DOWNSTATE
HEALTH SCIENCES UNIVERSITY

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IRB Guidance: Roles and Goals of IRB Members, Consultants, & Guests

KEY POINTS:

1. New IRB members should develop formal and informal mentoring relationships with current or past IRB members. The IRB will assign a new member to collaborate with a mentor; however, the new IRB member is encouraged to form other informal mentoring relationships from within and outside of Downstate.
2. To ensure quorum at IRB meetings, the IRB roster is divided into primary and alternate members. To achieve and keep a quorum, the majority of all primary members or one of their alternates must be present at the meeting, including one non-scientist. An MD must be present for review and approval of an FDA regulated clinical trial.
3. New IRB members should take part in a one-on-one orientation with an IRB office staff member to learn how to enter review comments in IRB System and review the training materials outlined in this guidance.
4. IRB members should let the IRB office know if they will be out for an extended period to ensure reviews are not assigned to them while they are out of the office; however, whenever possible, let the IRB Office know if they can complete assigned reviews and enter comments in IRB System.
5. Each IRB Committee member should complete assigned reviews and enter reviewer comments into IRB System ahead of the scheduled deadline; however, IRB member should let the IRB office know immediately if it is not possible to review a submission for any reason so that it can be immediately reassigned to another member.
6. The community IRB members advocate for the views and considerations of research participants.
7. Whenever possible, the IRB Office shall assign reviews within 10 business days of the deadline for the review; however, if this is not possible due to extenuating circumstances (i.e., potential lapse of continuing review, urgent review request from PI), the IRB Office will reach out to the IRB Member(s) to check their availability for a more rapid review and update the PI if the review is not possible.
8. The goal of IRB members is to enter their reviews and comments in IRB System as soon as possible, but no later than the **Close of Business (COB) on the Friday before the scheduled Full Board meeting date** and within **5-10 business days** for all other reviewer assignments.
9. All IRB Members should attend all meetings; however, the goal is for each member to attend at least five (5) out of the estimated six (6) meetings per calendar year, as based on the odd or even month for which they are designated as a primary member on the roster.

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INTRODUCTION

The SUNY Downstate Health Sciences University (Downstate) has an Institutional Review Board and Privacy Board (IRB) that consists of diverse people in various roles to ensure that the IRB approves research that is scientifically sound, ethical, and compliant. IRB members uphold and promote the highest standards of scientific honesty, academic quality, public responsibility, and social benefit when they review and oversee research. This guidance gives a summary of IRB members and their general duties, roles, and goals and provides essential information about the roles of consultants and guests. The main ideas of this guidance document are summarized below:

- **IRB members and their qualifications:** The document describes the structure, composition, and qualifications of the IRB members, who are appointed by the Downstate Institutional Official (IO) on behalf of the President. The IRB must have members with diverse backgrounds, expertise, and experience to review and oversee human research protocols. The IRB must include at least one scientist, one non-scientist, and one unaffiliated member.
- **IRB member roles and goals:** The document outlines the general roles and goals of the IRB members, such as reviewing research protocols, safeguarding the rights and welfare of research participants, maintaining confidentiality, attending IRB meetings, and completing IRB training. The document also specifies the special roles of community members and prisoner representatives.
- **IRB review process and types:** The document explains the IRB review process and the types of review that can be performed, such as full board, expedited, or exempt review. The document also provides information about guidance and checklists for the IRB members to conduct the reviews and enter their comments in the IRB Application and Reporting System (IRB System). The document also states the quorum and voting requirements for IRB meetings.
- **IRB appointment and term of service:** The document details the IRB appointment process and the term of service for IRB members. The initial appointment is usually for one year, and subsequent appointments are for three years. The IRB members are expected to attend at least five out of six meetings per year and complete their reviews on time. The IRB members may resign, request a leave of absence, or be removed by the IO for any reason.
- **IRB meeting preparation and process:** The document provides tips and suggestions for the IRB members to prepare for and conduct the IRB meetings. The IRB members should review the materials, enter their written comments in IRB System, consult with the IRB Chair or staff when needed, and limit their verbal summary to a few minutes at the convened meeting. The IRB members must declare a conflict and recuse themselves from any project where they have a conflict of interest.

IRB MEMBERS

Downstate Policy IRB-01 describes the role and the review process of the IRB, and the IRB's structure and composition should match the kind and volume of research that it reviews. The IRB aims to have members who represent the fields that cover most of the research done at Downstate and may also enlist consultants to help with the reviews.

The IRB will consist of qualified members who have the expertise and competence necessary to review and evaluate human research protocols. According to federal regulations, the IRB (roster) shall be comprised of professionally and ethnically diverse members, with a minimum of five members. The IRB must include at least one member whose primary concerns are in scientific areas ("Scientific Member") and at least one whose primary concerns are in nonscientific areas ("Nonscientific Member"). Additionally, the IRB shall include at least one member who is not otherwise affiliated with the Downstate and who is not part of the immediate family of a person who is affiliated with the Downstate ("Unaffiliated Member"). The IRB will maintain a balance of both female and male members and include professionals with significant expertise and experience with select vulnerable populations for which research at Downstate is often conducted, particularly children and pregnant women.

The IRB will always strive to ensure and promote a diverse and inclusive membership. It is highly desirable for the IRB members to have personal experience or knowledge with various factors that affect the research including race, ethnicity, immigration status, age, religious or non-religious affiliations, languages, disabilities, geographic locations, social economic status, social determinants of health, gender expression, sexual orientation, students, and trainees to reflect the research participant groups that may be part of the research that the Downstate IRB reviews. If specific knowledge or experience is missing during the review of a protocol with vulnerable groups or scientific knowledge, the IRB may seek input from consultants who have experience or knowledge in these areas. The IRB administrative staff may be appointed as voting IRB Members by the Downstate Institutional Official (IO).

SCIENTIST/NONSCIENTIST

IRB members who have the training, background, and profession that would make them see scientific activities from the viewpoint of someone who is part of a behavioral or biomedical research field should be called a scientist, while members who have the training, background, and profession that would make them see research activities from a perspective outside of any biomedical or behavioral scientific field should be called a non-scientist. Moreover, the IRB must have members who know enough about the specific scientific discipline(s) that are relevant to the research that it evaluates.

AFFILIATION

“Affiliated” means members of the Downstate workforce (as explained in Step 4a of the IRB Electronic Submission Process website). “Affiliated” members also include anyone who is on another committee or board at Downstate, or someone who has a close relative that is a member of the Downstate workforce or appointed to a Downstate committee or board.

”Unaffiliated” means anyone without a relationship with Downstate, except as an IRB Member, such as a community member for the purposes of contributing to the Downstate IRB or even if they serve` in a voluntary capacity with other Downstate committees. Unaffiliated members can be people who are now or were patients, or research subjects of Downstate. Unaffiliated members can get paid for their work without becoming otherwise affiliated nor does payment for their IRB work create a conflict of interest with the IRB.

COMMUNITY MEMBERS

There is no official definition of what makes someone a "Community Member", but they are usually not scientists and usually do not work for Downstate. Community members are selected for their experience, knowledge, or connection to the kinds of studies that the IRB reviews. They might be former research participants, patient advocates, teachers, clergy, members of vulnerable populations, retirees, or experts in multicultural affairs. The IRB might look for these members among the community groups that Downstate serves or who live nearby. These members can represent ethnic, socio-economic, or patient groups who participate in Downstate research and can contribute a valuable perspective towards IRB discussion and decisions.

The Community Member has a significant role in making sure that the local issues of the research community are considered to help keep the public's trust in research. Community members are in a special position on the IRB to prioritize research participants, as they are less likely to be swayed by personal goals, profits, scientific bias, or interests of Downstate or other institutions engaged in the research under review.

PRISONER REPRESENTATIVE

The IRB must have at least one member who is either a prisoner or someone who can represent the prisoners' perspectives based on their relevant background and experience, when the IRB evaluates research that includes prisoners. If the IRB cannot find someone with direct prison experience, they should find someone who knows about the prison conditions and the life of a prisoner. Possible candidates could include current or former prisoners; prison chaplains; prison psychologists, prison social workers, or other prison service providers; people who have advocated for the rights of prisoners; or anyone who can safeguard the rights and welfare of prisoners based on their suitable background and experience. The IRB must also have more than half of its members (not counting prisoner members) who are not affiliated with the prison(s) that are involved in the research. If the IRB does not have any prisoner representatives on its roster, it may refer the research that involves prisoners to another IRB that is constituted to review the research.

ALTERNATE MEMBERS

Alternate members have the same appointment and function as primary IRB Members. Downstate aims to ensure that the alternate's skills and point of view are like those of the primary member. The alternate member's role is to function as a voting member of the IRB when their primary member cannot attend a meeting.

The IRB roster shows the primary member(s) for whom each alternate member can replace. Both primary members and alternates can serve as primary or secondary reviewers. All members receive all materials for the IRB meeting.

Each alternate IRB Member has comparable experience, expertise, background, professional competence, and knowledge to that of the primary IRB Member whom the alternate would substitute, in relation to the function that the primary IRB Member was meant to perform.

QUORUM AND VOTING

The Executive Director works with the IRB Chair to assign primary and alternate members on the roster, so that the IRB meetings have enough members to meet the quorum requirements. For a convened (full board) meeting to take place, a quorum must be reached which is defined as half or more of all primary members (or their alternates) in attendance at the meeting, with at least one non-scientist and one scientist. A medical doctor must be present for an FDA regulated clinical trial to be reviewed and approved.

Each voting group has one vote at the meeting, either by the primary member or the alternate member. The alternate member present at the convened meeting votes if the primary member cannot vote for any reason (e.g., absence, recusal). The alternate member also votes at the convened meeting instead of the primary member for any agenda item they are assigned the review, even if the primary member is present at the meeting.

APPOINTMENT AND TERM

The IRB appointment process and terms for appointments are described below.

IRB APPOINTMENT PROCESS

The IRB members and IRB Committee composition are assessed regularly or as needed by the IO, IRB Chair, SVPR, and Executive Director to ensure they meet the institutional and regulatory requirements.

IRB Chairs, IRB Members, IRB Office Administrators, Department Chairs, or Deans typically

recommend candidates for IRB membership; however, anyone can propose a member, including themselves. Before proposing someone for a Chair or Vice-Chair position, the Dean or Department Chair should be contacted to confirm they support the proposal. The IO and SVPR may grant an “Also-Receives” (A/R) compensation or consulting payments, as applicable, for the Chair or Vice-Chair appointments, as determined by them; however, the A/R or consulting payments can be changed or removed at any time by the Senior Vice President and Chief Administrative Officer and the campus President.

Before any member is considered by the IO for an appointment, it is suggested that the potential member read this guidance and meet with the IRB Chair and Executive Director to learn about member expectations and verify the time commitment required to be a member. The potential member may also want to talk to his/her supervisor, Department Chair or Dean, and may wish to look at the IRB member training materials.

A nominee for consideration for appointment must provide a current Curriculum Vitae (CV)/resume, to be reviewed by the IO and to be maintained by the IRB office and if appointed must update their CV/resume with the IRB Office, as needed.

After receiving a nomination, the IO should determine the suitability of the candidate, based on qualifications, experience, reputation, and committee needs and may consult with the IRB Chair, IRB Vice Chair, President, SVPR, Deans, Department Chairs, Executive Director, Human Research Protection and Quality Assurance, RF Executive Director/Deputy Operations Manager, or others to decide whether to appoint the nominated candidate.

The final decision in choosing a new member, and appointment thereof, is made by the IO on behalf of the President. The Institutional Official (IO) appoints IRB members on behalf of the President.

TERM

The initial appointment will usually last for a one-year period. Subsequent appointments of IRB members who are in good standing are usually renewed for three years of service. Unless they are IRB Office Staff who can also be appointed as members, all other IRB Members are only expected to serve on the IRB for a limited time up to 4 terms (approximately 10 years), so that the IRB can benefit from new knowledge and experience from different engaging faculty and employees on a rotating basis; however, if there is a shortage of IRB members with specific experience, the IO may renew a member beyond their 4 terms on a temporary basis while looking for or while training new IRB members. Former IRB members are very valuable to the IRB and Downstate and are encouraged to join other Downstate committees and become consultants to either the IRB or Central Methodology Review Committee (CMRC) and provide mentorship to new IRB members.

An IRB Member can resign from the committee at any time for any reason. Chairs and Vice-Chairs must give 30 days' notice before they leave their appointed position.

IRB Members who are unable to complete their reviews promptly, stay involved, or participate in meetings regularly for any reasons should consider either leaving the committee voluntarily or taking a temporary pause from the IRB roster, so their lack of presence does not affect quorum requirements, until they can return in a fuller capacity. Members can ask for a pause for a specific time by sending an e-mail notice to both the IO and Chair with a copy to the Executive Director. Members can opt to become consultants and/or step down by sending a written notice to the Chair and IO, with a copy to the Executive Director. Members can be dismissed by the IO or campus President for any reason and a dismissal may be recommended by an IRB Chair, Department Chair, Dean, or SVPR of Research.

When there is a substantiated allegation of serious or continuing non-compliance or research misconduct investigation of an IRB Member, the IO, Campus President, or IRB Chair may remove the member from the IRB Roster until the situation is fully investigated and resolved. If an IRB member cannot maintain attendance or engagement or finish their reviews on time, the IO, Campus President, or Chair may remove them from the roster.

If a member resigns or is removed, they can join the committee again through the appointment process. A thank you letter should be sent to any IRB member who leaves or is removed due to time limits or resignation.

GENERAL QUALIFICATIONS FOR IRB MEMBERSHIP

An IRB member candidate should ideally have the following qualifications: effective communication skills, high respect from the research community, substantial human research or IRB experience, willingness to learn IRB policy and regulations, dedication to meet review deadlines, have basic computer, internet, and word processing skills, have the professional ability to review specific research activities, be prepared to receive training from the IRB Staff on how to do reviews and use IRB System, be prepared to read training materials from the IRB and be mentored by IRB Office Staff and IRB Members.

While not required, prior IRB experience is very valuable.

It is preferrable to appoint a Chair or Vice-Chair with an MD in a Faculty position at Downstate, with credentials at University Hospital SUNY Downstate.

GOALS OF IRB MEMBERS

Below is an outline of general goals for IRB members.

TRAINING AND EDUCATION

All IRB members should complete the following training:

- Meet with the IRB Chair and/or Vice-Chair.
- Meet with the Executive Director.
- Meet with their assigned mentee.
- Participate in a one-on-one orientation with an IRB office staff member to learn how to enter review comments in IRB System.
- Complete OHRP's Human Research Protection Foundational Training and provide a copy of the certificate to the IRB Office.
- Complete the online IRB Training assigned in the Downstate Learning Management System, and refresher training every three years.
- Review the FDA and Common Rule
    - 45 CFR 46 (2018 version)
    - 21 CFR 50, 56, 312, & 812
    - Expedited Review Categories
- Become familiar with and review all materials posted on the IRB Policy and Guidance website, including the information specifically titled "Guidance for IRB Members"
- Review The Belmont Report
- Review OHRP guidance on approval of research with conditions.
- Review books about statistical methods and research design. Contact the IRB for references, if needed.
- Become familiar with all IRB forms, templates, and guidance posted on the IRB website for both IRB Members and Investigators.
- Complete CITI training for investigators.
- Review the guidance associated with IRB reviews from the FDA and OHRP website.
- Take the OCAS HIPAA training and Conflict of Interest training modules.
- Complete the following optional CITI training modules.
    - GCP
    - IRB Member modules
    - IRB Chair modules, if applicable
    - Conflict of interest training, if OCAS training was not done (e.g., non-Downstate staff)
- Be familiar with Secretary's Advisory Committee on Human Research Protections (SACHRP).
- Attend educational sessions held or sponsored by the IRB.

GENERAL GOALS

Goals for IRB Members include, but are not limited to the following:

- IRB members should let the IRB office know if they will be out for an extended period to ensure reviews are not assigned to them; however, whenever possible, let the IRB Office

know if they can complete assigned reviews and enter reviewer comments in IRB System.

- Whenever possible, the IRB Office shall assign reviews within 10 business days of the deadline for the review; however, if this is not possible due to extenuating circumstances (i.e., potential lapse of continuing review, urgent review request from PI), the IRB Office will reach out to the IRB Member(s) to check their availability for a more rapid review and update the PI if the review is not possible.
- The goal of IRB members is to enter their reviews and comments in IRB System as soon as possible, but no later than the **Close of Business (COB) on the Friday before the scheduled Full Board meeting date** and within **5-10 business days** for all other reviewer assignments.
- Each IRB Committee member should expect to have an assigned review for any committee meeting and to be prepared to enter reviewer comments into IRB System ahead of the scheduled IRB meeting; however, IRB members should let the IRB office know immediately if it is not possible to review a project for any reason so that it can be immediately reassigned to another member.
- Let the IRB offices know immediately if it is not possible to review a project due to time constraints, absence, or conflict of interest, so that it can be immediately reassigned to another member.
- **Every Committee Member** MUST review and be familiar with **all** the IRB submission materials (protocols, consent forms, etc.) being reviewed/discussed at the convened IRB meeting, which they are expected to attend as a Primary Member for the month. All other members attending the meeting **must** review the study materials to be prepared for the meeting. Assigned reviewers **must** enter comments into IRB System ahead of the convened meeting; however, all IRB members are encouraged to submit reviewer comments in IRB System for any submission. ***Please note: The IRB Chair / Vice Chair will guide the determination of which comments are to be discussed at the convened meeting. All comments entered within IRB System, whether discussed at the meeting or not, will be considered and may be communicated to investigators, as necessary.***
- IRB members may update or amend their comments in IRB System after the meeting takes place after items are clarified in a meeting; however, they should do this within 24 hours of the meeting and notify the IRB Office of the update, so that the information is appropriately included in determination letters and minutes. *NOTE: Any updated items that were not voted on at the meeting would be considered a recommendation, unless the change is a regulatory or policy requirement.*
- Perform initial and continuing review of full board projects.
- Perform initial and continuing review for expedited projects.
- Perform reviews of other IRB submissions as necessary.
- Review and inform the IRB Staff of corrections or additions needed for meeting minutes.
- Review Amendments, Continuing Review/Progress Reports, Reportable Events, Closure (Final) Reports, or other considerations, as described in policy or regulations.
- Maintain continuing education in the fields of human research protections, ethics, and research methodology.

- Follow the SUNY Downstate Code of Ethics

GENERAL ROLES OF IRB MEMBERS

The general roles of IRB members are outlined below:

- IRB members respectfully provide reviews, advice, and counsel to researchers; safeguard the rights and welfare of research participants; and possess the professional competence necessary to review specific research activities.
- The purpose of the convened IRB committee is to review, deliberate and vote on the approval or disapproval of research protocols and recommend necessary modifications to protocols needed to further protect the rights and welfare of human participants.
- The IRB members may take on reviewer roles as assigned by the IRB Chair, Vice Chair, Executive Director, or IRB Staff.
- The IRB shall promote activities designed to enhance understanding of human research by participants, prospective participants, or their communities, as appropriate.
- When possible, the IRB shall promote the involvement of community members in the design and implementation of the research and the dissemination of results.
- Review IRB minutes and submit proposed revisions to the IRB Office.
- Notify the IRB Office when they are not available for meetings or when they will be out for more than two weeks.
- Attend outside educational events (such as web-based training, guest speakers, and conferences), which are in addition to educational sessions presented at the IRB meetings. Contact the IRB for suggestions about where to learn more.
- Notify the IRB of any potential, perceived, or real conflict of interest and absent themselves from deliberations and voting on these projects.
- Maintain confidentiality and sign a confidentiality agreement.
- Ask questions.

SPECIAL ROLES OF COMMUNITY MEMBERS

Special roles for community members are provided below:

- Most importantly, represent the community of research participants – not the interest of the institution. Be willing to be the “unsung hero” to the community.
- Review IRB applications each month and provide written feedback in IRB System.
- Be willing to voice your thoughts, opinions, and concerns in the IRB meeting or privately to IRB Chairs, the IRB Office Staff, or the Institutional Official.
- Review the participant facing materials, such as informed consents, parental permission forms, child assent forms, information sheets, and advertisements to ensure these documents would be understandable to research participants.
- Review the informed consent document to make sure all the required elements are provided.
- Assure that IRB applications included adequate protections for research participants.
- Voice any concerns about the research that might be viewed as unacceptable or unethical to the public or the local community.
- Provide your opinions and unique viewpoints.
- Be the voice of the research participants in the research process.

- Consider the values of the community, neighborhood, patients, public, and society when reviewing the research.

REVIEW ROLE AS AN IRB MEMBER

Given that the mission of the IRB is to protect the rights and welfare of human research participants, this goal drives every decision of an IRB member. It can be a challenge to avoid getting distracted by issues not related to protecting human research participants.

The review should be based on the Principles of The Belmont Report and other regulatory and policy requirements. The IRB guidance for full and expedited review outlines key information for the initial review of studies and is posted on the "Guidance for IRB Members" section of the Downstate IRB Policies and Guidance website.

The "111" criteria for IRB approval under the Common Rule are outlined in greater detail within this guidance, and are summarized below:

- Risks to research participants are minimized.
- Risks to research participants are reasonable in relation to the anticipated benefits to the research participants, and the importance of the knowledge that may reasonably be expected to result.
- Selection of research participants is equitable.
- Informed consent is prospectively sought, unless waived.
- Informed consent is documented, unless waived.
- The informed consent document meets all the regulatory requirements.
- When appropriate, there are adequate provisions for data and safety monitoring.
- When appropriate, there are adequate provisions to protect privacy and maintain the confidentiality of the data.
- When some or all the research participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these participants.

The elements of informed consent under the Common Rule are outlined in greater detail within this guidance, and are summarized below:

- Statement that the study involves research.
- Include research purpose, duration, and a description of research procedures and identify which are experimental.
- Reasonably foreseeable risks and discomforts
- Potential benefits
- Disclose, if any, alternative procedures, or treatment
- Provisions for confidentiality of identifiable information
- If greater than minimal risk, provide management of research related injury as appliable (compensation, medical treatments, further information)
- Contacts for additional information (who can answer questions about the research, about rights, who to contact in the event of a research related injury)

- Include statement about voluntary participation and the right to discontinue participation in the research without penalty.
- Description of the future use of identifiable private information or identifiable specimens (see full regulatory details in IRB guidance or regulations)

The additional elements of informed consent, under the Common Rule, when appropriate, shall include the following:

- Unforeseeable risks
- Anticipated circumstances for termination of participation by an investigator
- Additional costs
- Consequences of discontinuation of the research
- Notification of significant new findings
- Approximate number of research participants.
- Whether participant will share commercial profit for the use of specimens
- Disclosure of clinical and research results
- Whether the research might include whole genome sequencing.

If the research includes PHI, additional requirements must be included for the HIPAA Authorization.

The “111” criteria for IRB approval and the elements of informed consent for FDA regulated research is slightly different and is outlined in the IRB guidance for full and expedited review and is posted on the “Guidance for IRB Members” section of the Downstate IRB Policies and Guidance website.

An IRB member reviewing research should determine if a requiring a modification will safeguard participant rights and welfare or align with the "111" approval criteria. If not, they may approve the study without changes. Otherwise, they should withhold approval or require a modification.

IRB Member Action	Question	Answer	Decision
Focus on review	Will a change safeguard the rights and welfare of the research participant or align with the "111" criteria for IRB approval?	No	Consider approval of the research without requiring a change.
Focus on review	Will a change safeguard the rights and welfare of the research participant	Yes	Either 1) do not approve the research

	or align with the "111" criteria for IRB approval?		or 2) request the change.

REVIEW GOALS

To help the IRB staff and IRB Chairs to review and handle comments properly and promptly, the best practices for IRB members are:

- **Always check the box in IRB System to indicate their review is complete**. This will trigger an automatic message to the IRB Office staff, and,
- Submit full board reviews and comments in IRB System **right away**, and at the latest by the **End of Business (EOB) on the Friday before the planned meeting date**, or
- **Within 5-10 days** for all other reviewer assignments, as noted in the table below:

Type of event	Turnaround goals to enter reviewer comments in IRB System after notice of assignment.
Initial Review of new study via full board review process. *NOTE: Whenever possible, the IRB Office shall assign reviews within 10 business days of the deadline for the review; however, if this is not possible due to extenuating circumstances (i.e., potential lapse of continuing review, urgent review request from PI), the IRB Office will reach out to the IRB Member(s) to check their availability for a more rapid review and update the PI if the review is not possible.*	All comments should be entered in IRB System no later than COB on the **Friday before the scheduled meeting date**.
Initial Review of new study via expedited review process.	**ASAP**, and no later than **10** business days.
Initial Review of new study via exempt review process.	**ASAP**, and no later than **10** business days.
Expedited review of reportable event and other expedited review activities.	**ASAP**, and no later than **10** business days.
Urgent expedited review activities, such as SAEs, Privacy Breach, Information Security Breach and other serious events.	**ASAP**, and no later than **5** business days.
IRB Determination Requests (Made by IRB Office Staff who are also IRB Members)	**ASAP**, and no later than **5** business days.

IRB MEETING ATTENDANCE

IRB Meetings will mostly be held online using Zoom or Teams. If a meeting is planned to happen face-to-face, and members cannot be there physically, they can participate by phone or video call or hybrid remote Zoom/Teams session.

The goal is for each IRB Member to participate in at least five (5) of the expected six (6) meetings per year, based on the roster; however, are encouraged to attend all the meetings whenever possible.

IRB Members are welcome and expected to join every meeting, regardless of whether they have a protocol review assigned, because they will benefit from the discussions and activities that take place. Each IRB Member should attend the IRB meeting that matches their roster assignment. Please let the IRB Office know in advance if you anticipate missing any meetings for planned leave.

The Chair, IO, Campus President, Dean, or Department Chair may request a member to step down from the IRB or become an Alternate member or consultant, if they are absent, late, or must depart early from too many meetings, even if their absenteeism is with a good reason.

A prisoner representative IRB Member should aim to be present at the meetings where they conduct a review or prisoner research, and are encouraged to join all meetings.

Consultants should only plan to attend meetings when asked, but regular consultants are welcome to attend all IRB meetings.

CONSULTING AND MENTORSHIP

All IRB members should consult with the IRB Chair, Vice-Chair, Executive Director, and IRB Office staff as much as needed.

New IRB members are encouraged to develop informal mentoring relationships with current IRB members. A new IRB member will be assigned to a mentor who is either a current or former IRB member.

GUESTS ATTENDING THE IRB MEETING

Guests may attend the IRB meeting with advance approval or invitation from the IRB Chair, Vice-Chair, or Executive Director.

The Downstate Privacy Officer, Downstate Data Security Officer, IO, Campus President, Dean, Department Chair or members of the Downstate workforce representing Sponsored Research Administration (SRA), Office of Technology Commercialization (OTC), Voting members of the Downstate Conflict of Interest Committee (COIC), Office of Compliance and Audit Services

(OCAS), members of the Scientific Review Committee (SRC), members of the Central Methodology Review Committee (CMRC), or Investigators who attend the meeting by invitation for discussion of their research or particular items on the agenda related to their work are not required to sign a confidentiality (non-disclosure) agreement. All other guests and consultants who attend the meeting must sign a confidentiality (non-disclosure) agreement, prior to reviewing IRB submission materials or participation in IRB meetings.

Guests are NOT IRB Members and therefore cannot vote at an IRB Meeting.

CONSULTANTS TO THE IRB

The IRB may seek advice from biostatisticians, other experts, external scientific reviewers, or other departments such as finance or legal; however, consultants are not counted as voting members of the IRB, unless they also have an appointment as IRB Members.

Consultants may access IRB-related materials and/or join the IRB meeting with prior approval or invitation from the IRB Chair, Vice-Chair, or Executive Director. Consultants must sign a confidentiality (non-disclosure) agreement, before taking part in the meeting or accessing confidential materials, unless they are doing so as a representative of the Downstate workforce as the Downstate Privacy Officer, Downstate Data Security Officer, IO, Campus President, Dean, Department Chair, or members of SRA, OTC, COIC, OCAS, SRC, CMRC or similar position.

Consultants should be questioned about any possible conflicts of interest in the matter that they are reviewing. When relevant or determined by the IO, IRB Chair, Vice-Chair, or COIC, a consultant must provide their COI disclosures in COI Smart or provide a COI Adjudication Letter from the institution from where they are employed.

CONFLICTED IRB MEMBERS AND CONSULTANTS

IRB members fully disclose any conflicts and must not take part in study related reviews, discussions, or voting on any project where they may have a possible, apparent, perceived, or actual conflict of interest. In general, an IRB member who has a conflict must leave the meeting for the final discussions and deliberations and are recused from voting on an item during the IRB meeting. However, the Chair/Vice-Chair may allow a conflicted IRB member to stay during the meeting and the IRB may request additional information from a conflicted party.

The following are examples when IRB Members or Consultants are conflicted and must be recused:

- When an IRB Member or Consultant is also an Investigator or Key Personnel on a study
- When an IRB Member or Consultant has a separate competing business interest

An IRB Member or Consultant who is a patient of one of the Investigators or Key Personnel on a study must assess if he/she has a real or perceived conflict of interest and may seek advice from the IRB Chair or Vice-Chair for a decision.

Conflicted individuals may provide information to the IRB, consult with the IRB, give administrative feedback to the IRB, or attend IRB meetings as guests or consultants.

An IRB Member or Consultant who is uncertain if (s)he is conflicted for any reason must seek advice from the IRB Chair or Vice-Chair for a decision.

CONSIDERATIONS FOR FULL-COMMITTEE IRB MEETING

This section outlines important considerations for all IRB members to ensure an effective and meaningful IRB review and meeting process.

TIPS FOR IRB MEMBERS

The following tips are provided to IRB Members:

- Check the agenda to determine which items have been assigned for your review.
- Conduct the reviews and enter comments in IRB System on a timely basis, as indicated above.
- Members who are not assigned as a primary or secondary reviewer must also review the materials to prepare for the meeting.
- It is recommended that members review the informed consent document first but not make any changes; then review all other documents. Finally, read the consent form again and make any required corrections or recommendations. If desired, upload tracked changes with your reviewer notes in IRB System.
- Consult the IRB guidance for full or expedited review.
- It is best to get your questions answered before the meeting. Send an e-mail to the IRB Office, preferably via IRB System, if you would like a question answered by the investigator.
- Feel free to discuss the submission with the investigators, consultants, IRB members or IRB Office staff in advance of the meeting; however, be sure to summarize any discussion or findings in your reviewer notes in IRB System.
- It is a regulatory requirement to maintain all communications with the investigators, so they are available to inspectors from the FDA and OHRP. Keep track of all communications with the investigator and attach them in IRB System. If you prefer to remain anonymous, you may have the IRB Office contact the study team.
- Enter comments in IRB System. Be sure to inform the IRB Chair/Vice-Chair of any major concerns before the meeting takes place.
- **The IRB meeting is the place to discuss items and make decisions. Not everything written in IRB System needs to be reviewed at the meeting. The IRB Office Staff**

and Chair/Vice-Chair will make sure all relevant items are included in the IRB determination letters.

MEETING PREPARATION TIPS FOR IRB CHAIR AND VICE-CHAIR

The following tips are provided to help prepare the IRB Chair and Vice-Chair for the IRB meeting:

- Review all IRB member and IRB office comments in advance of the meeting.
- Determine which comments need to be discussed at the meeting.

IRB MEETING PROCESS

To function effectively, the IRB should function in a well-organized fashion. The following is a suggested outline for the IRB Chair/Vice-Chair for leading the order of the meeting for each item:

1) Primary Member reviewers:
   a) Limit summary of review to a few minutes.
   b) Discuss any major concerns related to the participant facing materials, 111 findings (45 CFR 46.111 or 21 CFR 56.111) and other determinations required to grant IRB approval (refer to reviewer checklist for details).

> ***An IRB member may want to think about whether a change is necessary to safeguard the rights and welfare of a research participant, or to align with the 111 criteria for approval, which are summarized below. If the answer is "no" they may decide to approve the protocol as it is. If the answer is "yes" they should no approve the proposed research or request changes.***

   c) The 111 findings are summarized below:
      i) Risks to subjects are minimized.
      ii) Risks to subjects are reasonable.
      iii) Selection of subjects is equitable.
      iv) Informed consent will be sought, unless waived.
      v) Informed consent will be appropriately documented or appropriately waived.
      vi) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
      vii) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
      viii) When subjects are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study to protect the rights and welfare of these subjects.
      ix) Additional criteria are met for vulnerable populations.
      x) Ensure the research is in compliance with regulations to the extent required by 45 CFR 46, subpart B, C, and D or 21 CFR part 50, subpart D.

xi) In addition, the following is required, as applicable to FDA regulated investigations: An IND or IDE may be required for a clinical investigation:
(1) For investigational device studies, the IRB may determine that a device study is significant risk (SR) or non-significant risk (NSR). A SR device study must have an IDE from the FDA before the IRB can approve the investigation.
(2) Clinical investigations for measuring bioavailability or demonstrating bioequivalence shall be subject to principles and requirements of 21 CFR 320.
(3) ICH-GCP requirements must be met for clinical trials which voluntarily follow ICH-GCP requirements.

2) Secondary Member Reviewers or other assigned reviewers:
   a) Focus should be on any disagreement with primary reviewer.
3) **DISCOURAGE QUESTIONS UNTIL AFTER THE PRIMARY AND SECONDARY REVIEWER HAVE MADE THEIR PRESENTATIONS**
4) Other IRB Members
   a) Be prepared. There should be no need to ask questions about specific items that are already outlined in the submission. Discuss any other major concerns not raised by the primary and secondary reviewers.
   b) Ask all relevant questions.
5) IRB Office Staff (non-IRB members)
   a) Do not interrupt member's discussion, unless called upon by the Chair/Vice-Chair for regulatory or policy guidance.
6) End the discussion with a motion made by the Primary reviewer. If the Primary reviewer is not able to attend, the Secondary reviewer or the Vice-Chair or Chair should make the motion. Possible motions:
   a) Approve.
   b) Approve with conditions (i.e., directed and/or specific changes made for the IRB to approve the study).
   c) Modifications required (i.e., request for modifications or answers to questions for the IRB to approve the study).
   d) Disapprove or not approve.
   Note: The IRB Chair/Vice-Chair may table the discussion or defer it to a future meeting without calling a vote.
7) Members vote on the motion, unless recused. Possible votes:
   a) Approve
   b) Disapprove
   c) Abstain

Note: If an IRB Chair or Vice-Chair entertains a motion under which the IRB votes on groups of studies (sometimes called "block voting"), IRB Members have the ability to voice their vote "for" on some studies, "against" on others, and "abstain" on others.

STATEMENT ON THE RESPONSIBLE USE OF GENERATIVE AI

The authors updated this guidance with the assistance of an AI language model by Microsoft Co-Pilot, to revise and generate draft text for the guidance document on April 1, 2024. Microsoft Co-Pilot was consulted to gather ideas for revising the text for clarity. While Microsoft Co-Pilot provided foundational text, the final document was developed through extensive research and analysis, incorporating a wide range of resources from the literature and feedback from others to ensure an accurate representation on the subject matter.

REFERENCES

- 21 CFR 50, 56, 312, & 812
- 45 CFR 46
- AAHRPP Accreditation Standards
- CARE-Q Certification Standards
- Downstate IRB Website
- Downstate IRB Policies and Guidance website.
- Downstate Policy IRB-01
- FDA guidance website.
- Institutional Review Board Member Handbook (Amdur & Bankert, 4th edition) (Available in IRB Office)
- IRB: Management and Function 3rd Edition (Public Responsibility in Medicine & Research (PRIM&R); Elizabeth A. Bankert, MA; Bruce G. Gordon, MD; Elisa A. Hurley, PhD; Sharon P. Shriver, PhD) (Available in IRB Office)
- OHRP guidance on approval of research with conditions
- OHRP guidance website.
- OHRP's Human Research Protection Foundational Training
- The Belmont Report

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REVIEW AND APPROVAL HISTORY

Original Issue Date: 06.05.2017

Revision Date: 08.15.2024

Date Reviewed & Approved	**Revision Required**		**Responsible Staff Name and Title**
	Yes	No	
07.10.2024	X		DHSU IRB & Privacy Board
08.15.2024	X		Kevin Nells, Executive Director, Human Research Protections & Quality Assurance *Reason: Removed information about Community Members being appointed as Research Volunteers.*