Title: Policy on Protection of Human Research Participants

Original Effective Date: July 1, 2009

Last Reviewed/Revised: April 19, 2022

Responsible Office/Area: Office of Research Subject Protection

POLICY OVERVIEW

The Broad Institute, Inc. (hereafter “Broad) is committed to the ethical treatment of all human subjects, human subject material, and private health information. In support of this commitment, the Broad will comply with all applicable federal, state, local and institutional regulations and guidelines. No research involving the participation of human subjects or use of human subject material will take place without the adherence to these regulations and guidelines.

PURPOSE AND SCOPE

The purpose of this policy is to outline institutional mechanisms designed to protect human research participants, thereby ensuring that all Broad research:

- Adequately protects the rights and welfare of human research participants
- Is guided by the ethical principles of respect for persons, beneficence, and justice as set forth in the Belmont Report
- Is conducted with the highest level of expertise and integrity
- Complies with applicable laws

This policy applies to scientific activities conducted at the Broad by a Broad staff member, researcher, or research affiliate, which involve the use of human subjects, biological specimens, or data derived from humans.

DEFINITIONS AND ACRONYMS

Human Research Protection Program (HRPP) is the integrated program with overall responsibility for the protection of the rights and welfare of human subjects in research conducted at the Broad. The HRPP includes specific oversight of research activities involving human subjects as approved by the Broad’s Institutional Review Boards (IRBs) of record; management of funding negotiations with government and private sponsors; provision and development of training and policies for researchers; coordination of interactions with potential as well as enrolled human subjects; conduct of quality improvement and assurance activities; and support of the compliance responsibilities of the institutions and investigators.
**Human subjects research** means activities that meet the Department of Health and Human Services’ (DHHS) definition, as described in the Code of Federal Regulations (45CFR46), of both research and involve a human subject. “Not human subjects’ research” is a designation indicating that the project either a) does not constitute research, or b) constitutes research, but does not involve human subjects.

**Research** is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

**Systematic investigation** is not defined in the federal regulations, however may be interpreted as a planned scientific or scholarly activity involving qualitative or quantitative data collection and/or data analysis that sets forth an objective(s) and a set of procedures intended to reach the objective(s), i.e., to acquire knowledge, develop a theory, or answer a question.

**Generalizable knowledge** is not defined in the federal regulations, however may be interpreted as information from which one may infer a general conclusion; knowledge brought into general use or that can be applied to a wider or different range of circumstances.

A **human subject** is a living individual about whom an investigator (whether professional or student) conducting research:

(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

An **interaction** is communication or interpersonal contact between investigator and subject.

An **intervention** includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

**Exempt research** is research involving human subjects that meet one of seven criteria outlined in the Code of Federal Regulations, and which are therefore exempt from some federal regulations that apply to non-exempt research. Research exemptions for Broad- based projects must be made by the Broad's Office of Research Subject Protection or the project's IRB-of-record.

**Identifiable private information** is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information

**Institutional Review Board** (IRB) is an institutional body charged with protecting the rights and welfare of human subjects, which reviews and has authority to approve, require modifications in, or disapprove all research activities involving human subjects or human material. Currently, Broad does not have their own IRB but rather has reliance agreements with our partner institutions.

**Home Institution** is the institution at which faculty have their primary faculty appointment.
Office of Research Subject Protection (ORSP) is part of the Office of Strategic Operations at the Broad. It is charged with helping Broad researchers and staff adhere to federal regulations and institutional policies governing the protection of the human subjects. The ORSP guides investigators and their teams through the submission processes at various IRBs. This includes careful review of research consent forms to confirm the appropriate use of human biological samples. The ORSP stores all submission records, and serves as the primary point of contact with the IRBs. It provides one-to-one and group training in human subject protection, regulatory requirements, and on-line submission systems. In certain regulatory-defined situations, the ORSP has the authority to make “Not Human Subjects Research” and “Not Engaged” determinations, thereby making some IRB submissions unnecessary.

An institution is “engaged” in human subjects research when it participates in non-exempt human subjects research in such a way that the regulatory requirements for human subjects protection are applicable. For example, the Broad Institute is engaged in human subjects research if a Broad investigator is obtaining subjects’ informed consent for participation in that project. It is important to note that engagement applies to an institution rather than an individual investigator.

**DESCRIPTION**

1. The Broad’s approach to the protection of human research subject protection is guided by the principles described in the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research’s Belmont Report. These principles are:

   - **Respect for persons**: protecting the autonomy of all research participants by ensuring that adequate standards for informed consent are met
   - **Beneficence**: maximizing benefits for the research project and minimizing risks to the research subjects
   - **Justice**: ensuring reasonable, non-exploitative, and well-considered procedures are administered fairly and equally

2. The basic legal principles governing human subject research, covered by the HRPP and applicable to individual protocols are:

   - Federal Policy for Protection of Human Subjects (Common Rule) in 45 CFR Part 46
   - Food and Drug Administration Regulations for the Protection of Human Subjects in 21 CFR Parts 50 and 56
   - Standard for Privacy of Individually Identifiable Health Information (HIPAA Privacy Rule) in 45 CFR Parts 160 and 164.

3. All Broad employees and affiliates must complete one of the following web-based Collaborative IRB Training Initiative (CITI)’s modules:
   - Biomedical Research
   - Introduction to Human Research Protections

All new hires are made aware of CITI training requirements by their managing supervisor, or by Broad’s electronic tracking system, Traincaster. For those taking the Biomedical Research
course, training must be renewed every three years. See “Oversight of Education Regarding Protection of Research Subject Rights and Welfare”.

4. Investigators may not commence non-exempt human subjects research prior to obtaining IRB review and approval. This includes recruiting, obtaining consent, screening participants, and sequencing samples.

5. For activities that are considered to be “exempt,” “not human subjects research,” or “not engaged”, a formal determination must be made by the Broad’s ORSP. For more details please see “Determining When Activities are Overseen by the HRPP”, “ORSP Project Intake Guidance”, and “Designating an Institutional Review Board of Record”. Determinations are communicated to research staff via email (see ORSP Portal – ORSP Portal Notifications Outline). Investigators may not commence such research activities prior to receiving a “not human subjects research” or “not engaged” determination from Broad’s ORSP.

6. All research that has been approved by an IRB or received a designation of “exempt,” “not human subjects research” or “not engaged” determination from ORSP, receives an internal ORSP number. Prior to commencing such research, researchers are required to obtain an ORSP number.

7. Relevant ORSP policies and procedures are made available to internal staff (including investigators and members of the research staff) via the ORSP Broad intranet site. Broad’s IRBs-of-record are notified by ORSP when local policies that impact IRB review are updated. Relevant policies and procedures are also made available to research sponsors upon request.

8. Current, prospective, or past research participants (or their designated representatives) who wish to discuss problems, concerns, and questions; obtain information; or offer input to an informed individual who is unaffiliated with a particular research protocol are directed to either the Broad’s Chief Compliance Officer (CCO) or an ORSP staff member. After identifying the protocol associated with the subject’s questions or concerns, the CCO or ORSP staff member is responsible for communicating the information to the appropriate representative at the IRB of record. This information should include the subject’s contact information, the question or concern presented, the protocol number, and the name of Principal Investigator. A plan for follow-up with the subject must be established, and carried out by either the IRB or the Broad’s CCO/ORSP. If no further contact between the Broad and the subject is planned, ORSP will seek confirmation from the IRB that the subject’s concerns and questions have been addressed and there are no additional issues to resolve.

**NON-COMPLIANCE**

Noncompliance will be considered a violation of this policy and may be grounds for denial of entry into Broad facilities and serious disciplinary action, up to and including termination of employment.

**REFERENCES**
1. ORSP Policy: *Oversight of Education Regarding Protection of Research Subject Rights and Welfare*

2. ORSP Policy: *Determining When Activities are Overseen by the HRPP*

3. ORSP Policy: *Designating an Institutional Review Board of Record*

**CONTACTS AND SUBJECT MATTER EXPERTS**

1. Chief Compliance Officer

2. Office of Research Subject Protection (orsp@broadinstitute.org)

**KEYWORDS**

ORSP, IRB, Human Subjects.