

Based on the requirements of federal regulations (45 CFR 46, and 21 CFR 50), the Institutional Review Board (IRB) shall be constituted of sufficiently qualified members in order to provide adequate review of research and safeguard the rights and welfare of human participants. Considerations in constituting the IRB include appropriate experience and expertise of members to reflect the type of research conducted, and diversity, including race, gender, cultural backgrounds and sensitivity to such issues as community attitudes.

1.0 IRB member composition.

The NDSU IRB is administered through the Office of the Vice President for Research & Creative Activity, and is charged with review and oversight of NDSU research involving human participants.

In accordance with Health & Human Services regulations under 45 CFR §46.107, IRB membership includes at least one scientist, at least one non-scientist, at least one non-affiliated member, as well as a member with knowledge of institutional policy and applicable laws and standards of professional conduct and practice. In order to promote adequate review, the board includes individuals possessing sufficient expertise in various disciplines of human subjects research commonly conducted by NDSU, which may include:

- social science
- behavioral science
- nutrition
- physiology
- biomedical science
- education research
- qualitative and quantitative research
- research involving children
- research involving vulnerable groups including cognitively impaired individuals

The board consists of an adequate number (at least 5 member) of members to fulfill relevant membership characteristics and expertise. A single member may possess expertise in more than one area. Although no member should be selected solely on the basis of race or gender, every effort will be made to ensure the board does not consist entirely of members of one race, gender or profession.

In situations where a prisoner is involved in research under IRB review and the Board does not already have a member with appropriate background and experience to serve in the capacity of prisoner representative, the Board will include an ad-hoc prisoner representative to serve in that capacity. This individual must have a close working knowledge, understanding, and appreciation of the prison conditions in the facility where the research will be conducted from the perspective of the prisoner.

2.0 Selection and appointment of members.

Members are appointed to the IRB by the Institutional Official (IO). To retain a majority of experienced members on the board, efforts are made to stagger the terms of the appointments. Members, other than student members, are appointed for an initial period of up to three years, expiring on August 31, and may serve additional terms.

2.1 Affiliated members.

Affiliated members may be considered non-scientists or scientists, and are selected based on need for relevant composition and/or expertise on the board. On behalf of the IO, HRPP staff request a recommendation from the College Deans for nominees to fulfill appropriate membership composition or expertise as outlined above; a nominee's biography or résumé should accompany each recommendation. Nominees are subject to approval by the IO; and if approved, are officially appointed to serve on the IRB.

An HRPP staff member serves as a permanent voting member of the board.

2.2 Non-affiliated members.

Non-affiliated members may be considered non-scientists or scientists, and are selected based on need for relevant composition and/or expertise on the board. HRPP staff and the IO consider recommendations for non-affiliated members from the board, university, community, or self-recommendations. Nominees are subject to approval by the IO; and if approved, are officially appointed to serve on the IRB.

2.3 Student members.

The board may also include members of the student body. HRPP staff and the IO consider recommendations for student members. The IO selects and appoints a suitable student nominee. Student members are appointed for a period of one year, renewable to a maximum total of three years.

2.3.1 Undergraduate student member.

A qualified undergraduate student member may be nominated to the IRB at the recommendation of the Vice President of Student Affairs and the IRB Chair.

Qualifications include, but are not limited to: second year or above student status at NDSU and working knowledge of human research methods.

2.3.2 Graduate student member.

A qualified graduate student member may be nominated to the IRB at the recommendation of the Dean of Graduate and Interdisciplinary Studies and IRB Chair.

A qualified nominee will possess a good working knowledge of human research methods.

2.4 Alternate members.

To facilitate quorum and review responsibilities, the board may include an appropriate number of alternate members with similar background and experience to serve in the absence of a regular member. Alternate members are selected and appointed with the same procedures as regular members, and serve the same term period as their designated regular member. Alternate members perform reviews and vote at convened meetings in the absence or recusal of their regular member. Alternates are welcome and encouraged to attend all convened meetings, even in a non-voting capacity, in order to gain experience and familiarity with the review process. Alternate members meeting criteria as an experienced reviewer may also perform expedited review functions, as outlined in *SOP 7.3 Expedited Review*.

3.0 Selection and appointment of officers.

3.1 IRB Chair.

The Chair of the IRB is selected and appointed by the IO, based on experience and expertise from among the current membership. The Chair must hold at least an academic-year appointment as a member of the NDSU faculty, with a degree at the doctoral level. The Chair is appointed for a period of one year, and may be reappointed.

3.2 IRB Vice Chair.

The Vice Chair is selected and appointed by the IO, based on experience and expertise from among the current membership. The Vice Chair must hold at least an academic-year appointment as a member of the NDSU faculty, with a degree at the doctoral level. The Vice Chair is appointed for a period of one year, and may be re-appointed

3.3 Substitute Vice Chair.

The substitute Vice Chair is elected by a majority of those members present and voting at a convened meeting of the IRB. At least one regular board member shall be nominated by any member (self-nomination appropriate), followed by a period of time for consideration and evaluation by the board members. The substitute Vice Chair serves in the temporary absence of the Chair and Vice Chair.

4.0 Board vacancies.

The following process is employed for vacancies of affiliated and non-affiliated members. When a vacancy occurs prior to expiration of a term, the newly appointed member completes the remainder of the term.

4.1 Affiliated members.

Upon expiration of an affiliated member's term, HRPP staff may request another nominee from the College Dean(s) to fill appropriate composition or expertise on the board. Re-nomination is subject to approval and appointment by the IO. Affiliated members always have the option of not serving their full term and resigning from the board. Such vacancies shall be filled according to procedures outlined above (2.1) for new members.

If a member is unable or unwilling to fulfill expected duties and responsibilities on the board, they may be asked to resign, or may be removed from the board by the IO, in consultation with the IRB Chair, three additional members of the board, and HRPP staff. A recommendation for removal may also originate from the affiliated member's Dean to the IO, providing sufficient written justification for why the member is unable to fulfill expected duties and responsibilities on the board. The request is subject to the approval of the IO, in consultation with the IRB Chair, three additional members of the board, and HRPP staff.

4.2 Non-affiliated members.

Upon expiration of a non-affiliated member's term, they may be re-appointed to an additional term, subject to need for appropriate composition and expertise, and approval by the IO. Non-affiliated members always have the option of not serving their full term and resigning from the board. Such vacancies shall be filled according to procedures outlined above (2.2) for new members.

If a member is unable or unwilling to fulfill expected duties and responsibilities on the board, they may be asked to resign, or may be removed from the board by the IO, in consultation with the IRB Chair, three additional members of the board, and HRPP staff.

4.3 Student members.

Upon expiration of a student member's 1-year term, they may be reappointed to a maximum total of three years. Student members always have the option of not serving their full term and resigning from the board. Such vacancies shall be filled according to procedures outlined above (2.3) for new members. If a vacancy occurs mid-term, a new student appointment may be delayed until the next academic year.

4.4 Alternate members.

Upon expiration of an alternate member's term, the vacancy may be filled according to procedures outlined above for affiliated or non-affiliated members, as appropriate. Alternate members always have the option of not serving their full term and resigning from the board. Such vacancies may be filled according to procedures outlined above (2.4) for new members.

If a member is unable or unwilling to fulfill expected duties and responsibilities on the board, they may be asked to resign, or may be removed from the board by the IO, in consultation with the IRB Chair, three additional members of the board, and HRPP staff. A recommendation for removal may also originate from the affiliated member's Dean to the IO, providing sufficient written justification for why the member is unable to fulfill expected duties and responsibilities on the board. The request is subject to the approval of the IO, in consultation with the IRB Chair, three additional members of the board, and HRPP staff.

4.5. IRB Chair.

Should the Chair be unable or unwilling to fulfill expected duties and responsibilities as Chair on the board, they may be asked to resign or may be removed as Chair by the IO.

A recommendation for removal cannot be issued directly to the board by anyone other than the IO. If removed as Chair, that member may retain their membership on the board, unless otherwise removed.

5.0 Member responsibilities.

The charge of the IRB is to ensure protection of the rights, safety and welfare of participants in NDSU research projects, in accordance with federal regulations, state laws and institutional policy. This is accomplished through the prospective and continuing review of research protocols, adherence to appropriate operating procedures for the NDSU human research protection program, and providing educational opportunities for the campus research community in the ethical conduct of the research involving human subjects.

5.1 Regular members.

In carrying out responsibilities, regular IRB members are expected to:

- maintain good working knowledge of relevant ethical principles, federal regulations, state laws and NDSU policies and procedures related to protection of research participants by completing initial and continuing education requirements as in SOP *5.1 Training and Education: IRB Chair and Members*;

- satisfactorily complete IRB member orientation;
- when qualified, perform timely review of protocols via the expedited method, as assigned by HRPP staff;
- perform timely review of full board protocols, including primary reviewer duties as assigned by HRPP staff;
- follow federal regulations, state laws, and NDSU policy and procedures related to subject protections in the review of research protocols;
- disclose any conflict of interest with respect to review of research protocols;
- attend convened meetings, or arrange for their alternate to attend, or notify HRPP staff of known absences;
- actively participate in meeting discussion and deliberation In a professional manner; and
- participate in discussion of issues related to the subject protection program and contribute to development of policy or procedures, as appropriate.

5.2 Alternate members.

In carrying out responsibilities, alternate members are expected to:

- maintain good working knowledge of relevant ethical principles, federal regulations, state laws and NDSU policies and procedures related to protection of research participants by completing initial and continuing education requirements as in SOP *5.1 Training and Education: IRB Chair and Members*;
- satisfactorily complete IRB member orientation;
- if qualified, perform timely review of protocols via the expedited method, as assigned by HRPP staff;
- perform timely review of full board protocols, including primary reviewer duties as assigned by HRPP staff;
- follow federal regulations, state laws, NDSU policy and procedures related to subject protections in the review of research protocols;
- disclose any conflict of interest with respect to review of research protocols;
- be available to attend IRB meetings in the absence of regular member;
- actively participate in meeting discussion and deliberation when attending convened meetings in a professional manner; and
- participate in discussion of issues related to the subject protection program and contribute to development of policy or procedures, as appropriate.

5.3 IRB Chair.

In carrying out responsibilities, the IRB Chair is expected to:

- provide leadership to the IRB to help ensure protection of NDSU research participants;
- maintain good working knowledge of relevant ethical principles, federal regulations, state laws, and NDSU policies and procedures related to protection of research participants by completing initial and continuing education requirements as in SOP *5.1 Training and Education: IRB Chair and Members*;
- conduct convened meetings in a professional manner, or arrange for the Vice Chair or substitute Vice Chair to fulfill role of Chair;
- lead efforts to resolve controversial issues relating to the review or conduct of human research projects;
- perform timely reviews of expedited and full board protocols as assigned by HRPP staff;
- disclose own conflict of interest, and request that IRB members with conflicts do not participate in the review and voting of relevant research protocols;
- regularly consult with IO and HRPP staff on procedures and issues related to the human research protection program; and
- actively participate with HRPP staff in initial assessment of complaints, unanticipated problems and issues of noncompliance.

5.4 IRB Vice Chair.

The Vice Chair and substitute Vice Chair have all the associated responsibilities and obligations of the Chair whenever the Chair is unavailable or unable to serve. Except when serving as acting Chair, they shall have the same duties and responsibilities as a regular IRB member.

6.0 Assessment of member composition and performance.

As part of the HRPP quality improvement program, membership composition and member review timeliness and quality is periodically assessed.

6.1 Member composition.

IRB Chair and HRPP staff periodically review the board composition, to ensure it meets federal regulatory standards and contains appropriate expertise based on the type of research conducted by NDSU. Recommendations for any changes are made to the IO, and procedures for nomination and appointment are followed as described above.

6.2 Member performance.

To facilitate efficient and compliant protocol review, the IRB Chair and HRPP manager may periodically assess members for their performance of expected duties and responsibilities. The IO and HRPP staff perform a similar assessment of the IRB Chair.

7.0 IRB Registration with OHRP.

A designated HRPP staff member serves as the human subjects administrator and files and maintains the IRB registration with The Office of Human Research Protections (OHRP) as required.

8.0 Use of Consultants.

The IRB may invite individuals with expertise in special areas to assist in the review of issues beyond or in addition to the available expertise on the board. These individuals serve as consultants on an as-needed basis, providing either written or verbal information to the board, but are not considered members and do not vote with the IRB. For more information, refer to SOP 7.3 *Expedited Review* and SOP 7.4 *Full Board Review*.

DEFINITIONS:

Affiliated member: someone associated with NDSU as either a faculty, staff or current student, or the immediate family member of a faculty or staff person.

Non-affiliated member: someone whose only affiliation with NDSU is through membership on the IRB; and who is not an immediate family member of a person affiliated with NDSU.

Non-scientist member: someone whose primary concerns are in nonscientific areas: 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 nonscientist.

Quorum: the presence of a majority of members, including one non-scientist member.

Conflict of interest: an interest (financial or other) in the outcome of the research that conflicts, with or has the potential to create a bias in, consideration for the protection of the safety and welfare of research participants.

REFERENCES:

[45 CFR 46.107](#) and [21 CFR 56.107](#) IRB membership
[45 CFR 46.108](#) and [21 CFR 56.108](#) IRB functions and operations
[45 CFR 46.109](#) and [21 CFR 56.109](#) IRB review of research
[OHRP guidance on Written Procedures](#)
OHRP FAQs: [IRB Registration](#)

RELATED STANDARD OPERATING PROCEDURES:

3.1 Roles and Responsibilities – Investigator and Research Team
3.2 Roles and Responsibilities – Institutional Official and Institutional Review Board
5.1 Training, Education and Outreach - IRB Chair and Members
7.3 IRB Review Process - Expedited Review

7.4 IRB Review Process - Full Board Review