Title: Recruitment of Broad Community Members as Research Participants

Responsible Office/Department: Office of Research Subject Protection (ORSP)

Original Effective Date: December 2, 2021

Last Revised:

**POLICY OVERVIEW**

Members of the Broad community may be recruited for research participation; however, an employee/affiliate may not be required to participate in research as a condition of employment. Individuals and groups should not be selected solely on the basis of convenience when they would not otherwise be appropriate for inclusion. Examples of when recruitment of Broad community members might be appropriate include, but are not limited to: projects that explore a particular topic that may be unique to Broad’s population (e.g. a study investigating the microbiomes of researchers before and after travel abroad, or a sociobehavioral study exploring professional networking patterns of junior staff scientists); projects that recruit broadly from the same geographic area in which Broad employees live and work (e.g. a study exploring COVID-19 transmission in the Boston area, provided that the research does not target Broad employees exclusively); and clinical trials that offer potential benefit to Broad staff members suffering from a particular disease or condition (e.g. a phase 3 cancer study for which an individual Broad staff member meets eligibility criteria).

Recruitment of potential participants who are Broad community members must be designed to minimize the possibility of coercion, the perception of coercion, or undue influence. In general, potential participants should be solicited from a “broad base” of individuals meeting the conditions for study, rather than from individuals who report directly to the research investigator(s). Strategies to minimize the potential influence of an investigator when recruiting his/her own employees include recruitment through a third party unassociated in a supervisory relationship with the employee, postings or sign-up sheets, or other methods that require an employee interested in participation to initiate contact with the investigator(s).

Investigators must consider strategies to ensure voluntary participation when the subjects of research include employees who are directly supervised by the investigator(s). An employee’s decision about research participation may not affect (favorably or unfavorably) performance evaluations, career advancement, or other employment-related decisions made by peers or supervisors.

Except in unusual circumstances, investigators should not enroll employees under their direct supervision into research studies that involve greater than minimal risk without the prospect of direct benefit. Such studies should proceed only where the IRB determines that adequate provisions have been made to minimize the possibility of coercion, and the research is of significant importance and cannot be conducted without the enrollment of these employees.
Additional safeguards may be needed to protect the privacy interests of employees who are also research participants. Workplace conditions may make it difficult for investigators to keep an individual’s participation confidential, which could pose risks to participants, e.g., when stigma is associated with the condition or question under study. In such situations, additional internal review and approvals may be necessary.

Protecting the confidentiality of research participants’ personal information when the participants are employees may also present additional challenges. The extent to which medical information and/or research data may be accessible to supervisors or others not directly involved in the research must be considered and disclosed to potential participants in the informed consent process.

In cases where regular workplace activities are also the topic of research, investigators must clarify for potential research participants those activities that are optional and distinct from any mandatory workplace activities that would take place even without the research.

**PURPOSE AND SCOPE**

The federal regulations do not specifically mention the inclusion of employees in research, but their designation as a special population stems from the U.S. Code of Federal Regulations, 45 CFR 46.111(b): “When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.”

This regulation does not prohibit the inclusion of employees in research, or provide specific criteria for inclusion. Published guidance from the federal Office of Human Research Protection (OHRP), while allowing the possibility of enrolling these individuals, emphasizes the need for carefully considering whether their inclusion can be justified since the investigator’s, or any other study team member’s, relationship with them is potentially coercive.

In regard to research study conduct, this policy applies to all Broad affiliated researchers and members of their labs, whether paid or unpaid. It applies to all regulatory categories of research involving human biospecimens or data, including research that is reviewed by an Institutional Review Board (IRB); as well as research that involves the use of human-derived samples or data, but does not require IRB review (i.e. human research that is reviewed internally by the Broad’s Office of Research Subject Protection).

In regard to study participation, this policy applies to all members of the Broad Institute community. This policy also applies to researchers who wish to engage in self-experimentation. Federal regulations do not distinguish between self-experimentation and research on subjects who are recruited for a specific project.

**DEFINITIONS AND ACRONYMS**
An “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. The Broad Institute does not maintain its own IRB, and therefore enters into agreements with other institutions to confer this authority and oversight responsibility.

“IRB-of-record” is used to refer to the IRB that assumes IRB responsibilities for another institution for a specific study, group of studies, or for all research conducted by the other institution.

“Members of the Broad community” includes, but is not limited to employees, associated personnel, Broad appointments, faculty appointments, postdoctoral appointments, student appointments, other research appointments, non-research appointments, temporary workers, independent contractors, and consultants.

**DESCRIPTION**

1. Prior to recruitment or enrollment of Broad employees, each new project involving human-derived biospecimens or data must be reviewed by ORSP, via an application to the online ORSP portal system at [https://orsp.broadinstitute.org/](https://orsp.broadinstitute.org/). Projects that involve interactions with human subjects, or receipt of identifiable biospecimens or identifiable data must also be reviewed by one of the Broad’s IRBs-of-record. The ORSP/IRB application must describe:
   a. the rationale for recruitment and enrollment of Broad employees and why alternative recruitment pools are not a reasonable option
   b. whether the data and/or samples will be de-identified
   c. any recruitment materials (e.g. fliers, intranet or Slack posts) that will be used on Broad property or in Broad electronic systems
   d. a description of any plans to return individual level research results to Broad employees
   e. how informed consent will be obtained, and by whom (consents must specify that research results will be shared only with study team members and collaborating researchers who have IRB approval to access them)
   f. how the privacy and confidentiality of Broad employees and their data will be protected
   g. if self-experimentation is planned, the following must also be addressed:
      i. the rationale for self-experimentation
      ii. whether the same procedures will be performed on the researcher as on any other subject in the study
      iii. who will obtain informed consent, and who will perform the study procedures
      iv. a description of how the data obtained from the researcher will be analyzed and processed and who will perform the analysis

2. Following ORSP/IRB approval, but prior to a project’s initiation, ORSP will inform a designated contact in Human Resources (HR) and work together with the study team and HR to address any concerns about recruitment at Broad.

3. If the research project intends to recruit from among Broad community members and involves any of the following, additional approval by an internal review group (made up of the Chief
Compliance Officer, the Chief Operating Officer, and other senior leadership as needed) will also be required:

a. Germline sequencing
b. Any sequencing (e.g. germline, microbial, tumor, etc) that includes return of individual results to Broad community members or their physicians
c. Any questionnaires, surveys, or focus groups that would retain a link to individual participants
d. Large collections of metadata, even when individual data elements are not considered identifiable, if the totality of information may result in individual employee participants being identified

REFERENCES


CONTACTS AND SUBJECT MATTER EXPERTS

Office of Research Subject Protection

Chief Compliance Officer

KEYWORDS

Research Recruitment