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|  | **SUNY Downstate Medical Center****University Hospital of Brooklyn****College of Medicine****College of Health Related Professions****College of Nursing****School of Graduate Studies****Graduate Program in Public Health** | **Roles and Goals of IRB Members, Consultants, and Guests** |
| For more information please contact the IRB at 718-613-8480 or IRB@downstate.edu or the IRB Chair at 718-613-8355 or Phyllis.Supino@downstate.edu **KEY POINTS:*** The IRB Chair, Department Chair or other officials may nominate individuals to become IRB members; however they are appointed by the Institutional Official (IO) for a renewable five-year period of service.
* The various categories and general qualifications of IRB membership are described within this guidance.
* New IRB members are encouraged to develop informal mentoring relationships with current IRB members.
* In order to ensure quorum requirements are met at IRB meetings, the IRB Chair ensures roster is divided into primary and alternate members. In order to maintain 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.
* New IRB members should participate in a one-on-one orientation with an IRB office staff member to learn how to enter review comments in IRBNet and review the training materials outlined in this guidance.
* IRB members should let the IRB office know if they will be out for an extended period of time to ensure reviews are not assigned to them.
* 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.
* The community IRB member represents the community of research participants – not the interest of the institution.
* Ideally, IRB members should enter their reviews and comments in IRBNet ASAP, but the goal is to enter comments for full board studies by the COB on the Friday before the scheduled meeting date and within 10 days for all other activities. This allows the IRB staff and IRB Chairs to review and process comments appropriately.
* The goal for any urgent review activities, such as SAEs, Privacy Breach, Information Security Breach and other serious events is ASAP but should be completed within 5 days.
* All IRB Members are encouraged to attend all meetings; however, the goal is for primary members to attend at least eight (8) IRB meetings per calendar year. The goal for alternate members is to attend at least six (6) IRB meetings per calendar year.
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# Introduction

The SUNY Downstate Medical Center (DMC) Institutional Review Board (IRB) is comprised of a diverse set of members to ensure that any research approved by the IRB is scientifically valid, ethical, and in compliance with all research requirements. IRB members are exemplify and promote the highest level of scientific integrity, scholarly validity, public accountability, and social responsibility in the review and oversight of research. Below is summary of IRB membership and general responsibilities and goals. This guidance provides important information regarding the roles of consultants and guests.

# IRB Members

While the duties of the IRB and the IRB review process are described in SUNY Downstate Medical Center Policy IRB-01, the structure and composition of the IRB must be appropriate to the amount and nature of the research that is reviewed. Every effort is made to have member representation that reflects the areas of specialty that encompasses most of the research performed at DMC.

The IRB will consist of qualified members with the experience and expertise necessary to review and deliberate on human research protocols. Consistent with federal regulations, the IRB 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 DMC and who is not part of the immediate family of a person who is affiliated with the DMC ("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 DMC is often conducted, particularly children and pregnant women. If the IRB is asked to review protocols that involve members of other vulnerable populations, the IRB will make every effort to engage individuals with the necessary competence related to the specific population in the review of particular protocols. The IRB may include the IRB administrative staff as voting IRB Members, if so appointed by the DMC Institutional Official (IO).

## Exclusion from IRB Membership

Individuals from the Pre-Award and Post-Award Divisions of the Office of Research Administration or the Office of Technology Commercialization (OTC) may not serve as members of the IRB or carry out day-to-day operations of the review process. Individuals from these offices may provide information to the IRB and attend IRB meetings as guests or consultants.

## **Scientist/Nonscientist**

Members whose training, background, and occupation would incline them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline should be considered a scientist, while members whose training, background, and occupation would incline them to view research activities from a standpoint outside of any biomedical or behavioral scientific discipline should be considered a non-scientist. In addition, the IRB must have members with sufficient knowledge of the specific scientific discipline(s) relevant to the research that it reviews.

## **Affiliation**

An employee or agent of the DMC (or a member of that person’s immediate family) is considered affiliated. Affiliated members include, but are not limited to, individuals who are: part-time employees; current students; members of any governing panel or board of the institution; paid or unpaid consultants; healthcare providers holding credentials to practice at the institution; and volunteers working at the institution on business unrelated to the IRB. An individual that has no affiliation with the DMC, other than as an IRB Member, is considered unaffiliated with the entity operating the IRB. Unaffiliated members may include people who are current or former patients, or research participants of DMC. Paying unaffiliated members for their services would not make the member “otherwise affiliated” as stated in the regulations, or cause the member to have a conflicting interest.

## Community members

Community members are usually non-scientific and not affiliated with the DMC. Community members come from a variety of backgrounds and are chosen for experience, knowledge, or relationship to the types of studies reviewed by the IRB. These members often are former research participants, patient advocates, teachers, nurses, members of vulnerable populations, retirees or experts in multicultural affairs may be sought for IRB service. These members are often drawn from a community group served by DMC and those who live in the surrounding area. These members may represent ethnic, socio-economic or patient groups that add a needed voice to IRB decisions.

The Community Member plays a key role in ensuring that local concerns of the research community are addressed to help maintain the public’s trust in research. Community members are uniquely positioned on the IRB to put people first, as they are not likely to be influenced by personal ambition, profits, or scientific bias.

## Prisoner Representative

At least one member of the IRB shall be a prisoner or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one board only one board need satisfy this requirement.

In the absence of choosing someone who is a prisoner or has been a prisoner, the IRB should choose a person who has a close working knowledge of prison conditions and the life of a prisoner. Suitable individuals could include present or former prisoners; prison chaplains; prison psychologists, prison social workers, or other prison service providers; persons who have conducted advocacy for the rights of prisoners; or any individuals who are qualified to represent the rights and welfare of prisoners by virtue of appropriate background and experience.

When reviewing research involving prisoners, a majority of the IRB members (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the IRB.

## **Alternate Members**

In order to ensure quorum requirements are met at IRB meetings, the IRB Chair ensures roster is divided into primary and alternate members. In order to maintain 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.

The appointment and function of alternate members is the same as that for primary IRB Members. DMC strives to ensure that the alternate's expertise and perspective are comparable to those of the primary member. The role of the alternate member is to serve as a voting member of the IRB when his/her primary member is unavailable to attend a meeting; however, he/she must still meet attendance goals, as attendance is required at multiple meetings to stay informed and educated.

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

With respect to the capacity in which the primary IRB Member was intended to serve, each alternate IRB Member has experience, expertise, background, professional competence, and knowledge comparable to that of the primary IRB Member whom the alternate would replace. The minutes of an IRB meeting should document the attendance of all primary and alternate IRB Members who attended any part of the IRB meeting. If both a primary IRB Member and his or her alternate(s) attend the same IRB meeting, the IRB assumes that the primary member is acting as the official voting member of the IRB for review of research protocols, unless the minutes clearly indicate otherwise. A designated alternate IRB member for a primary IRB member may substitute for the primary IRB Member for an entire meeting or at any time during a meeting. Substitution during a meeting commonly occurs when the primary member is (a) absent from the room for part of the meeting, or (b) recused from review of certain research protocols because the primary IRB member has a conflicting interest with respect to a specific research protocol. Whenever this occurs, the minutes of the IRB meeting should indicate clearly that the alternate IRB Member has replaced the designated primary IRB member. The reason for the substitution of the alternate IRB member may be documented in the minutes, but this is not required.

# Appointments and Term of Service

The IRB Chair and the IO identifies a need for a new, replacement, or alternate member. A candidate may be nominated by the IRB Chair, Institutional Official (IO), Department Chairs, or by other officials within DMC. He/she must submit a current Curriculum Vitae (CV), to be kept on file with the IRB office upon initial appointment consideration and should update his/her CV as needed. The IO receives the nomination and consults with the IRB Chair to determine the appropriateness of the candidate, based on qualifications, experience, reputation, and needs of the particular committee.

Where there are no nominees, the appropriate Department Chairs or Program Directors or Deans may be contacted for nominees.

The final decision in selecting a new member, and appointment thereof, is made by the IO. Appointments are made for a renewable five-year period of service. Members may resign by written notification to the Chair or IO. Members may be removed on a for-cause basis by the IO. If a member is removed by the IO, the member can only return to the committee through the appointment process.

On at least an annual basis, the IRB Chair and the IO review the membership and composition of the IRB to determine if they continue to meet regulatory and institutional requirements.

When there is a substantiated allegation of serious or continuing non-compliance of an IRB Member, the IO or IRB Chair may remove the member from the IRB Roster until the situation is fully investigated and resolved. A member who is removed can only return to the committee through the appointment process.

# General Qualifications for IRB Membership

When considering whether to appoint an IRB member, the following qualifications are highly desirable, but not necessarily required of all members depending on their roles.

* Excellent communication skills
* Achieved respect among the research community
* Substantive human research or IRB experience
* Willingness to learn IRB policy and regulations
* Be willing to provide a considerable time commitment and adhere to review deadlines.
* Possess basic computer, internet, and word processing skills.
* Possess the professional competence necessary to review specific research activities.
* Be willing to be trained by the IRB Staff on how to do reviews and use the online IRB review system.
* Be willing to read training materials provided by the IRB and be mentored by IRB Office Staff and IRB Members.

While not necessary, prior IRB experience is highly desirable.

# Goals of IRB Members

Below is an outline of general goals for those who serve as IRB members.

## Training and Education

All IRB members should complete the following training:

* Meet with the IRB Chair and/or Vice-Chair
* Participate in a one-on-one orientation with an IRB office staff member to learn how to enter review comments in IRBNet
* At a minimum, review all materials provided by the IRB, including the following:
	+ IRB-01 policy
	+ Guidance on IRB approval criteria
	+ Mission, Vision, Values statements of the IRB
	+ IRB Member Handbook (Amdur and Bankert)
	+ 45 CFR 46
	+ 21 CFR 50, 56, 312, & 812
	+ The Belmont Report
* Review books regarding statistical methods and research design. Contact the IRB for references, if needed.
* Become familiar with all IRB forms, templates, and guidance posted in IRBNet for both IRB Members and Investigators
* Take CITI training for investigators
* 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 the reference materials cited in IRB-01 policy

## General Goals

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

* Let the IRB office know if you will be out for an extended period of time to ensure reviews are not assigned to you during this period.
* 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.
* Review and be familiar with **all** of the IRB applications materials and consent forms being reviewed at the convened IRB meeting. Any IRB member may submit reviewer comments for any submission.
* Perform initial and continuing review of full board projects.
* Perform initial and continuing review for expedited projects.
* Perform continuing review of other research activities 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.
* With the exception of the Prisoner Representative, all IRB members should review IRB application materials within IRBNet and submit their reviews in IRBNet.
* Follow the SUNY Downstate Medical Center 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 IRB 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. These activities are evaluated on regular basis through audits and performance improvement activities.
* 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 if issues are found resolve them with the IRB staff.
* 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.
* Absent yourself from deliberations and voting on any project where there is a potential, perceived, or real conflict of interest.
* Maintain confidentiality and sign a confidentiality agreement.

### Special Roles of Community Members

There are special roles for those willing to serve as a community member and 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 at least 1-2 IRB applications each month and provide written online feedback to the IRB, preferably at least 1 week before the date of the meeting, but no later than 2 days before the meeting.
* 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 informed consents, parental permission forms, child assent forms, or information sheets for the IRB application for which they are assigned. Make sure these documents are written in a manner which would be understandable to community 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 to the research process.

## Review Goals

IRB Members should try their best to complete their reviews within the timeline goals outlined in the table below. This allows the IRB staff and IRB Chairs to review and process comments appropriately.

*NOTE: IRB Members must check the box in IRBNet to indicate their review is complete. This will trigger an automatic message to the IRB Office staff.*

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| **Type of event** | **Turnaround goals to enter reviewer comments in IRBNet after notice of assignment.** |
| Initial Review of new study via full board review process. | All comments should be entered in IRBNet no later than the **Friday before the scheduled meeting date**. |
| Initial Review of new study via expedited review process. | Within **10** business days. |
| Initial Review of new study via exempt review process. | **ASAP**, but no later than **10** business days. |
| Expedited review of reportable event and other expedited review activities. | **ASAP**, but no later than **10** business days. |
| Urgent expedited review activities, such as SAEs, Privacy Breach, Information Security Breach and other serious events. | **ASAP**, but no later than **5** business days. |
| IRB Determination Requests (Made by IRB Office Staff who are also IRB Members) | **ASAP**, but no later than **3** business days. |

## Attendance Goals

All IRB Members are encouraged to attend all meetings even if they have not been specifically assigned to review a protocol, as they will gain knowledge from ongoing attendance and participation.

Each IRB Member should attend the IRB meeting for which they are part of the assigned roster. Please notify the IRB Office in advance of any anticipated absences (due to vacations, etc.). Excessive absences may result in a request from the Chair or IO for resignation from the committee.

When members cannot attend in person, they are encouraged to participate via audio or video conferencing.

Primary members should do their best to attend at least eight (8) of twelve (12) IRB meetings per calendar year, per each committee for which (s) he is appointed. Alternate members should do their best to attend at least six (6) of twelve (12) IRB meetings per calendar year, per each committee for which (s) he is appointed. Excessive absences (including excused absences) may result in a request from the Chair or IO for resignation from the committee or a change to Alternate member status.

IRB Members who discover they cannot attend meetings on an ongoing basis due to heavy workload are encouraged to take a temporary leave of absence from the IRB roster, so their absences do not affect quorum requirements, until they can return in a fuller capacity. They may also elect to become consultants or resign.

Experienced prisoner representatives should try to attend the meetings for which they conduct a review; however, they are encouraged to attend all meetings.

Consultants should only plan to attend meeting when requested.

## Consulting and Mentorship

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

New IRB members are encouraged to develop informal mentoring relationships with current IRB members.

## Performance Evaluations

Written annual performance evaluations of IRB members, Chairs, and Staff are done to improve the overall IRB process, recognize the ongoing efforts of IRB members, and to help achieve future AAHRPP accreditation. All outstanding IRB members will be given accommodation letters.

The IO will review the performance of the IRB Chair. The IRB Chair will review the performance of all IRB members. Each member will have the opportunity to discuss the results of their evaluation with their reviewer.

# Guests Attending the IRB Meeting

Guests may attend the IRB meeting with advance approval from the IRB Chair, Vice-Chair, or Executive Director. All guests must sign a confidentiality agreement, prior to participation in the meeting. Guests are NOT IRB Members and therefore cannot vote at an IRB Meeting.

Investigators who only attend the meeting during the discussion of their Research are not required to sign a confidentiality agreement.

# Consultants to the IRB

The IRB may consult with biostatisticians, other experts, external scientific reviewers, or other departments such as finance or legal; however, these consultants are not considered voting members of the IRB, unless they are also appointed as IRB Members.

Consultants may review IRB-related materials and/or attend the IRB meeting with advance approval or invitation from the IRB Chair, Vice-Chair, or Executive Director. All Consultants must sign a confidentiality agreement, prior to participation in the meeting or review of confidential materials.

Consultants should be asked about any potential conflicts of interest in the matter in which they are reviewing. When deemed relevant by the IO, IRB Chair, Vice-Chair, or Executive Director, a consultant must provide COI disclosures in COI Smart or provide a COI Adjudication Letter from their institution.

# Conflicted IRB Members and Consultants

Conflicted IRB Members and Consultants must recuse themselves from a study-related reviews and final IRB deliberations. Conflicted IRB Members cannot vote. Conflicted IRB Members and Consultants may provide information requested by the IRB. 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

When an IRB Member or Consultant is a patient of one of the Investigators or Key Personnel on a study, he/she must determine if he/she has a real or perceived conflict of interest.

# References

* + IRB-01 policy
	+ Mission, Vision, Values statements of the IRB
	+ [IRB Member Handbook (Amdur and Bankert)](https://www.amazon.com/Institutional-Review-Board-Member-Handbook/dp/1449647448)
	+ [45 CFR 46](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html)
	+ [21 CFR 50, 56, 312, & 812](http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm155713.htm)
	+ [The Belmont Report](https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html)
	+ [AAHRPP Accreditation Standards](http://aahrpp.org/apply/process-overview/standards)

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# Review and Approval History

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| **Date** **Reviewed & Approved** | **Revision Required** | **Responsible Staff Name and Title** |
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