

**Human Research Protection Program**

**Policy on the Recruitment of Research**

**Participants**

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1. **PURPOSE**

[Recruitment](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#recruitment) is considered the beginning of the participant selection and informed consent/assent processes. In accordance with “Respect for Persons” in [*The Belmont Report*](https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html), [research personnel](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#researchpersonnel) are obligated to respect an individual’s reasonable expectation for privacy when considering how information is gathered about a potential participant, and who will invite an individual to participate in the research.

Recruitment methods used to solicit volunteers into research must be equitable and free of bias, not exert [undue influence](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#undue) and [coercion](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#coercion) to volunteer, not imply a guarantee of benefits beyond the scope of the research, and must respect the [privacy](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#privacy) and [confidentiality](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#confidentiality) of potential participants.

The Brown University Institutional Review Board (IRB) and the Human Research Protection Program (HRPP) are charged with reviewing and approving the methods, materials, procedures, and tools used to recruit potential research participants before any recruitment strategies are implemented.

1. **SCOPE & APPLICATION**

This policy ensures the equitable recruitment of potential research participants by providing information regarding appropriate methods and mechanisms for recruiting research volunteers. This policy applies to all researchers at Brown University or its research affiliates who conduct recruitment activities under the auspices of Brown University, and includes full Board, Expedited and Exempt study types.

Recruitment plans for research studies should fully consider the many forms diversity takes in prospective study populations, including, but not limited to:

* Race and ethnicity
* Age and generation
* Gender and gender identity
* Religious and spiritual beliefs
* Culture and heritage
* Disability and ability
* Socioeconomic status
* Sexual orientation

Efforts to identify and recruit potential research participants should be designed to respect personal rights to privacy and confidentiality.

The IRB/HRPP will evaluate all recruitment methods to ensure compliance with federal regulations. All print, electronic, video, and audio advertisements used to solicit potential research participants must be reviewed and approved by the IRB/HRPP prior to their use.

1. **RECRUITMENT PLANS**
   1. **Recruitment Time Frames and Settings**

Recruitment activities must be designed and conducted in a manner that permits potential research participants sufficient time, determined by the nature and risks of the research, to consider whether or not they wish to participate. In approving a recruitment plan, the IRB/HRPP will consider the length of time between recruitment, the informed consent process, and the first research procedure in order to ensure potential participants have time to consider the research, and avoid undue pressure or excessive inducements.

Recruitment activities must be carried out in a setting that provides the potential participant privacy, free of situational or environmental influences or intimidations.

* 1. **Considerations for Special Populations**

Researchers must be aware of special populations that may have a vulnerability beyond the regulatory definitions. Individuals and classes of participants may be vulnerable depending on the research, the situation, their condition, and susceptibility to undue influence and/or coercion. Researchers are expected to take special precautions when recruiting potential participants who have a compromised ability to act with autonomy and/or understand the expectations of research.

1. Prisoners

Prisoners are considered vulnerable because their movements are restricted and monitored in a way that affords them few opportunities to make choices, earn money, communicate with outsiders, or obtain medical care.

When the recruitment process involves participants who meet the definition of prisoner, the research is considered to involve prisoners *even if* participants no longer meet the definition of prisoner at the time research activities occur.

When proposed research seeks to involve prisoners at the State of Rhode Island Department of Corrections (RIDOC), the recruitment process may not begin without approval from RIDOC. Instructions regarding how to obtain such approval can be found on the [Conducting Research at RIDOC webpage](http://www.doc.ri.gov/administration/planning/research.php).

1. Children

[Children](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#children) are considered vulnerable because they have not attained the legal age to consent to participate in research.

Although children are not at the legal age to consent, they should be involved in the recruitment process if they are capable of understanding the study. A separate recruitment process for parents/legal guardians will be necessary, depending on the scientific design of the study and/or the age of the children involved.

1. Adults with diminished decision-making capacity

Adults with [diminished decision-making capacity](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#diminished) are considered vulnerable because their capacity to understand, appreciate, and express interest in a study may fluctuate over time. Decision-making capacity is study- and situation-specific.

Although adults with diminished decision-making capacity may not be fully capable of understanding a research study, researchers should make every attempt to involve them in the recruitment process. A separate recruitment process for [legally authorized](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#legally) [representatives](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#legally) may be necessary, depending on the scientific design of the study and/or if the study population is not expected to demonstrate adequate decision-making.

Brown’s [*Policy for Determination of Decisional Capacity to Consent by Adult Persons*](https://www.brown.edu/research/conducting-research-brown/preparing-proposal/research-integrity/hrppirb-home-page/brown-univ-pol-proc#4)[*for Human Subjects Research*](https://www.brown.edu/research/conducting-research-brown/preparing-proposal/research-integrity/hrppirb-home-page/brown-univ-pol-proc#4) should be referenced for more detailed information about recruitment for this population.

1. Brown University students and staff

Researchers intending to recruit their own students or staff to participate in a research study must ensure that the recruitment plan minimizes any perception of undue influence or coercion, as these populations are vulnerable to perceived pressures to appear to professors, supervisors, and/or colleagues as cooperative and supportive of the researcher, the research and/or Brown.

Such pressure may manifest itself with respect to both the initial decision to participate in the research, and any subsequent decisions to continue or discontinue participation. The recruitment plan must assure the potential participant that their relationship with Brown and their grade, standing, employment, etc. is not dependent on or will be affected by their decision to participate.

Recruitment of students must adhere to [*The Family Educational Rights and Privacy Act*](https://studentprivacy.ed.gov/audience/researchers)[*(FERPA)*](https://studentprivacy.ed.gov/audience/researchers)[[1]](#footnote-1)and must be conducted in accordance with the [*Brown University Student Data*](https://www.brown.edu/about/administration/data-governance/sites/datagov/files/Student_data_release_policy_8-2018.pdf)[*Release Policy and Guidelines*](https://www.brown.edu/about/administration/data-governance/sites/datagov/files/Student_data_release_policy_8-2018.pdf). Researchers must also ensure that they follow any other applicable policies if they intend to recruit Brown students and staff through internal email listservs to which they have access as a result of their appointment or employment at Brown.

1. **RECRUITMENT METHODS**

All recruitment methods must be thoroughly described in the IRB Application. The investigator should carefully consider the study aim(s), targeted research population(s), participant privacy, and potential for bias and influence when designing recruitment activities.

* 1. **Advertisements**

The materials used to recruit volunteers must be included with the study Application for IRB/HRPP review. The IRB/HRPP will review and approve the final version of all [advertisements,](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#advertisement) which include:

* Printed material
* Newsletters used for recruitment purposes
* Electronic advertisements
* Telephone
* Email
* Video and/or audio scripts

This material may not be used prior to IRB/HRPP approval. After approval, if an investigator intends to modify approved or add new advertisements, the material must be submitted to the IRB/HRPP using the amendment process.

* 1. **Electronic Recruitment**

Examples of electronic recruitment include advertising on a website or electronic bulletin board, text message, e-mail solicitation, chat rooms, instant messaging, banner ads, discussion forums, blogs, Amazon Mechanical Turk, YouTube, and other social media sites (e.g., Facebook, Twitter, craigslist, etc.).

Recruitment materials must be clearly identified as recruitment for a voluntary research study. This material may not be located or posted in such a way that they could be easily mistaken for, or confused with, employment or paid work.

Non-public electronic mailing lists or forums may be used for recruitment only with the permission of the list owner. Researchers are not required to submit a copy of the list owner’s permission with the Application, but must keep a copy of that permission on file with the study’s research records and make it available upon request.

When recruiting through electronic forums or communities, researchers are expected to conduct their activities in accordance with that site’s terms of use, privacy policy, and/or permission of the community’s moderator/administrator, and be respectful of the user community’s culture and expectations.

* 1. **Third-Party Recruitment**

[Third-party](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#third) recruitment occurs when an investigator asks a person or organization, outside of the research team, to recruit on behalf of the research team. This includes physicians or school administrators who are asked by an investigator to provide their patients or students with information about the research study. Third parties may also include commercial entities hired by an investigator to aid in recruitment.

When an investigator asks a third-party recruiter to mail information to potential participants, the mailing should be clear that the third-party recruiter is not engaged in the study, describe the purpose of the study, and request that the potential participant return a card, respond by e-mail, or make a telephone call to the research team indicating their interest. Researchers should not assume passive agreement by the potential participant if they do not respond to the mailer or otherwise use an “opt out” method requiring the potential participant to respond if they *do not* want to participate.

Potential participants who receive multiple unsolicited requests for research participation may feel harassed. Therefore, if an investigator does not receive a response within a pre-determined time period, they may re-send the mailer no more than two (2) times.

Third-party recruiters *may not*:

* collect any research-related information used to determine eligibility
* provide information about potential participants to an investigator that would impact the confidentiality or privacy of future participants (for example, names or private contact information)
* receive compensation for recruitment, unless they are a commercial entity with no relationship with the potential participants

The IRB/HRPP may approve researchers to ask enrolled research participants to recruit additional participants (referred to as “snowball sampling”) provided certain conditions are met. The IRB/HRPP generally agrees that enrolled participants who do not receive rewards or compensation for referrals are unlikely to induce bias, or feel undue influence or coercion.

* 1. **Brown-specific Recruitment Tools**
     1. Today@Brown

Solicitations through [Today@Brown](https://www.brown.edu/university-communications/news/faculty/today) for human subjects research recruitment are permitted for Brown research faculty if the study is supported by sponsored funding and has Brown IRB/HRPP approval to use this recruitment procedure.

When requesting to use this recruitment process, researchers must adhere to the approval criteria laid out in this policy (see [Section IV](#_bookmark0)). The recruitment material must include the subject line that will be used in the Today@Brown posting as well as the full text to be used in the advertisement. The subject line may not feature or highlight any study compensation.

After approval by the IRB/HRPP, researchers who wish to use Today@Brown must:

* obtain a letter from the Brown HRPP affirming that the Brown IRB/HRPP has approved the use of Today@Brown as a recruitment tool for a specific study; and
* e-mail the approval letter to [Today@brown.edu](mailto:Today@brown.edu) on the same day as their submission to Today@Brown; and
* include the following copy in the Today@Brown submission message: “Use of Today@Brown for recruiting participants has been approved by Brown’s Human Research Protection Program.”

*The following types of research are excluded from this opportunity:*

* *Student research*
* *Research under a reliance agreement (i.e., IRB Authorization Agreements [IAA]) in which Brown relinquishes IRB oversight*
  + 1. Sites.brown.edu

[Sites.brown.edu](https://sites.brown.edu/) is a self-service platform for Brown faculty and staff who wish to host individual, lab, conference or other non-departmental or non-administrative organization websites on the brown.edu domain.

Investigators may use *Sites.brown.edu* to:

* create a website for prospective or active study participants to learn more about a study approved by the Brown IRB/HRPP; and
* collect Level 1 Risk Data

It is not permissible to use *Sites.brown.edu* to collect Level 2 or 3 Risk Data at this time.

* 1. **Recruitment Lists, Databases, and Registries**

Researchers may create and maintain a list of research volunteers who previously were screened for or who took part in a research study, or expressed interest in being contacted for future research opportunities if the below conditions are met.

Researchers *must*:

* receive permission from volunteers to retain their name and pertinent information for future research; and
* provide volunteers the opportunity to remove their name and pertinent information from the list at any time

IRB/HRPP review and approval is required for the use of this recruitment procedure before the topic is broached with a participant by an investigator. The IRB/HRPP will evaluate how permission is sought, the appropriateness of the data being requested, and the confidentiality and security measures in place to secure the data.

* 1. **Publicly-Available Information**

Researchers may use information that is [publicly-available](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#publicly) to contact potential participants. Researchers do not need prior permission from potential participants to collect or use publicly- available contact information, as long as such contact information does not explicitly identify the directory, etc. as not to be used for solicitation purposes in its Acceptable Use Policy (or equivalent).

1. [**APPROVAL CRITERIA**](#_bookmark0)

Unless specifically waived by the IRB/HRPP, advertisements must meet the following criteria for IRB/HRPP approval:

* Must describe the study as a “Brown University research study”
* Must include the name and contact information of the investigator or a member of the research team knowledgeable about the research and research procedures
* Must include the study protocol number
* May state that participants will be paid, but cannot emphasize the compensation by font or design enhancements
* Cannot state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the Application or consent process
* Cannot state or imply that that research procedures are known to be equivalent or superior to practices or procedures available to potential participants outside of the research context
* Cannot describe research procedures as “new” or “safe” without highlighting that the procedures are investigational
* Cannot include exculpatory language through which a participant or their legally authorized representative waive legal rights or releases the investigator, the sponsor, or Brown from liability or negligence

Advertisements should generally be limited to the information that potential participants need to determine their eligibility and interest in the research.

1. **RECRUITMENT INCENTIVES OR BONUSES**

Payment arrangements among sponsors, organizations, researchers, and those referring research participants may place participants at risk of coercion or undue influence, or cause inequitable selection of participants. Payment, compensation, reward, or bonuses in exchange for referrals of potential participants from others (“finder’s fees”) is not permitted. Similarly, payments designed to accelerate recruitment that is tied to the rate or timing of enrollment (“bonus payments”) are also not permitted.

1. **NON-RECRUITMENT COMMUNICATION**

There are forms of communication involved in research that is not intended for recruitment purposes and therefore do not need IRB/HRPP review.

* 1. **Communication with Key Informants or Third-Party Recruiters**

[Key informants](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/hrpp-glossary#key) providing information about topics other than themselves and third-party recruiters do not meet the definition of human subjects research participants or research staff. Therefore, communication with these populations and their activities (if limited to recruitment) do not require IRB/HRPP review.

This communication and their activities are distinct from the recruitment *materials* they may use to recruit on behalf of the research team.

* 1. **Press Releases**

Press releases (for example, news stories, bulletins, announcements, etc.) about an on-going research study are generally not considered recruitment and may be submitted without IRB/HRPP approval, as long as the information disseminated is not intended to recruit participants.

However, if the press release includes eligibility criteria and/or a description of how a potential participant may contact the research team or access more information about the study, this press release would be considered recruitment material and IRB/HRPP review is required prior to publication.

* 1. **Clinical Trials Directories**

Electronic directories of clinical trials are not considered recruitment when the format of the directory limits the information provided to only the basic trial information (for example, study title, eligibility criteria, investigator’s contact information, etc.).

Examples of clinical trial directories that do not need IRB/HRPP review include National Institutes of Health (NIH) ClinicalTrials.gov, the NIH National Cancer Institute’s cancer clinical trials listing, FDA Clinical Trials, and the government-sponsored AIDS Clinical Trials Information Service (ACTIS).

When information posted on a clinical trials website goes beyond direct listings, such information is considered part of the recruitment process and required IRB/HRPP review.

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1. https://studentprivacy.ed.gov/audience/researchers [↑](#footnote-ref-1)