinations are required when a project is studying the effectiveness or safety of a device and when any device is not FDA approved for the proposed use. When a researcher proposes to use an investigational device they will complete and submit a Device Form, explaining how the device will be used and providing a risk determination. The IRB must determine whether the device is significant risk (SR) or non-significant risk (NSR).

A device is NSR is the answer is “no” to the questions below:

- Is it intended as an implant and presents a potential for serious risk to the health, safety, or welfare of the participant?
- Is it purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of the participant?
- Is the device for the use of sustainable importance in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of the participant?
- Does the device otherwise present a potential for serious risk to the health, safety, or welfare of the participant?
6.14 Research involving Drugs

IND Criteria (21 CFR §312.2(b))
1) The clinical investigation of a drug product that is lawfully marketed in the United States.
2) The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug.
3) If the drug that is undergoing investigation is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product.
4) The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product;
5) The investigation is conducted in compliance with the requirements for institutional review set forth in part 56 and informed consent in part 50.
6) The investigation is conducted in compliance with the requirements of 312.7.

Similar to reviewing devices, drugs may be considered investigational and there are additional determinations needed from the IRB. For research that involves investigational drugs, the IRB needs to decide if it is exempt from IND requirements. See box for criteria. If determined IND exempt, then FDA approval is not needed. If not IND exempt, then an IND application is required to be submitted for FDA approval.

IDE Categories (21 CFR §812.2(c))

1) A device, other than a transitional device, in commercial distribution immediately before May 28, 1976, when used or investigated in accordance with the indications in labeling in effect at that time.
2) A device, other than a transitional device, introduced into commercial distribution on or after May 28, 1976, that FDA has determined to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976, and that is used or investigated in accordance with the indications in the labeling FDA reviewed under subpart E of part 807 in determining substantial equivalence.
3) A diagnostic device, if the sponsor complies with applicable requirements in 809.10(c) and if the testing:
   (i) Is noninvasive,
   (ii) Does not require an invasive sampling procedure that presents significant risk,
   (iii) Does not by design or intention introduce energy into a subject, and
   (iv) Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.
4) A device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk.
5) A device intended solely for veterinary use.
6) A device shipped solely for research on or with laboratory animals and labeled in accordance with 812.5(c).
7) A custom device as defined in 812.3(b), unless the device is being used to determine safety or effectiveness for commercial distribution.
6.15 Foreign Language Translations

When research includes non-English speaking participants, the researcher should take additional steps to ensure that participants understand the information needed to make an informed decision about participating as well as what is happening as part of the research. Researchers need to effectively convey information to participants in a language that they are comfortable reading, understanding, and speaking. If the project population targets a particular group that does not speak and/or read English, the recruitment material(s) (e.g., approach letters, flyers) and informed consent document(s) must be translated into the language understood by the targeted group (45 CFR 46.116-117 and 21 CFR 50.20).

6.16 External Sites

If a project involves sites outside of WCM, then the submission would include a Letter of Support (LoS) or site IRB approval. When reviewing a submission, make sure to review the LoS to ensure that it allows for the proposed activities. It is the researcher’s responsibility to ensure that they are adhering to all requirements of all sites. In some instances, WCM IRB review may be conducted prior to review at external sites. In this instance, the research is approvable, but with the stipulation that no research can begin at external sites until the appropriate approvals have been obtained.

6.17 Researcher Conflict of Interest

There may be instances where researchers have a conflict with the research that they are conducting. This is determined by the Conflict of Interest Office through annual disclosures. Disclosures are reviewed by the Conflicts Advisory Panel (CAP), which is a faculty committee that advises the Dean of WCM regarding conflicts of interest and commitment related matters. The goal of coordinating the reviews of the CAP and the IRB is first and foremost to prevent financial interests from adversely affecting the welfare of participants and secondly to protect the credibility of the research and WCM. Detailed information about investigator conflict of interest is included on both the HRPP and CAP websites. Procedures are in place for coordinating the reviews of the CAP and the IRB regarding conflicts of interest in human research. Once financial interests are disclosed, they are evaluated by the CAP to determine if a conflict exists, and a management plan is put in place to manage the conflict. Should a researcher have a conflict, the management plan is reviewed by the IRB to ensure that the proposed research incorporates any management plans. The IRB has authority to decide whether any management plan is appropriate in the context of the conduct of the research to adequately protect the safety and rights of the participants. The IRB will be advised if the CAP recommends that the study not be funded and/or conducted at WCM. In that case, the study will be withdrawn and not reviewed any further by the IRB.

Section 7: The IRB Meeting

As discussed in Section 5, full board reviews are discussed at the IRB meeting and an assigned reviewer will present the submission to the members present. Presentations should not take so long that it a) hinders ethical discussion, and b) delays discussion of other protocols on the agenda. It is the Chair/Vice Chair/delegate’s responsibility to ensure that discussions about protocols are resolved in a timely fashion.
7.1 Presenting New Protocols (initial submissions)

1. Provide an initial brief summary of the study and your review.
2. Focus on the salient points and/or comments from your completed reviewer checklist. Remarks, observations, and/or concerns may be documented in ‘Reviewer Comments’ fields located throughout the reviewer checklist.

7.2 Presenting Amendments (modifications to already approved studies)

1. Provide a brief summary of the study and what the proposed changes are (one to two sentences).
2. Present any major problems/questions.
3. Indicate whether the amendment affects the criteria for approval or determinations.

7.3 Presenting Continuing Reviews (annual reviews of already approved studies)

1. Provide a brief summary of the study and verify previous determinations are appropriate.
2. Present any major problems/questions.
3. Indicate whether the progress report affects the criteria for approval.

7.4 Sequence of Events at Meetings

The format for discussion of protocols at the full board committee meeting is not set by federal regulations or guidance documents. Thus, IRBs can develop a routine that works for their institution and membership.

What follows is a basic order of WCM IRB meetings:

1. The meeting starts once quorum is established.
2. The first order of business is the review and approval of the minutes from the previous meeting.
   a. Members should have reviewed the minutes prior to the meeting and communicated with staff if any revisions are needed.
   b. Any concerns about the minutes will be discussed at this time.
3. The Chair reminds members about the IRB member Conflict of Interest Policy and asks if any conflicts exist among those present.
4. The Chair or assigned IRB members present continuing review submissions to update the board on the status of the studies, and votes are taken to renew their approval periods.
5. The board reviews each initial submission as follows:
   a. The primary reviewer presents a BRIEF summary of study. The Board members should have already read the protocol, so there is no need for the primary reviewer to explain the entire protocol.
   b. The primary reviewer presents ALL major problems/questions.
      i. If any board member has expertise in a given area of concern, s/he should address them now
c. The secondary reviewer also provides a summary. The secondary reviewer does not need to repeat what has already been discussed unless they have something substantive to add. If there are no issues, they may state so. Specific minor revisions (including mention of minor consent revisions) do not need to be discussed. Reviewers can simply note that minor consent changes will be forwarded to the analyst.

d. Substantive issues are discussed, one by one.

e. Recommended revisions to the research should be confined to the criteria for approval and should be stated directive if possible.

f. Investigators may be asked, or may ask, to attend the IRB meeting in which their study is discussed, though they must leave before the IRB calls for a vote.

g. The Chair confirms the regulatory determinations (e.g., 111 approval criteria, vulnerable population criteria, IND/IDE status, HIPAA waiver, etc.) including protocol specific justifications.

h. The Chair ends the discussion and states the action (i.e., to approve, accept with contingencies, table, or disapprove) and votes are taken.

6. The Chair or assigned IRB members present amendments to previously approved studies if any, and votes are taken.

An ideal meeting environment is one that promotes an open discussion and encourages all members to express their views in a warm atmosphere, and all IRB members participate in identifying and discussing the issues. There is no formula for this process, so it is essential that the IRB chair manage this aspect of the meeting. The chair determines when all the important issues have been raised, declares the discussion over, and calls for the vote. Questions of regulatory or policy matters are often addressed by the Chair or IRB Analyst as IRB members are not expected to be as expert in these areas.

At any point during the meeting, if quorum is lost, all business is stopped. Reviews of submissions is resumed once quorum is re-established, or submission(s) are moved to the agenda for the next IRB meeting.

7.5 Action Options at Meetings

The following are for use during a convened IRB meeting. Note that the determinations that can be made by an expedited review include approved, modifications required, or refer the study to the full board.

7.5.1 Approved

The study meets the regulatory criteria for IRB approval as defined by 45 CFR 46.111 and/or 21 CFR 56.111. The application has secured approval; thus, the investigator is not required to make changes to the protocol or IRB application. IRB approval is valid for one year unless the committee designates a shorter period due to higher levels of risk. An approval letter is sent to the investigator. The consent documents (if any) are stamped with the IRB approval dates. The investigator may start enrolling subjects.

7.5.2 Modifications Required

Depending on the extent of the modifications the IRB requires, it may issue one of two types of a modifications required determination:
Directive Modifications Required. A determination of Directive Modifications Required applies when the committee understands that all approval criteria have been met, but needs confirmation of this assumption, and thus asks for non-substantive changes are to gain final approval. Examples of directive changes include:

- Confirmation of specific assumptions or understandings on the part of the IRB regarding how the research will be conducted (e.g., confirmation that the research excludes children);
- Submission of additional documentation (e.g., certificate of ethics training);
- Directed language changes to protocol or informed consent documents; or
- Directed changes to protocol or informed consent documents along with clearly stated parameters that the changes must satisfy.

The investigator’s response to directed changes does not need to go back to the full board for approval, but can be reviewed by the chair, a member, or staff on behalf of the IRB outside of the meeting, depending on the type of modifications requested. After the meeting, staff send a letter to the investigator specifying the necessary revisions required for approval.

Substantive Modifications Required. A determination of Substantive Modifications Required applies when the committee is unable to determine, based on the materials submitted, if all approval criteria have been met. The investigator’s response to the requested changes will come back to the full board for review.

A Substantive Modifications Required determination must be made if any of the items listed below are requested:

- Elaboration
- Clarification
- Explanation
- Justification

7.5.3 Disapproved

A study may be disapproved if the magnitude and/or number of concerns, questions, and problems are such that an “approved pending” or “deferred” decision are inappropriate (e.g., the research is illegal, or will require participants to engage in illicit activities in which they would otherwise not engage). In contrast to deferral, which implies that the study may be approvable pending substantive changes, disapproval of research should be reserved for when the board cannot reasonably imagine revising the study in such a way that the benefits outweigh the risks.

7.6 Voting Options at Meetings

Once the action and determinations has been stated by the chair, the members will vote on that recommendation. There are four voting options, for, against, abstain, and recuse.
7.6.1 For
A vote “for” means that the member agrees with the action and determinations. When the majority of members present vote for an action, that action stands.

7.6.2 Against
A vote “against” means that the member does NOT agree with the action and/or determinations.

7.6.3 Abstain
When a member does not want to vote on a proposed item for a reason other than a conflict of interest (i.e., did not have enough information to make decision), the member can “abstain.” Abstentions count toward quorum.

7.6.4 Recuse
If an IRB member has a conflict of interest as discussed in Section 5, they are recused for the review of that submission. The IRB may ask the conflicted member to provide information to assist with the review of the submission. The IRB member must leave the room. The meeting minutes will reflect this.

Section 8: Post Approval Monitoring

After a research project is approved, there are many situations requiring communication with the IRB during the conduct of the research. These communications result from events that unfold (and may or may not be expected) as the research is taking place. Investigators are required to submit reports or communication on adverse events, unanticipated problems, audits, expiration of approval period, and terminations/suspensions. In some instances, the IRB will be asked to make non-compliance determinations.

8.1 Reportable Events: Adverse Events and Unanticipated Problems

After a potential reportable event occurs, the principal investigator is required to submit a reportable event form to the IRB through the WRG system. These reports must be submitted within 5 days of becoming aware of the problem. The Principal Investigator’s report should contain enough information for the IRB to determine whether the event increases the level of risk to participants, requires a research design change, or necessitates modification to the informed consent form. The WCM IRB also requires investigators to report various other events, such as unresolved subject complaints or protocol deviations that may place subjects at increased risk. For a full list of reporting requirements, refer to the “Immediate Reports” policy. Definitions of adverse event, serious adverse event, and unanticipated problem can be found on the website.

8.2 Audits

Clinical studies are periodically audited by the JCTO Quality Assurance Unit (QAU), which then issues reports to the Data Safety Monitoring Committee (DSMC). If the QAU or DSMC conclude there is cause for an IRB audit, the Human Research Compliance team will conduct a for-cause audit on behalf of the IRB. In an effort to support ethical research, the IRB may audit ongoing human research. Options include:

- Full on-site assessment conducted by WCM HRC staff.
• Full audit of all records and processes.
• Consent document review: Conducted either by WCM IRB or HRC staff. For a consent only assessment, the researcher may be informed to submit all signed consent/assent signature pages for all participants enrolled during a specified period.
• Consent process review: Conducted by researcher. When a project is viewed as sensitive, high risk or when the IRB has concerns regarding the process for obtaining informed consent, the WCM IRB may request a consent process review. Using a checklist, researchers verify while conducting a consent conversation that it contained all components.
• Consent process observation: Conducted by WCM IRB staff. When a project is viewed as sensitive, high risk or when the IRB has concerns regarding the process for obtaining informed consent, the WCM IRB may request a consent observation. The WCM IRB informs the researcher(s) that consent observation is required, and it is the responsibility of the researcher(s) to coordinate with WCM IRB staff.

8.3 Expiration of Approval Period

The WRG-HS system issues expiration notices 90, 60, and 30 days prior to the protocol expiration date, as well as on the day of expiration. If the investigator does not submit a continuing review form through WRG in time for review and approval by the expiration date, IRB approval has expired. After 90 days post-expiration date, the study will be closed in the system, and a new application must be submitted by the researcher if the study is to continue. Failure to have a project approved or closed prior to the IRB approval expiration date is non-compliance. When IRB approval expires on a project, a formal non-compliance determination is issued. If a PI has a pattern of IRB approval expiring for projects under their oversight, compliance training will be required, and a fully convened IRB may review the non-compliance. Even if IRB approval has expired, the PI is still responsible for closing the project.

In the event that a protocol expires, and the withdrawal of research interventions may place study subjects at risk, the investigator may request (through WRG) that the IRB grant permission to allow the continuation of activities required for subject safety prior to renewal of IRB approval. If subject safety would be compromised by study closure, investigators can request that the IRB allow continuation of study activities for currently enrolled subjects. If research-related interventions have been continued with subjects on an expired protocol, the IRB must be immediately informed of the circumstances that necessitated this action by means of a Protocol Exception request.

Requests justifying continuation of currently enrolled subjects will be forwarded to an IRB Chair for consideration. If the IRB Chair grants permission to allow the continuation of research interventions with previously enrolled subjects for reasons related to subject safety, the IRB will send written notification to the investigator. Other research activities (such as recruitment, enrollment, data analysis, identifiable data use/storage, etc.) may only be resumed after the investigator receives continuing approval for the research.

8.4 Termination/Suspension of a Study

Termination is when the IRB permanently withdraws approval of ALL research activities for a particular study and all research activities must cease. Terminated research is no longer required to undergo continuing review.
Suspension is when the IRB temporarily or permanently withdraws approval of some or all research activities. All research activities must cease during the suspension. Suspended research is still under the jurisdiction of the IRB and still requires continuing review. [a.k.a. Enrollment hold, Study hold/halt, Recommendation by the IRB to temporarily suspend]

If there is an urgent situation requiring suspension of all or part of a study, the IRB Chair or Vice Chair or the convened IRB may make this determination. [The IO may only suspend institutional approval of a study, but NOT IRB approval] When IRB approval is suspended by the Chair or Vice Chair, it must be reported to the convened board at the next available meeting. The convened IRB will then:

- Determine if the suspension should continue, be lifted, or be modified.
- Consider any actions necessary to ensure that the rights, safety, and welfare of subjects are appropriately protected, including notification to subjects.
- Notify the PI in writing (a call or email may precede the written notice if appropriate), including:
  - The reason(s) for the suspension.
  - Any requirements or conditions associated with the suspension (e.g., notification of subjects).

The investigator is given the opportunity to respond in person or in writing. Reports of suspensions of IRB approval must be made by the IRB within 30 days of the IRB’s determination to the OHRP, Common Rule agencies and/or FDA, depending on a variety of factors. If reporting to these federal agencies is not required, the IO must still be notified. Reports are written by a designee of the Executive Director of Human Research Protection and Compliance and reviewed by the Executive Director of Human Research Protection and Compliance. The IO will sign off on these reports.

A copy of the report is supplied to the PI for their regulatory records, with the following parties cc’d:

- Executive Director, Clinical Trials (if the finding is related to a clinical trial involving the JCTO (Joint Clinical Trials Office))
- Director, Cancer Clinical Trials Office (CCTO), if the finding is related to research under the auspices of the Meyer Cancer Center
- PI’s Division Chief if the Principal Investigator is from the Department of Medicine
- PI’s Department Chair if the Principal Investigator is not from the Department of Medicine
- Others as deemed appropriate by the IO

8.5 Non-compliance

There are several instances where a project may need a non-compliance review:

- **General** – failure on the part of the PI or any member of the research team to adhere to IRB determinations and/or abide by applicable laws, regulations, or policies. General non-compliance may vary in severity based upon the overall risk potential of the non-compliance and its frequency. Non-compliance determined to be general in nature and not serious and/or continuing is not reportable to regulatory authorities or sponsors.
- **Serious** - failure to adhere to IRB determinations and/or abide by applicable laws, regulation, or WCM policies when that failure increases risk to participants or adversely affects the rights and welfare of the participants.
• **Continuing** - a pattern of ongoing activities that indicate a lack of understanding of human research protection requirements that may affect participants or the validity of the research.

NOTE: Serious and Continuing Non-compliance for federally funded research must be reported to regulatory authorities and the sponsor.

Non-compliance reviews start with designated IRB staff collecting information, then review by the Chair(s) and when necessary, review by the convened IRB. When reviewing non-compliance, there are specific considerations for review:

- Read the report and supporting documentation.
- Determine whether there is non-compliance, serious non-compliance, or continuing non-compliance.
- Determine whether the non-compliance was resolved successfully by the PI.
- Determine if corrective actions are required. Potential determinations include:
  - Education of the researcher(s).
  - Modification to the protocol or other documents.
  - Require that participants be re-consented.
  - Notify current participants when information may relate to their willingness to continue participating in the research.
  - Providing additional information to past participants.
  - Suspension or termination of the research.
  - Require further post approval monitoring.
  - Change the period for continuing review.

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**Section 9: WRG Instructions**

Weill Research Gateway instruction guides and FAQs are available on the [WRG Information page](https://wrg.weill.cornell.edu/) on the ITS website; please refer to those documents if you have any questions about WRG.

**9.1 Accessing WRG:**

Log in at [https://wrg.weill.cornell.edu/](https://wrg.weill.cornell.edu/) using your WCM credentials.

**9.2 Activating account:**

IRB Chairs must submit a WRG [Central Access Request Form](https://wrg.weill.cornell.edu/) for new members, specifying to which Board the member should be added in the IRB Member box under the Human Subjects Access section of the form:
9.3 Email address:

Confirm that your correct email address is listed in the system by going to “My Profile”.

9.4 Checking CITI training status:

Confirm that your CITI training is active and showing in your user profile. Log into WRG-HS, click on the “my profile” link, and then “certification & training” to view your CITI course completions and expiration dates.

9.5 Notification of Review Assignment:

When you are assigned a review, you will receive an automated email from the WRG system with the subject line stating: “IRB Notification: Review Assignment”

- The IRB analyst who is assigned to your submission should be included in ALL EMAIL COMMUNICATION regarding your review.

9.6 Completing reviewer’s checklist:

Once a submission has been assigned to you for review, you will receive an email both in your Outlook inbox, as well as your Messages on WRG. You will also receive an Action Item in WRG. Under the Form/Document section,
you will find the Reviewer Checklist and IRB Application. You must answer the questions contained on your specific Reviewer Checklist while reviewing the IRB application, as appropriate. After you conduct your review and answer the questions on your Reviewer Checklist, click the Save button, followed by the Complete checkbox.

For more information about completing your review, please see KB article How To: Conduct an IRB Review