Provost's Office

Research Support

79 Fifth Avenue, 17th Floor

New York, NY 10003

www.researchnewschool.com/hrpp

# The New School HRPP Policy: IRB Member Responsibilities

Effective Date: September 1, 2018 Last Updated: December 18, 2018 Last Reviewed: December 18, 2018 Next Review: September 1, 2019

Functional Owner: Program Manager for Research Integrity, Office of Research Support

# **Regulatory Background**

An IRB member is an individual who has been appointed by the Institutional Official (IO) on the Federalwide Assurance (FWA), to serve on the Institutional Review Board (IRB) of The New School. The IRB member is listed on the official IRB registration (IRB00000585) with the Office for Human Research Protections (OHRP) to review human subjects research in accordance with applicable federal regulations and university policies.

#### **Policy Statement**

The Provost's Office will assist the IO and the Human Protections Administrator (HPA) on the FWA in recruiting members to The New School IRB. In determining the composition of the IRB in accordance with <u>45 CFR 46.107</u>, the IO will consider recommendations for membership from the HPA, the IRB Chair, current and former members, Provost Office staff, the University community, and from interested individuals. The IO in collaboration with the HPA will ensure the official IRB registration with OHRP remains current.

Each IRB member's primary duty is the protection of the rights and welfare of the individual human beings that are volunteering as the participants of human subject research conducted by university investigators. This protection extends to identifiable private information or identifiable biospecimens from living human beings. In order to fulfill his or her duties, IRB members are expected to be knowledgeable of the regulations governing human subject protection, ethical principles of justice, beneficence and autonomy as described in the <a href="Belmont Report">Belmont Report</a>, and the policies of the New School Human Research Protection Program (HRPP). The IRB must be perceived to be fair and impartial, immune from pressure either by the institution's administration, the investigators whose protocols are brought before it, or other professional and nonprofessional sources.

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For research involving human subjects, the IRB will review and have authority to approve, require modifications (to secure approval), or disapprove all regulated research activities covered by the FWA. In fulfilling these responsibilities, the IRB reviews all research related documents and activities that bear directly on the rights and welfare of the human subjects and of the proposed research. The IRB in collaboration with HPA will notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it will include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

Each IRB member is responsible for assessing and determining whether or not a research protocol: minimizes risks and maximizes benefits; enrolls subject populations that best address the research question; includes a consent process to appropriately inform subjects of the research and potential risks; or needs additional protections based on the research subjects, the methods being used, and the locations where the research will be conducted.

In addition to the IRB member responsibilities the IRB Chair will provide oversight of the IRB and facilitate discussions of the proposed research at convened meetings. The IRB Chair in collaboration with the HPA will determine eligibility of IRB members to conduct reviews.

## **Reason for the Policy**

This policy was created in order to:

- Comply with The New School's obligations under its FWA with OHRP as well as other relevant federal regulations and state or local laws.
- Provide clear information to faculty, students, and staff about IRB Member Responsibilities.
- Establish expectations for tracking, monitoring and recording of IRB Member Responsibilities by The New School.

#### References

45 CFR 46.107; OHRP: IRB Registration Process FAQs; OHRP: Membership Requirements for Institutional Review Boards; The Belmont Report; 45 CFR 46.109

For more information on the process, please find guidance documents for HRPP available on the Research Support website at <a href="https://www.researchnewschool.com/hrpp/">https://www.researchnewschool.com/hrpp/</a>. Please also feel free to reach out to us via email (<a href="https://www.researchnewschool.edu">hrpp@newschool.edu</a>) for any questions.