

Brown University
Human Subjects Research Application GUIDANCE
**Use this tool to assist with the completion of the Human Subjects
Research Application. Do not submit this guidance document.**

1. Provide the scientific background of the study.

In lay language, without using scientific or disciplinary jargon, briefly summarize the importance of the proposed study and any relevant background information on the topic.

1. Explain how the study will be applicable to previous and/or continuing work in the field.
2. Discuss why novel inquiry is necessary.
3. If there is a gap in knowledge, explain how the research should address the gap.
4. If this research is intended to replicate previous research, provide the rationale for replication.

2. Identify the specific aims of the study and how the study will contribute to generalizable knowledge.

See the HRPP guidance [Does My Project Need IRB Review?](#) for more information on systematic investigation, generalizable knowledge, and human subjects in research.

Verify that your study meets the federal definition of *research*. Federal law for the protection of human subjects defines *research* as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.”

1. Clearly outline the specific research question(s).
2. Include the study objective(s) and/or hypothesis.
3. Briefly describe the intended research purpose(s) of the any findings/knowledge gained from the study.

3. Participants

In order to approve research, the IRB must determine that the selection of participants is equitable, and related to the purposes of the research and the setting in which the research will be conducted. The IRB must be particularly aware of the unique concerns of research that involves populations who may be vulnerable to coercion or undue influence depending on their situation, condition, or the research.

Identify and describe all participant groups.

Describe each participant population and provide the scientific rationale for including each participant population. When including any vulnerable populations in the study, explain why inclusion of this population is necessary to accomplish the research aims.

List all eligibility criteria for each population, such as age range, race or ethnicity, gender, language and literacy, etc.:

- a. List the inclusion criteria and scientific rationale.
- b. List the exclusion criteria and scientific rationale.

Address whether or not participants must be fluent in English and/or if any of the study activities (i.e. recruitment, consent, assessments, etc.) will be carried out in a language other than English.

Discuss the number of participants needed for the research and provide a rationale for the targeted number:

- a. State the total number of participants who will be enrolled (that is, go through a consent process). This number should account for any attrition from participants who may withdraw or be withdrawn from the study without completing the procedures.
- b. If targeting more than one population, provide numbers needed for each population.
- c. If there are multiple research activities, provide participant numbers needed for each activity.

Select all applicable populations

- | | | | | |
|---|--|--|--|---|
| <input type="checkbox"/> Adults (18+ years) | <input type="checkbox"/> Children (30 days – 17 years) | <input type="checkbox"/> Justice-Involved | <input type="checkbox"/> Decisionally-Impaired | <input type="checkbox"/> Substance Users |
| <input type="checkbox"/> Students | <input type="checkbox"/> Known Interpersonal Relationships | <input type="checkbox"/> Unauthorized Immigrants | <input type="checkbox"/> Refugees | <input type="checkbox"/> At Risk of / Experiencing Homelessness |
| <input type="checkbox"/> LGBTQ+ | <input type="checkbox"/> Pregnant People | <input type="checkbox"/> Fetuses/Neonates | <input type="checkbox"/> American Indian/ Alaskan Native | |

Adults and Children: The age of majority – the age at which a person is legally recognized as an adult – may be different depending on where you conduct your research. Different countries, even different US states, have different ages of majority. Do not assume that all people reach the age of majority at 18 years of age.

- a. Adults: Any person who has attained the legal age for consent to treatments or procedures involved in research under the applicable law of the jurisdiction in which the research will be conducted.
- b. Children: Any person who has not attained the legal age for consent to treatments or procedures involved in research under the applicable law of the jurisdiction in which the research will be conducted.

Justice-Involved: Any person who may interact with the justice system (e.g. law enforcement, court system, etc.) and have insufficient power or resources to protect their own resources, which may make them susceptible to undue influence and/or coercion depending on their situation, their condition, or the research.

- a. This population does not have to meet the federal definition of *prisoner* to be involved with the justice system.
- b. The federal law for the protection of human subjects considers prisoners to be any individual involuntarily confined or detained in a penal institution (e.g., prison, jail, or juvenile offender facility) encompassing (1) individuals sentenced to such an institution under a criminal or civil statute; (2) individuals detained in other facilities (e.g., psychiatric units, hospitals, or drug treatment centers) by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution in a penal institution; and (3) individuals detained pending arraignment, trial, or sentencing.
- c. Probationers and individuals wearing devices that monitor their movements are generally not considered to be *prisoners*, however they are considered to be *justice-involved* participants.

Decisionally-Impaired: Any person with limited ability to make a meaningful decision about whether or not to participate in a research study (e.g. persons experiencing: degenerative diseases affecting the brain; developmental disorders with reduced cognitive or emotional functions; intoxication from drugs or alcohol; and/or pain, distress, or confusion, etc.).

- a. The four elements of decisional capacity for enrollment in research are a participant's ability to (1) understand the information presented to them, (2) appreciate the risks and benefits involved, (3) reason and engage with research personnel about the information presented to them, and (4) express a clear choice about whether they want to participate.

Students: Any individual who is or has been in attendance at an educational agency or institution, and regarding whom the agency or institution maintains education records.

- a. Depending on the design of your study, the school(s) you intend to conduct research with might also need to obtain their own IRB approval.
- b. The US Department of Education (ED) federal regulations (34 CFR 97) require that all institutions engaged in human subjects research obtain IRB approval. Many academic institutions maintain their own IRBs for this purpose (e.g. Baltimore City Public Schools, New York City Department of Education, School District of Wisconsin Dells, etc.).
- c. The [Family Educational Rights and Privacy Act](#) (FERPA) is a federal law that protects the privacy of student education records. This law applies to all schools that receive funds under an applicable program of the ED.
- d. The [Protection of Pupil Rights Amendment](#) (PPRA) is a federal law that regulates research with students being asked questions about themselves or their family on the following topics:
 - 1) Political affiliations or beliefs
 - 2) Mental or psychological problems
 - 3) Sex behaviors or attitudes
 - 4) Illegal, anti-social, self-incriminating, or demeaning behavior
 - 5) Critical appraisals of other individuals with whom the students have close family relationships
 - 6) Legally recognized privileged or similar relationships (e.g. lawyers, doctors, clergy)
 - 7) Religious practices, affiliations, or beliefs
 - 8) Income (other than that required by law to determine eligibility for enrollment in a program or for receiving financial assistance under such program)

Known Interpersonal Relationships: Any person with whom research personnel have a known social association, connection, or affiliation that may vary in degree of intimacy, duration, reciprocity, and/or power distribution. These relationships may be intimate, familial, professional, or informal.

At Risk of / Experiencing Homelessness:

- a. At Risk of Homelessness: Any person who (1) has an annual income below 30% of the median family income for the area they live, as determined by the US Department of Housing and Urban Development (HUD); and (2) does not have sufficient resources to support networks, immediately available to prevent them from moving to an emergency shelter or place not meant for habitation; and (3) exhibits one or more risk factors of homelessness,

- including recent housing instability or exiting a publicly funded institution or system of care (e.g. foster care or a mental health facility).
- b. Experiencing Homelessness: Any person who (1) does not have a fixed, regular, and adequate nighttime residence (e.g. living in an emergency shelter, transitional housing, or places not meant for habitation); or (2) will quickly lose their primary nighttime residence (within 14 days), if no housing has been identified and the person does not have a support network or resources needed to obtain housing; or (3) under the age of 25 or part of a family with children who have not leased/owned a home in the last 60+ days, have had two or more moves in the last 60 days, and who is likely to continue to be unstably housed due to disability or multiple barriers to employment; or (4) is fleeing or attempting to flee domestic violence, has no other residence, and does not have the resources or support network to obtain other permanent housing.

Unauthorized Immigrants: Any person who enters or lives in the US without official authorization, either by entering illegally or by violating the terms of their admission (e.g. entering without inspection, overstaying their authorization period, or working without authorization). These individuals may also be known as “illegal aliens” or undocumented workers.”

Refugees: Any person who is outside any country of their nationality, or in the case of a person not having a nationality, outside any country in which a person last habitually resided, and who is unable or unwilling to return to, and is unable or unwilling to avail themselves of the protection of that country because of persecution or a well-founded fear of persecution on account of race, religion, nationality, membership in a particular social group, or political opinion.

LGBTQ+: Any person who identifies as, or is a part of the community of, the lesbian, gay, bisexual, transgender, queer, questioning, asexual, and/or other sexual orientation and gender identity.

Pregnant People: Any person who exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

Fetuses / Neonates:

- a. Fetuses: Any product of conception from implantation until delivery.
- b. Neonates: Any person who is a newborn (0 – 29 days).

American Indian / Alaskan Native: Any person who is a member of an American Indian / Alaskan Native (AI/AN) tribe, band, nation, pueblo, village, or community that the Secretary of the Interior acknowledges as a federally-recognized tribe.

- a. Depending on the design of your study, the AI/AN tribe you intend to conduct research with might also need to obtain their own IRB approval.
- b. The Indian Health Service (IHS), a federal health program within the Department of Health and Human Services, is responsible for providing federal health services to AI/ANs. It is important to note that all human subjects research conducted in IHS facilities, and/or engaging IHS resources and/or staff must be approved by an IHS IRB. Review and approval by an IHS

IRB are required regardless of whether the research sites are tribal or urban, as both fall under the IHS [Federalwide Assurance](#) (FWA). The IHS has one national IRB and eight area IRBs.

- a. Many tribal and urban facilities in AI/AN communities may have their own FWA and/or maintain their own IRB (e.g. Cherokee Nation, Chickasaw Nation, etc.), while other communities may rely on IRBs at Tribal Colleges and Universities (e.g. Diné College, Haskell Indian Nations University, etc.).

Other: Any person that does not fit in the categories/groups listed on this application.

4. Recruitment N/A

In order to approve research, the IRB must determine that participants are:

- a. *Respected and provided with adequate information to voluntarily enter the research.*
- b. *Selected for reasons directly related to the study aims and questions of the research, rather than due to their easy availability, their compromised position, or their manipulability.*

Describe the recruitment methods.

See the Brown IRB [Policy on the Recruitment of Human Subjects Research Participants](#) and the HRPP guidance [Recruitment](#) for more information on recruitment plans, methods, and approval criteria.

Describe the process and/or method by which participants will be identified, approached, and recruited for the research.

1. Describe when and how each step of the recruitment process will occur (i.e., initial contact, introductions, follow-ups, etc.).
2. Discuss any relevant permissions you will need to reach the participant population (e.g., access to listservs, online databases, etc.).
3. If you will request to access to electronic health records for recruitment purposes, be sure to include an Appendix G: Use of PHI and consider that your study may require a reliance agreement.

List any recruitment materials that will be used, such as advertisements, flyers, or verbal scripts. If no recruitment materials will be used, explain why they will be unnecessary.

Explain which research roles (e.g., PI, Research Assistant, etc.) will recruit participants and how they will be trained.

Describe if screening tests and/or procedures will be used to ensure that potential participants are eligible to participate.

1. State if this screening information will be destroyed once eligibility is determined.
2. If you intend to keep this screening information for research purposes, ensure that a screening consent process is described.

If recruitment procedures involve a language other than English, describe how the recruitment process will be modified and the resources used to support non-English speaking participants.

5. Consent N/A

In order to approve research, the IRB must determine that informed consent will be:

- a. Sought from each prospective participant or their legally authorized representative, with sufficient information about the research, and be given the opportunity to choose what shall or shall not happen to them if they enroll.*
- b. Presented in a manner and context, free of coercion or undue influence, to allow prospective participants time for consideration and opportunities to question researchers.*
- c. Appropriately documented or appropriately waived.*

Explain the informed consent process

Describe how you will ask with prospective participants (or their [legally authorized representatives](#)) for their consent to enroll in the study, provide the required elements of informed consent, and time to consider what should or should not happen if the prospective participant volunteers.. Describe which research roles (e.g., PI, Research Assistant, etc.) will conduct the consent process and how that person will be trained (e.g. previous experience or related training, one-on-one training with PI, etc.) to conduct this process, especially if the prospective population is vulnerable.

Describe how you will ensure that the prospective participants understand all aspects of their involvement in the research.

Describe any special provisions for individuals who might have trouble comprehending the consent information.

Describe how assent to enroll children and parent permission will be obtained and documented.

Describe how you will remove concerns or feelings of [coercion](#) and [undue influence](#) from consent process, and give prospective participants time to think over whether they want to volunteer and ask research personnel any questions.

For example:

1. Describe where and when the informed consent process will take place (i.e., in-person in a private room, by phone, online etc.).
2. Describe if there are any cultural or religious considerations, group permission requirements, or age of majority or technological limitations, etc.

In certain circumstances, the IRB may approve a consent process which does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent. If applicable to your research study, request the appropriate type of consent waiver and provide a justification for your request.

For example:

1. Your study involves secondary data and it would be impracticable for you conduct a consent process, the IRB may approve a request for a waiver of consent.
2. Your study involves [deception](#) or [incomplete disclosure](#), the IRB may approve a request for an alteration of consent.
3. Your topic of research inquiry and/or eligibility criteria may increase risk for your participants (e.g. domestic violence, illegal activity, health information, etc.), the IRB may approve a request for a waiver of documentation of consent.
4. Your study takes place in a location or with a participant population where signing documents is not culturally expected or appropriate, the IRB may approve a request for a waiver of documentation of consent.

5.1 Request for a waiver or alteration of consent □ N/A

- The research involves public benefit and service programs conducted by or subject to the approval of state or local officials
- The research involves no more than minimal risk to the subjects;
- The research could not practicably be carried out without the requested waiver or alteration;
- The research involves using identifiable private information or identifiable biospecimens and could not practicably be carried out without using the data in an identifiable format;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.
- The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

5.2 Request for a waiver of documentation of consent □ N/A

- The only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality.
- The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
- Subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm and there is an appropriate alternative mechanism for documenting that informed consent was obtained.

6. Deception/Incomplete Disclosure □ N/A

In order to approve research, the IRB must determine that participants have authorized the deception or incomplete disclosure through a prospective agreement to participate in circumstances in which they are informed that they will be unaware of or will be misled regarding the nature or purposes of the research.

Describe if the study design involves deception or incomplete disclosure.

See the HRPP guidance Research Involving Deception and Incomplete Disclosures for more information on consent requirements, debriefing, and investigator responsibilities.

1. Ensure that the research meets your discipline's professional code of ethics.
2. Describe the deception or incomplete disclosure.
3. Justify the reasons for deceiving or withholding information from participants.
4. Explain why deception or incomplete disclosure is necessary for the study.
5. Describe how the potential benefits of the research justify the deception or incomplete disclosure.
6. Ensure that there is prospective agreement in the consent process to inform participants that they are being asked to enroll in research in which some portions of the study will not be explained to them until the study has ended.
7. Describe the debriefing process, including (1) when, (2) how, and (3) who will provide the information to participants.
8. Provide a copy of the debriefing script.

7. Procedures

In order to approve research, the IRB must determine that the research plan makes adequate provision for monitoring the data collected to ensure the safety and protect the privacy of participants. The study design, methods and procedures for data collection must adequately describe all human subjects research activities. The IRB must also be able to differentiate those procedures that are performed for research purposes from those that are performed for routine care or evaluation.

Describe the study procedures.

Clearly describe the methods and procedures being used.

1. Provide a detailed timeline of events including all elements of participant interaction.
2. Address any requests for audio or video recording.
3. Provide details for any procedures that require the download and use of an app or website.
4. Provide details on any equipment or devices that participants will be expected to use, including how they will receive the items, expectations for return of items, and plan of action for missing or damaged items (this includes study phones).
5. Address the location of study procedures including recruitment sites and any concerns with transportation.
6. List any assessments, instruments and materials that will be used with participants, and provide a rationale for their use
7. Explain if participants will receive any reimbursement for costs associated with their enrollment (e.g. travel or child care). Describe the amount and nature of the reimbursement and when it will be provided.
8. List any letters of support/permission that may be necessary.

8. Compensation N/A

In order to approve research, the IRB must determine that compensation for participation does not present an undue influence and interfere with prospective participants' ability to give voluntary informed consent.

Describe the compensation.

See the HRPP guidance [Compensation](#) for more information on compensation methods, taxes, and consent language. As a reminder, providing compensation to participants is not required.

Describe the compensation method, amount(s), and payment schedule you offer participants for their time.

State the amount and nature of the compensation (e.g., ClinCard, cash, gift card, course credit, etc.).

Be clear if the amount will be in US dollars or another currency.

Explain how and when compensation will be provided, including:

- a. Payment schedules,
- b. Whether or not compensation will be pro-rated if the participant does not complete all activities in the study,
- c. If there are any raffles or bonuses, how will participants know if they earned this compensation,

- d. If compensation will be provided in-person and/or electronically (e.g. by email, electronic gift card, physical gift card)

Explain how the method and amount of compensation is appropriate for the participant population and study activities (e.g., based on time commitment, number of study visits, travel expenses, age of participant population, etc.).

State whether compensation will be provided by a third party (e.g. crowd sourcing platform).

If there is the possibility that there will be costs to the participant or to a third party (e.g., an insurer), identify the specific expenses (e.g., drug tests, procedures, hospitalization, travel, etc.) and provide a justification for those costs.

9. Is the study a clinical trial?

Yes No

See the HRPP guidance [Clinical Trials](#) for more information.

10. Does the study involve the use of drugs or substances?

If yes, Complete and upload Appendix C: Use of Drugs

Yes No

See the HRPP guidance [Studies Involving Drugs and/or Devices](#), and [Management of Human Research Studies Involving Drugs and Medications](#) for more information.

11. Does the study involve the use of devices?

If yes, Complete and upload Appendix D: Use of Devices

Yes No

See the HRPP guidance [Studies Involving Drugs and/or Devices](#) for more information.

12. Risk to Participants

In order to approve research, the IRB must determine that the possibility of harm to participants is:

- a. *Minimized by using procedures consistent with sound research design that do not unnecessarily expose participants to risk, and whenever appropriate, by using procedures already being performed on participants for diagnostic or treatment purposes.*
- b. *Justified and reasonable in relation to the anticipated benefits to participants, if any, and the importance of the knowledge that may reasonably be gained. If research does not include anticipated direct benefits to participants, every effort must be made to reduce risks, secure the well-being of participants, and protect them from harm.*

Describe the possible research risks to participants.

Describe any reasonably foreseeable risks of harm or discomforts for individuals and/or groups that may result from participation in the research. Consider the likelihood of the risks occurring (probability), and if they do, the consequences (magnitude) they might have for your participants.

Even if the risks associated with participation in your study are minimal, all research carries some risk. Risks can only be decreased, they can never be completely removed.

1. Describe any information potential risks (e.g., loss of privacy and / or breach of confidentiality).
2. Describe any potential psychological or emotional risks (e.g., fear, stress, confusion, guilt, loss of self-esteem, depression, triggering of past emotional experiences).
3. Describe any potential social risks (e.g., social stigma, chance of being ostracized or shunned), economic risks (e.g., change in employment or insurability).
4. Describe any potential physical risks or harms (e.g., fatigue, pain or discomfort, potential for injury, illness or disease, or death, side effects and contraindications of drugs or substances used in the research).
5. Describe any potential legal risks (e.g., risk of prosecution, mandatory state reporting).
6. Describe any potential genetic privacy risk (e.g., stigmatization, self-stigmatization, limits to insurance coverage or employability, misattributed paternity, etc.).
7. For each risk you identify, explain all of the following:
 - a. Likelihood of the risk occurring.
 - b. Magnitude of the effects the risk would have should they occur.
 - c. How the risk will be minimized.
8. If your study involves an intervention, describe the how the risks of the research intervention compare to the “standard of care” and/or the risks participants experience in their daily lives.
9. When appropriate, describe any provisions for data and safety monitoring for the progress of the research and the safety of the participants.
 - a. If there is a separate Data and Safety Monitoring Plan (DSMP), state this and attach.
 - b. If there is an established Data and Safety Monitoring Board / Committee (DSMB/C) to monitor the progress of the research and the safety of participants, clearly indicate this. The frequency and operations of the DSMB/C should be covered in the DSMP.

13. Benefits

In order to approve this research, the IRB must determine that the anticipated benefits to research participants are reasonable in relation to the probability and magnitude of possible harm.

Describe the anticipated benefits to participants.

Describe any potential benefits that may result from the research.

Describe any direct benefits participants could expect to receive that may result from participation (e.g., weight loss, results of clinical tests, etc.). If there are no direct benefits to participants, clearly state this.

Ensure that participants will not lose any benefits by their enrollment in the research.

Describe any benefits that may families of participants.

Describe any benefits that may affect the general population or special.

14. Secondary Data (identifiable information or identifiable biospecimens) N/A

a. Provide the source of the data

b. Describe the type(s) of data / biospecimens and date range(s) of the data you will use and the characteristics of the study research population (e.g., age range, sex, and any other pertinent demographic information).

Click or tap here to enter text.

c. Describe how will you use, study, or analyze the data / biospecimens

Click or tap here to enter text.

15. Use of PHI from a HIPAA-covered entity N/A

Complete and upload Appendix G: Use of Protected Health Information (PHI) in Research. If applicable, upload a HIPAA Authorization form.

Describe how authorization to access the data will be obtained.

See the HIPAA Privacy Rule Guidance for Brown University Researchers for more information on research covered by HIPAA, use and disclosure of PHI, and record keeping.

When using PHI from a HIPAA-covered entity, describe (choose the appropriate method):

1. How HIPAA Authorization will be requested from participants,
2. You will request an IRB **partial waiver** of the authorization requirement for recruitment purposes only,
3. You will request an IRB **full waiver** of the authorization requirement for the entire research study,
4. You will request an IRB **alteration** of the authorization requirement to change/remove some of the require elements of authorization,
5. You will access a limited data set from the data holder of the PHI. .

Complete [Appendix G. Use of Protected Health Information \(PHI\) for Research](#) and include with the application.

16. Use of Family Educational Rights and Privacy Act (FERPA) or Protection of Pupil Rights

Amendment (PPRA) data N/A

What type of FERPA or PPRA data will be accessed for this research?

- Directory information
- Education records
- Instructional material
- Personally identifiable information (PII)
- Other, please describe: Click or tap here to enter text.

Describe how authorization to access the data will be obtained.

See the [Family Educational Rights and Privacy Act](#) (FERPA) and the [Protection of Pupil Rights Amendment \(PPRA\)](#) for more information on recruitment plans, methods, and approval criteria.

Describe how authorization to access student, staff, or educator information will be requested and obtained when your research involves the use of FERPA or PPRA data from an educational agency.

Ensure that you specify whether your process involves directly requesting authorization from the participant (and their parents, when applicable) or the educational agency.

17. Is a Data Use Agreement (DUA), Material Transfer Agreement (MTA), or other agreement required by the source to obtain, use, study, or analyze the data / biospecimens?

If "yes," please upload a copy of the Agreement(s) (draft or executed) to the study record.

Yes No N/A

See Research Agreements and Contracting [Data Use Agreements](#) for more information.

18. What type of data will be collected or received?

- Identifiable health data (PHI) / biospecimens
 - Limited dataset
- Identifiable personal data (PII)
- Coded data and the study team has access to the linking file / key
- Coded data and the study team does not have access to the linking file / key
- Anonymous data
- FERPA-protected and/or PPRA-protected data
- Publicly-available data
- Other, please describe:

19. Describe the research plan for monitoring the data collected to ensure participant safety.

In order to approve research, when appropriate, the IRB must determine that the research plan makes adequate provisions for monitoring the data collection to ensure the safety of participants.

- N/A

See the HRPP guidance [Data and Safety Monitoring](#) for more information on monitoring data, monitoring for safety, and responsibilities for monitoring boards.

Data and safety monitoring is the process of reviewing data collected as your research progresses to ensure the continued safety of current and future participants, as well as the scientific validity and integrity of the research.

If the research includes a data and safety monitoring plan (DSMP), consider the following:

1. Who will perform the monitoring?
2. Will the plan evaluate the data collected regarding risks and benefits to determine participant safety? If so, how often?
3. What data will the plan review?
4. How will the safety information be collected?
5. Is a [Data and Safety Monitoring Board](#) (DSMB) required? (See HRPP's [DSMB Charter Template](#) for guidance)
6. What conditions would trigger a suspension of the research?
7. What will the procedures be for notifying any appropriate entities (i.e. investigators, sponsors, IRB, etc.) of the results?

20. How will you protect the privacy of participants? *In order to approve research, when appropriate, the IRB must determine that there are adequate provisions to protect the privacy of participants.*

Privacy is a participant's right to control who has access to them, their location, and their space. It is the recognition that a participant has the right to determine the extent, timing, and circumstances of sharing themselves (physically, behaviorally, or intellectually) with researchers.

Limit the information you collect to the minimum amount of data necessary to meet the aims and objectives of the research study.

1. Identify the steps you will take to minimize a participant's possible feelings of intrusiveness or discomfort that may be caused by study activities. What is the research plan to protect participant privacy during and after their participation?
2. Ensure that research activities are conducted and information collected under conditions that protect participants from being inadvertently seen, heard, or caught off guard by people not involved with the research study or that specific research activity. For example, a participant may feel uncomfortable:
 - a. Being seen entering a location that they view as stigmatizing, such as an HIV clinic or pregnancy counseling center;
 - b. Having physical measurements recorded in a public setting or with multiple people present;
 - c. Discussing their personal medical history in a public setting or with someone other than a healthcare provider;
 - d. Answering sensitive interview questions while they are at home or at work.
3. Consider if participants will be comfortable with the research procedures and where they will take place (i.e. interviews in a private space or at a location chosen by the participant)
4. Will the door to the room be open or closed?
5. How many researchers will be present during research activities?

21. Does the study have or will apply for a Certificate of Confidentiality (CoC)?

Studies funded by NIH are automatically issued a CoC.

Yes No

See HRPP's [Certificates of Confidentiality](#) (CoCs) for more information on limits to CoCs, the consent process, and investigator responsibilities.

22. How will you maintain the confidentiality of participant data?

In order to approve research, the IRB must determine that there are adequate provisions to maintain the confidentiality of data.

Confidentiality is how a researcher has agreed to handle, manage, and disseminate the information disclosed by or data regarding a participant. There is a relationship of trust between these parties, and the expectation that confidential information or data will not be divulged to others by the researcher without the participant's permission in ways that are inconsistent with the agreement regarding disclosure of the information or data.

Consider the nature, probability, and magnitude of harms that would be likely to result from an unauthorized release of your collected information. The greater the sensitivity of your research data, the more robust your measures must be to maintain participant confidentiality. The research plan to protect participant confidentiality should address and mitigate these possible harms.

1. Will you only collect anonymous information?
2. If you will collect identifiable data, what techniques will you use to protect confidentiality (i.e. coded data, limited data set, etc.?)
3. What are plans for data storage, access restriction, etc.?
4. Are you collecting information in situation in which confidentiality cannot be offered, such as a focus group?
5. Will you share information with a data repository? If so, confidentiality may not be guaranteed (See Brown's [Data Repository FAQs](#) for guidance).
6. Will you share results with research participants? If so, could this impact whether participants are able to identify each other based on shared information?
7. Do you intend to collect participant consent to retain their contact information to join a subject pool for future research studies?

23. Who will have access to your study data / biospecimens?

Brown PI and other Brown research team members (including advisor).

Describe how unauthorized access by others will be prevented.

Data will be shared with research collaborators external to Brown.

This data sharing intent **must** be described as part of your consent process / form. Note that an Outgoing Data Use Agreement is required when sharing identifiable data external to Brown.

Describe how you will securely share / transfer the data outside of Brown.

Data will be shared with a data repository.

This data sharing intent **must** be described as part of your consent process / form. (Please see Brown's [Data Repository FAQs](#) for guidance).

Describe how you will securely share / transfer the data outside of Brown.