



## SOP: IRB Member Addition (Appointment and Re-Appointment)

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### 1 PURPOSE

- 1.1 This procedure establishes the process to appoint and re-appoint a member to an IRB Panel.
- 1.2 The process begins when an individual applies, is nominated, or expresses interest in joining an IRB. (This may be a new IRB member or a re-appointment of a previous member.)
- 1.3 The process ends when the individual is listed on an IRB roster and the new Member has completed training.

### 2 PREVIOUS VERSION

- 2.1 Revised from previous version dated 10/27/2022

### 3 POLICY

- 3.1 The appointment or re-appointment of an IRB panel member, including their designation as either a scientist or non-scientist, affiliation status, and representative capacity, is thoroughly vetted and approved by the IRB Executive Director, IRB Manager, or designee.
- 3.2 IRB members/alternates are appointed for a three-year term. Members/alternates are eligible for re-appointment at the end of their term.

### 4 RESPONSIBILITIES

- 4.1 The IRB Manager is responsible for the appointment and re-appointment of members to an IRB Roster.
- 4.2 The IRB Manager is responsible for determining the IRB Member's status on the IRB Roster at the time of appointment and re-appointment.
- 4.3 IRB Office Staff will assist the IRB Manager with these responsibilities by collecting required documentation, scheduling interviews, and managing correspondence. The IRB Office Staff will complete the Appointment and Re-Appointment Checklists to track the progress of this process.

### 5 PROCEDURE

- 5.1 Application Process
  - 5.1.1 Nominations or requests to join an IRB Panel are emailed to the IRB Office mailbox: [irb@northwestern.edu](mailto:irb@northwestern.edu).
  - 5.1.2 The email must include a brief letter of introduction, a curriculum vitae or resume, and a completed application "FORM: IRB Member Information (HRP-202)."
  - 5.1.3 If any of these elements are not included in the email, IRB Office Staff will follow up to obtain the required documentation.
  - 5.1.4 IRB Manager will review the request, the introduction letter, curriculum vitae or resume, and the application to ensure completeness.
  - 5.1.5 IRB Office Staff will create an electronic folder for the applicant to store all related documents.
  - 5.1.6 IRB Office Staff will schedule a panel observation for the applicant. The applicant's availability determines the Panel of choice.
  - 5.1.7 IRB Office Staff will schedule an interview between the applicant and the IRB Manager to assess suitability and availability.
- 5.2 Interview and Training Process
  - 5.2.1 IRB Office Staff will schedule a time for the applicant to attend and observe an IRB Panel Meeting(s), as applicable.
  - 5.2.2 IRB Associate Director or designee will interview the applicant to assess suitability and to determine the IRB Member status, including, but not limited to, the appropriate designation as a scientist or non-scientist.



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- 5.2.2.1 IRB Office Panel Analyst will ensure the applicant signs a Confidentiality Agreement and that the IRB Meeting Minutes reflect the guest's attendance.
- 5.2.2.2 The IRB Office Staff will add the signed Confidentiality Agreement to the Minutes of the meeting they are conducting.
- 5.2.3 IRB Manager or designee will hold a training session for the applicant. The training will provide an overview of Northwestern's HRPP, highlighting the role and responsibilities of IRB Members and an orientation to the eIRB+ system.
- 5.2.4 The applicant will complete Human Participant Protection Training and provide documentation to the IRB Office Staff.
- 5.3 IRB Member Appointment Determination
  - 5.3.1 After reviewing all materials and documentation from the interview, the IRB Manager will determine and document the IRB Member's appointment and status on the IRB Roster. In any instance for which the scientific or non-scientific status, representative status, or affiliation status of a newly appointed or re-appointed IRB member may be questionable, the IRB Manager will discuss further with the IRB Executive Director before proceeding with the appointment. The status determinations to be made will include the following:
    - 5.3.1.1 IRB Panel Appointment (Panel A, B, C, D, E, or Q)
    - 5.3.1.2 Membership Status – The Member will be designated as a voting member or an alternate member of the Panel(s) to which they are appointed. If the new Member will have additional membership designations as a part of their appointment (e.g., Chair, Vice-Chair, or Designated Reviewer), that will be determined as a part of the Membership Status. The IRB Manager will review the Panel's composition to determine how the membership status of the new Member will affect the quorum on the Panel.
    - 5.3.1.3 Scientific Status – The Member will be designated as either a Scientific or Non-Scientific member. If the Member is appointed to multiple panels, this status will be consistent across all the Panels to which they are appointed. In accordance with HHS and FDA regulations at 45 CFR 46.107(c) and 21 CFR 56.107(c), the IRB Manager will determine whether the Member's primary concerns are in scientific or non-scientific areas and will follow the current guidance from OHRP that states: "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."
      - 5.3.1.3.1 In any instance for which the scientific or non-scientific status or affiliation status of a newly appointed or re-appointed IRB member may be questionable, the Institutional Official or designee will be consulted before proceeding with the appointment.
    - 5.3.1.4 Affiliation Status – The Member will be appointed as either an affiliated or non-affiliated member. This status refers to the individual's relationship to Northwestern University and/or its affiliates. An individual that has no direct affiliation with Northwestern University and/or its affiliates, other than as an IRB member, is considered unaffiliated. This status will be consistent across all the panels to which they are appointed if the Member is appointed to multiple panels.



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- 5.3.1.5 Representative Capacity – The Member’s knowledge and experience with vulnerable or special populations (e.g., pregnant women, children, prisoners, persons who are disabled, cognitively impaired, or economically disadvantaged) will be ascertained to determine if they have the knowledge and experience to serve in a representative capacity.
- 5.3.1.6 Indications of Experience - The IRB member’s experience and areas of expertise will be determined to ensure that the Panel(s) have members with sufficient knowledge of the specific discipline(s) relevant to the research it reviews.
- 5.3.1.7 Designation of Alternate Members – The designated alternates on the Panel will be reviewed and updated as appropriate, given the membership status of the new Member. If the new Member will be an alternate member, the IRB Manager or designee will identify the current voting members on the Panel for which the new Member may serve as an alternate. If the new Member will be a voting member, the IRB Manager will identify the current alternate members who may serve in place of the new voting member. This designation of the alternate members will be made with respect to the capacity in which the voting IRB member was intended to serve such that each alternate IRB member has the experience, expertise, background, professional competence, and knowledge comparable to that of the voting IRB member whom the alternate would replace.
- 5.3.1.8 Appointment Term – The IRB Member will be issued a three-year appointment term. At the end of the appointment term, the IRB Member’s appointment and status on the IRB Roster, as outlined in section 5.3.1, will be re-evaluated as outlined in Section 6. PROCEDURE – IRB Member Re-Appointment.
- 5.4 Once the Appointment determinations have been made and documented on the IRB New Member Appointment Checklist, the individual will be added to the IRB Roster by the IRB Manager or designee, and the IRB Member is assigned as a Designated Reviewer in accordance with “SOP: Designated Reviewers (HRP-030).”
- 5.5 IRB Office Staff will prepare a “TEMPLATE LETTER: IRB Member Appointment (HRP-560)” to communicate the IRB Appointment determination to the new Member.
  - 5.5.1 IRB Manager will review the IRB Roster and the IRB Member Appointment Letter.
- 5.6 IRB Executive Director will discuss the justifications for the new IRB Member’s appointment with the IRB Manager, and the IRB Executive Director will document approval by signing the IRB Member Appointment Letter. Once approved and signed, the IRB Office Staff will send the letter to the IRB Member and Finalize the IRB Roster.
  - 5.6.1 IRB Office Staff will send the new Member the Acceptance and Acknowledgement Form, the Conflict of Interest and Recusal Agreement, and the Confidentiality Agreement. These can be sent with the Appointment Letter.
  - 5.6.2 IRB Office Staff will ensure the new member signs and returns these documents.
- 5.7 If applicable, the IRB Office Staff will ensure that the new Member provides any additional documents or information required for receiving compensation (such as a W9 for Non-Affiliated IRB Members, or Affiliated IRB Members who do not have an employment relationship with Northwestern University).
- 5.8 If the appointment is for an IRB Chair (10%) or Vice Chair (5%), send an email to the OR Finance and Administration Business Manager to record the appointment and salary percentage in the myHR system or execute the relevant Independent Contractor agreement for IRB Chairs or Vice Chairs who do not have an employment relationship with Northwestern University.



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- 5.9 IRB Office Staff will ensure the new IRB Member has all necessary access for their role, including working with ORIT to create their eIRB+ profile and ensuring they have appropriate access to the suite for IRB panel meetings and conducting non-committee reviews (when applicable).
- 5.10 IRB Office Staff will notify the IRB Panel's Analyst and Chair regarding the new Member's appointment and will work with the Panel and the new Member to coordinate a time for their first meeting.
- 5.11 The IRB Manager will ensure the updates to the roster are captured in the next update to the IRB's registration, in accordance with OHRP's 90-day timeline.

### 6 PROCEDURE – IRB Member 360 Evaluation and Re-Appointment

- 6.1 This procedure applies to renewing the appointment of: (1) a current member at the end of their three-year appointment term, and (2) a current member to an additional or different panel than their original appointment.
  - 6.1.1 The IRB Office Staff member keeps track of the appointment terms. At the time of re-appointment, the IRB Office Staff will request updated IRB Member documentation, including the Member's current curriculum vitae or resume and a fully updated application "FORM: IRB Member Information (HRP-202)".
  - 6.1.2 IRB Office Staff will ensure the IRB Member has current Human Participant Protection Training.
  - 6.1.3 The IRB Manager will review the updated materials to reassess, determine and document the IRB Member's re-appointment status as follows:
    - 6.1.3.1 If the re-appointment of the IRB Member will only be to the Panel(s) as initially appointed, the IRB Manager will review the updated materials to determine if any changes need to be made to the previous determinations outlined in section 5.3.1.
    - 6.1.3.2 If the re-appointment of the IRB Member will be to an additional or different panel(s), the IRB Manager will also review the updated materials to determine the IRB Member's status, as applicable to each new or different Panel.
  - 6.1.4 Designated IRB Office staff will send the 360 Evaluation Survey to each IRB Member in accordance with "SOP: Panel Member 360 Evaluation and Reappointment Procedure (HRP-062)".
    - 6.1.4.1 For IRB Members that are also part of the IRB Office staff, the employee's annual Performance Excellence (PEX) will be utilized in place of the 360 Evaluation Survey.
  - 6.1.5 Once the Re-appointment determinations have been made and documented on the IRB Member Re-appointment Checklist, the Member's status on the IRB Roster will be updated as documented by the IRB Manager or designee.
  - 6.1.6 IRB Office Staff will prepare a "TEMPLATE LETTER: Panel Member 360 Evaluation and Re-appointment (HRP-554)" to communicate the re-appointment decision. IRB Office staff will include any additional pertinent information provided by the IRB Chair, by the member self-evaluation, and remove any template statements that may not be applicable.
    - 6.1.6.1 IRB Manager will review the IRB Roster and the IRB Member Re-Appointment Letter.
    - 6.1.6.2 IRB Executive Director will review, and IRB Panel Chair will review and sign the IRB Member Re-Appointment Letter as also outlined in section 5.5.2.
  - 6.1.7 Once approved and signatures obtained, the IRB Office Staff will send the letter and finalize the IRB Roster.



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- 6.1.7.1 IRB Office Staff will include the Acceptance and Acknowledgement Form, the Conflict of Interest and Recusal Agreement, and the Confidentiality Agreement with the letter.
- 6.1.7.2 IRB Office Staff will ensure the new member signs and returns these documents.
- 6.1.7.3 IRB Office Staff will file all documentation related to the re-appointment in the member file.
- 6.1.8 IRB Office Staff will notify the IRB Panel's Lead Analyst and Chair regarding any changes related to their Panel's roster, the status of the panel members, and any changes to quorum.
- 6.1.9 The IRB Manager will ensure the updates to the roster are captured in the next update to the IRB's registration with OHRP in accordance with OHRP's 90-day timeline.

### 7 MATERIALS

- 7.1 FORM: IRB Member Information (HRP-202)
- 7.2 TEMPLATE LETTER: IRB New Member Appointment (HRP-560)
- 7.3 TEMPLATE LETTER: IRB Member Thank You (HRP-561)
- 7.4 TEMPLATE LETTER: Panel Member 360 Evaluation and Re-appointment (HRP-554)
- 7.5 SOP: Panel Member 360 Evaluation and Re-appointment Procedure (HRP-062)
- 7.6 SOP: Designated Reviewers (HRP-030)
- 7.7 IRB New Member Appointment Checklist (HRP-1403)
- 7.8 IRB Member Re-Appointment Checklist (HRP-1404)
- 7.9 IRB Member Appointment Letter (HRP-560)
- 7.10 Confidentiality Agreement (HRP-1206)

### 8 REFERENCES

- 8.1 45 CFR §46.107, 45 CFR §46.108(a)(2), 45 CFR §46.115(a)(5).
- 8.2 21 CFR §56.107, 21 CFR §56.115(a)(5).