# Researcher information

|  |  |
| --- | --- |
| Principal Investigator Name |  |
| Affiliation (check all that apply) | [ ] Faculty[ ] Graduate Student[ ] Post-Doc[ ] Undergraduate[ ] Extension School Student[ ] Staff[ ] Visiting Scholar[ ] Other (specify): |
| Faculty Sponsor (if PI is not [PI Eligible](https://cuhs.harvard.edu/am-I-PI-eligible))  |  |
| Other Advisor Name (if applicable) |  |

# Study information

|  |  |
| --- | --- |
| Study Title |  |
| ESTR Number |  |
| Version Number |  |
| Is this a re-submission of a previous Harvard IRB-approved study that has been closed? | [ ] Yes - Include previous IRB submission # here: [ ] No |

# I. funding information

1. Is your study funded (either directly or through a sub-award) by a Federal Agency (i.e., NIH, NSF, DOD, DOE, DOJ, or EPA, etc.)?

[ ] Yes

[ ] No

1. Is your study funded (or will it be) by the National Institutes of Health (NIH)?

[ ] Yes

[ ] No (please go to next section)

1. Does your study meet the NIH definition of a “[Clinical Trial](https://grants.nih.gov/policy/clinical-trials/definition.htm)”?

[ ] Yes

[ ] No

# II. Research collaborations and locations

## Locations

*Locations refer to the geographic location that the research will take place, not to the people or institutions that you may be collaborating with. Knowing the location helps the IRB determine the local context of the research as well as if there are additional laws, regulations, and policies researchers need to adhere to. If conducting online studies, please indicate the location of the researcher who is hosting.*

1. Where will this study take place?

[ ] Harvard University

[ ] At another location in Massachusetts

[ ] In another state in the U.S. - *Please specify here:*

[ ] Internationally – *Please specify here:*

1. Are there any state laws that the IRB will need to consider when reviewing this study?

[ ] Yes

[ ] No

1. Thinking about all of the locations where this study will take place, are there any permissions that must be obtained from cooperating institutions, community leaders, government officials? *This may include a review by a local ethics board, school district, Ministry of Health, or other institutional approval process, whether domestic or international. A statement that formal review is not required along with your source of information that the proposed research is in accordance with local laws, regulations, and customs is also acceptable.*

[ ] Yes

[ ] No

1. Are there any community or cultural differences for the local population of participants that require consideration?

[ ] Yes (see below)

[ ] No

***If you chose “Yes” describe:***

## collaborations/sites

*Collaborations, known as “sites” in ESTR, refer to people or institutions that are also taking part in the research study. An important part of knowing about these collaborations is knowing what each person/institution is doing in the research in order to determine the scope of IRB review.*

1. Will you be collaborating with any researchers not affiliated with Harvard University Area to carry out this study? *HMS, HSPH, and HSDM are not part of Harvard University Area.*

[ ] Yes

[ ] No (skip to next section)

1. Will the actions of these collaborators include any of the following: Have contact with human subjects; Have access to data that is identifiable; OR Are responsible for the design, conduct, or reporting of the research?

[ ] Yes

[ ] No (skip to next section)

1. If Yes, will these collaborators receive their own IRB review?

[ ] Yes (skip to next section)

[ ] No

1. Is another institution and/or researcher requesting that the Harvard University Area IRB act as the IRB of record (“Reviewing IRB”) for that institution’s or that researcher’s activities on the study?

[ ] Yes

[ ] No

1. If the Harvard University Area IRB will be providing review for the non-affiliated collaborating researchers, indicate which institutions they are affiliated and their role and activities on this study (are they involved in recruitment, data collection, analyzing data, etc.) Add additional lines as necessary.

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Institution | Role on Study | Description of Activities that They will be Conducting |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

# III. study team qualifications and training

1. Describe the Principal Investigator’s experience with the proposed research procedures, population, and local context.
2. Describe how the study staff are trained to ensure that they are adequately informed about this study and study-related duties.
3. Are there any other additional study staff whose role in this study requires special qualifications in addition to ethics training (e.g., licensed clinical psychologist, phlebotomist, etc.)?

[ ] Yes (see below)

[ ] No

***If you chose “Yes” describe:***

# IV. Research purpose

1. Provide a brief, non-technical description of the purpose of the research, including the research questions that you hope to answer.
2. Describe the scientific background, rationale for the study, and importance of this research in adding to existing knowledge.

# V. characteristics of the study population

1. Indicate the estimated number of participants, by subgroup if applicable. *If it is not possible to estimate the number of participants (e.g., open online survey), please indicate that it is not possible and provide an explanation of why it is not possible.*
2. Describe the criteria for enrollment – Will you be limiting your enrollment to a certain age range, gender, people with certain health conditions, etc.? Please also describe any criteria that will exclude people from enrollment.
3. Are there any potential vulnerable populations or individuals proposed for involvement in the research? Check all that apply.

[ ] Children

[ ] Wards of the State

[ ] Prisoners/Detainees

[ ] Pregnant Women

[ ] Adults not Competent to Consent

[ ] Non English Speaking

[ ] Employees of Harvard University (as a focus of the study)

[ ] Undergraduate Students of Harvard University (as a focus of the study)

[ ] Staff or students that are part of your lab

[ ] Other (please describe):

### *children*

*Skip this section if not applicable.*

1. What is the age range of children participating in your study?
2. Are there any special considerations that need to be taken into account? For example, do the children have a learning disability?

### *PRISONERS*

*Skip this section if not applicable.*

1. Describe any advantages that prisoners may accrue through their participation in the research, especially in comparison to the general living conditions, medical care, quality of food, amenities, and earning opportunities in the prison.
2. Explain whether the risks of the research are commensurate with risks that would be accepted by non-prisoner research participants.

### *employees or students of harvard university*

*Skip this section if not applicable.*

1. Explain how you will minimize the potential for employees and/or students of Harvard University to feel coerced or experience undue influence to participate in the research.

# VI. recruitment procedures

1. Will potential participants be provided with information about the study?

[ ] Yes (see below)

[ ] No

***If yes, indicate how, when, where, and by whom participants will be recruited. If you are recruiting from a Harvard University Study Pool, describe how you meet their requirements.***

1. Are there any materials that will be used to recruit participants (e.g., websites, emails, posters, oral scripts)?

[ ] Yes (see below)

[ ] No

***If yes, list the materials by document name here, and be sure to attach a copies to the “Consent and Recruitment Materials”, item 2, Recruitment Materials section in the ESTR SmartForm.***

***HRP-315 WORKSHEET: ADVERTISEMENTS which may be found in the ESTR library provides an overview of items pertaining to advertisements that may be helpful to the study team.***

# VII. screening procedures

1. Will you be screening participants for eligibility?

[ ] Yes

[ ] No (skip to next section)

1. Explain what your screening criteria will be and how you will conduct the screening process.
2. Do you plan to destroy the data from people who participate in the screening process and do not qualify to be in the study, as soon as the screening process is over?

[ ] Yes

[ ] No

1. If so, explain why you will keep the data collected in the screening process for people who are not eligible to participate in this study.

# VIII. informed consent process procedures

*If you plan on having more than one consent process (such as signed, written consent for one population and use of an online “click” consent script for another population), please explain which variations of the study will use which types of consent process with each of these questions.*

*For definitions of the different types of informed consent forms,* [*click here*](https://cuhs.harvard.edu/definitions-0?admin_panel=1)*.*

## Adult participants

*If you will not include adults in your study, please skip this section.*

1. Check which type of informed consent process you plan to use in this study:

[ ]  Long-form consent for adult participants

[ ]  Short-form consent for adult participants

[ ]  Information sheet

[ ]  Will not be obtaining consent (skip to next section after answering below)

***If you will not be obtaining consent, explain why:***

1. Will the consenting process involve obtaining a signature?

[ ]  Yes

[ ]  No (see below)

***If a signature is not obtained, explain why:***

1. Where will the consent process take place?

[ ] In-person

[ ] Online

[ ] Over the telephone

[ ] Other (see below)

***If other, please describe:***

1. Who will obtain consent from participants? *Will the Principal Investigator, other members of the Harvard University research team, collaborating researchers from other institutions, or another third party (such as a survey firm) obtain consent?*
2. Describe the process that will be used to obtain consent.

## children participants

*If you will not include children in your study, please skip this section.*

*If you are including children in your research study, know that “consenting” a child is comprised of two parts: child assent and parent permission.*

1. Check which type of assent process you plan to use in this study:

[ ]  Assent form for minors

[ ]  Information sheet

[ ]  Will not be obtaining assent (skip to next section after answering below)

***If you will not be obtaining assent, explain why:***

1. Will the assenting process involve obtaining a signature?

[ ]  Yes

[ ]  No (see below)

***If a signature is not obtained, explain why:***

1. Where will the assent process take place?

[ ] In-person

[ ] Online

[ ] Over the telephone

[ ] Other (see below)

***If other, please describe:***

1. Who will obtain assent from child participants? *Will the Principal Investigator, other members of the Harvard University research team, collaborating researchers from other institutions, or another third party (such as a survey firm) obtain the assent?*
2. Describe the process that will be used to obtain assent from children.

## PARENT PERMISSION

*If you will not be including children in your research, please skip this section.*

1. Check which type of parent permission process you plan to use in this study *(please see “Types of Informed Consent” in Definitions section for more information)*:

[ ]  Parent Permission form

[ ]  Information sheet

[ ]  Will not be obtaining parent permission (skip to next section after answering below)

***If you will not be obtaining parent permission, explain why:***

1. Will the parent permission process involve obtaining a signature?

[ ]  Yes

[ ]  No (see below)

***If a signature is not obtained, explain why:***

1. Where will the parent permission process take place?

[ ] In-person

[ ] Online

[ ] Over the telephone

[ ] Other (see below)

***If other, please describe:***

1. Who will obtain permission from the parents? *Will the Principal Investigator, other members of the Harvard University research team, collaborating researchers from other institutions, or another third party (such as a survey firm) obtain the permission?*
2. Describe the process that will be used to obtain permission from parents.

## Other types of participants

*If this section is not applicable, skip to next section.*

1. If you will be including Wards of the State, explain how consent of legal guardian(s) of ward(s) will be obtained. How will you ensure that the appropriate person granted permission for each ward to participate?
2. If you will be obtaining consent from special populations such as non-English speaking participants, illiterate participants, or adults not competent to consent, please explain how you will obtain consent from those individuals.

***Please be sure to attach copies of all informed consent/parent permission/assent materials to the “Consent and Recruitment Materials” section in the ESTR SmartForm.***

# IX. Study procedures

1. Which research procedures does the study involve? *(please check all that apply)*

[ ] Surveys, Questionnaires, and/or Psychometric Testing

[ ] Interviews and/or Focus Groups

[ ] Observational and/or Ethnographic Research

[ ] Audio/Video Recording and/or Photographs

[ ] Deception/Incomplete Disclosure of Research Purpose or Procedures

[ ] Using Previously Collected Material (including obtaining data or biological materials and secondary data analysis)

[ ] Magnetic Resonance Imaging (MRI), EEG, ECG, Eye Tracker, or other device

[ ]  Specimen Collection and/or Analysis, including genetic analysis

[ ] Device (as a focus of the study; FDA approved or experimental)

[ ] Drug (as a focus of the study; FDA approved or experimental)

[ ] Other (see below)

***If you selected “other” research procedures. Please specify:***

1. Provide a complete overview of the study. Describe the procedures participants will be asked to complete or undergo. Explain step by step what participants will be asked to do.

***If your study includes multiple variations of the procedures, please make clear which procedures are included in the variations.***

***The below sections contain additional questions depending on the type of research that you are conducting and is meant to supplement the study overview. Please complete each section, as applicable.***

## surveys/ questionnaires/psychometric testing

*Skip this section if not applicable.*

1. List the names of all surveys/questionnaires/psychometric tests to be used in this study and a description of any that are not standard/formally named (such as study-specific questionnaires).
2. How often will participants be asked to complete the surveys/questionnaires/psychometric tests and how long will it take to complete?
3. Will you be using any survey software (such as Qualtrics)?

[ ] Yes (see question below)

[ ] No

***If “Yes” which survey software will you be using?***

## interviews/oral history/focus groups

*Skip this section if not applicable.*

1. Explain where interviews/focus groups will take place (including possible online venues such as Skype, online chat rooms, etc.)
2. Describe any steps you will take to protect the participant’s privacy during the interview/focus group.
3. Describe the number of interviews/focus group sessions you anticipate for each participant and approximately how long you expect each interview/focus group to last.

## observational/ethnographic research

*Skip this section if not applicable.*

1. If you will be actively participating in the field (as in participant-observation), describe what this will entail.
2. Describe what and whom will be observed and in what settings (such as public events, religious ceremonies, household activities, work meetings, internet chat-rooms and social media sites, etc.)
3. Will any observational data be considered private, according to the standards of that community?

[ ] Yes

[ ] No

1. Explain if the data you collect will contain any information that identifies specific individuals or if you intend to quote their remarks.
2. Will you notify participants that they are being observed?

[ ] Yes

[ ] No (see below)

***If you chose “No” explain the circumstances why you would not be able to let participants know they are being observed.***

1. If permission from that group is obtained (e.g., from a community leader), how will you ascertain whether there are individuals who do not want to participate, and how you will manage such a situation.

## Audio-recording/video-recording/photographs

*Skip this section if not applicable.*

1. Explain what types of data will be recorded or photographed.
2. If you will be collecting sensitive data, will you use any procedures to de-identify or anonymize the recordings or photographs?
3. Explain what will happen to the recordings/photographs at the end of the study.

## deception and incomplete disclosure

*Skip this section if not applicable.*

1. Describe what information will be withheld from participants or what misinformation will be provided to participants.
2. Explain why this research involves no more than minimal risk to participants and why it would be impracticable to carry out the research without the use of deception or incomplete disclosure.
3. Describe the plans for debriefing participants after their participation. If you do not plan to debrief participants, explain why.

***Please be sure to attach a copy of the debriefing script (if applicable) to the “Supporting Documents” section in the ESTR SmartForm.***

## using previously collected material (Data and biological materials)

*Skip this section if not applicable.*

1. Indicate the identifiability of the data and/or biological materials

[ ] Will not contain any direct or indirect identifiers; will be anonymous.

[ ] Will not be identifiable but there will be a code held by the data source that links to the identities; will be coded.

[ ] Will contain direct or indirect identifiers but this research team will remove them upon receipt; will be de-identified data.

[ ] Will contain direct identifiers; will be identifiable.

## For data

*Skip this section if not applicable.*

1. Describe which data sets you plan to analyze, who is providing the data to you, and whether the data are public use data sets, restricted access datasets, or another type of dataset.
2. Provide an overview of the types of variables that are contained in the dataset (for example, identifiable data such as names, dates of birth, addresses, or any data that are considered sensitive).
3. Was the data you plan to analyze collected in a previous research study?

[ ] Yes (see below)

[ ] No

***If you chose “Yes”, provide the title/name of the previous research study and which institution and researcher collected the data for the previous study. If the data were collected in a previous Harvard University research study, provide the ESTR number assigned to that study.***

1. Will any of your data be obtained from internet sites (including data mining and data scraping activities)?

[ ] Yes (see question below)

[ ] No

***If “Yes”, what websites will you access to obtain the data? Please know that it is your responsibility to check the terms of service of any websites from which you plan to collect data to determine whether your planned data collection is compatible with the terms of service.***

1. Is the data publically available on the internet (i.e., freely available without permission, sign-in, or other restrictions)?

[ ] Yes

[ ] No

1. Do you plan to access any data that is Protected Health Information (PHI) under the HIPAA law (for example, data held by a hospital or other healthcare provider or insurer)?

[ ] Yes

[ ] No (skip to question #30)

1. Which organization will provide the HIPAA PHI to you?
2. How will permission to allow the use/disclosure of individual’s protected health information (PHI) be obtained?

***HRP-330 WORKSHEET: HIPAA which may be found in the ESTR library provides an overview of items pertaining to HIPAA that may be helpful to the study team.***

1. Do you plan to access any data that is FERPA protected (data that are held as education records by an educational institution)?

[ ] Yes

[ ] No

***HRP-331 WORKSHEET: FERPA COMPLIANCE which may be found in the ESTR library provides an overview of items pertaining to FERPA that may be helpful to the study team.***

1. Do you plan to obtain data from E.U. citizens residing in the E.U.?

[ ] Yes (see below)

[ ] No

***If “YES”, the data you obtain may be subject to the E.U. General Data Protection Regulation (GDPR). Click*** [***here***](https://www.eugdpr.org/) ***for more information.***

***Note that this regulation may also apply to data obtained over the internet.***

## for biological materials

*Skip this section if not applicable.*

1. How will you obtain the material? (check all that apply)

[ ] Residual clinical material

[ ] Material obtained from a vendor

[ ] Active collection as part of this research study

[ ] Material that was collected as part of another research study (please see below)

[ ] Other – specify:

***If you chose “another research study” provide the title/name of the previous research study and which institution and researcher collected the specimens for the previous study. If the specimens were collected in a previous Harvard University research study, provide the ESTR number assigned to that study.***

1. Will the material consist of any of the following? (check all that apply)

[ ] Embryonic tissue

[ ] Embryonic stem cells

[ ] Stem cells

[ ] Fresh human fetal tissue

[ ] None of the above

1. Provide an overview of the types of variables that will accompany the biological materials (for example, identifiable data such as names, date of birth, addresses, or any data that are considered sensitive).

## Devices

*Skip this section if not applicable.*

1. List the device(s) that you plan to use in this study (add additional lines as necessary):

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Device Brand Name | Generic/Common Name | Manufacturer | Purpose | Function/Operation |
|  |  |  |  |  |

1. Is the device(s) that you plan to use FDA-approved/cleared?

[ ] Yes

[ ] No

1. If any of the devices that you plan to use require a certified professional to operate, please explain who is certified to operate this device and whether they are on your study team.

***Please complete HRP-307 WORKSHEET: DEVICES which may be found in the ESTR library and attach to the Supporting Document section in the ESTR SmartForm.***

## drugs

*Skip this section if not applicable.*

1. List the drug(s) or biologic(s) that you plan to use in this study (add additional lines as necessary):

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Drug/Biologic Brand Name | Generic/Common Name | Manufacturer | Purpose | Function/Operation |
|  |  |  |  |  |

1. Is the drug(s)/biologic(s) that you plan to use FDA-approved/cleared?

[ ] Yes

[ ] No

1. Please explain who is qualified to dispense this drug/biologic and whether they are on your study team.

***Please complete HRP-306 WORKSHEET: DRUGS which may be found in the ESTR library and attach to the Supporting Document section in the ESTR SmartForm.***

# X. participant compensation

1. Will your study offer any compensation/incentive to participants (including cash, gift cards, course credit, etc.)? *Please refer to the* [*Harvard University Financial Policy on Human Subject Payments*](https://policies.fad.harvard.edu/pages/human-subject-payments)*.*

[ ] Yes

[ ] No (skip to next section)

1. What type of compensation will you provide to participants?

[ ] Cash

[ ] Check

[ ] Gift Card/Gift Certificate

[ ] Course Credit

[ ] Lottery/Raffle

[ ] Other

***If you chose “Other” please specify:***

1. What amount will the compensation be worth?
2. Describe which participants will receive compensation and when the compensation will be given.
3. Will you provide partial compensation for participants who do not complete all of the study procedures?

 [ ] Yes

 [ ] No

***If you chose “Yes” please explain how partial compensation will be managed:***

***HRP-316 WORKSHEET: PAYMENT which may be found in the ESTR library provides an overview of items pertaining to payment that may be helpful to the study team.***

# XI. data security and management

1. Which category of information best describes the data you will be recording? *Please refer to the* [*Harvard University Data Security Policy*](https://vpr.harvard.edu/pages/harvard-research-data-security-policy)*.* ***Please know that it is the researcher’s responsibility to ensure compliance with the Harvard University Data Security Policy at all times.***

[ ] LEVEL 1 - Data that is publicly available or not identifiable. Examples:

* Research data that has been de-identified in accordance with applicable rules;
* Published research data; published information about the University;
* Course catalogs;
* Directory information about students who have not requested a FERPA block;
* Faculty and staff directory information.

[ ] LEVEL 2 - Information the University has chosen to keep confidential but the disclosure of which would not cause material harm. Examples:

* Research data that is identifiable but is not considered sensitive;
* Patent applications and work papers, drafts of research papers;
* Building plans and information about the University physical plant.

[ ] LEVEL 3 - Information that could cause risk of material harm to individuals or the University if disclosed. Examples:

* Information protected by the Family Educational Rights and Privacy Act (FERPA) to the extent it is not covered under Level 4 including non-directory student information and directory information about students who have requested a FERPA block;
* HUIDs associated with names or any other information that could identify individuals;
* Harvard personnel records (employees may discuss terms and conditions of employment with each other and third parties);
* Institutional financial records;
* Individual donor information;
* Other personal information protected under state, federal and foreign privacy laws not classified as Level 4 or 5.

[ ] LEVEL 4 - Information that would likely cause serious harm to individuals or the University if disclosed. Examples:

* High Risk Confidential Information (HRCI) and research information classified as Level 4 by an IRB;
* Personally identifiable financial or medical information;
* Information commonly used to establish identity that is protected by state, federal, or foreign privacy laws and regulations;
* Individually identifiable genetic information that is not Level 5;
* National security information (subject to specific government requirements);
* Passwords and Harvard PINs that can be used to access confidential information.

[ ] LEVEL 5 - Information that would cause severe harm to individuals or the University if disclosed. Examples:

* Research information classified as Level 5 by an IRB or otherwise required to be stored or processed in a high security environment and on a computer not connected to the Harvard data networks;
* Certain individually identifiable medical records and genetic information, categorized as extremely sensitive.
1. In what format will the research data be collected and stored?
2. Explain where the research data will be stored while the study is active (e.g., personal laptop, thumb drive, departmental computer server, office file cabinet, etc.).
3. Will the data be physically housed at Harvard or stored remotely under the management of Harvard researchers?

[ ] Yes

[ ] No

1. Do you anticipate that the research data will be transferred or transported at any time?

[ ] Yes

[ ] No (skip to question #7)

1. Explain what methods you will use to transfer/transport the data and how you will minimize the risks of a data breach during the transmission process.
2. Will (or has) a Certificate of Confidentiality (CoC) be/been obtained for this study? *If your study meets the definition of a clinical trial according to the NIH, a CoC will be automatically issued with your funding.*

[ ] Yes

[ ] No

# XII. sharing Data with others

1. Will the data be released to anyone who is not on the Harvard University Area research team?

[ ] Yes

[ ] No (skip to question #4)

1. Other than the Harvard University Area research team, who will have access to the data?

[ ] Colleagues/Collaborators at other institutions

[ ] Transcribers/coders hired by the research team

[ ] Sponsor/Funding Agency

[ ] Other (see below)

***If you selected “Other” please specify here:***

1. How will the data be shared/disclosed beyond the Harvard University Area research team?

[ ] Without any identifiers

[ ] Coded

[ ] With Identifiers

1. Will you be sharing research findings with study participants?

[ ] Yes (see below)

[ ] No

***If “Yes” please describe which findings will be shared, when they will be shared, and how they will be shared with participants (in-person, over the telephone, etc.):***

1. Does the study include establishing a repository for sharing data or specimens with other researchers?

[ ] Yes (*If so, please know that a separate IRB submission will be needed if a data or specimen repository will be created)*

[ ] No

## genomic data sharing

1. Will you be submitting data to a national data repository (dbGaP, GEO, etc.)?

[ ] Yes

[ ] No (skip to next section)

1. Include a description of all fields to be submitted to the repository:
2. Describe the plan for de-identifying data for inclusion in the repository, including how the key linking the identity of participants will be maintained and who will have access:

***If data will be prospectively collected, specific elements are required to be included in the informed consent form that you will be using in this study. Please see the***[*NIH guidance document*](https://osp.od.nih.gov/wp-content/uploads/NIH_guidance_elements_consent_under_gds_policy.pdf)*.*

***If data that will be submitted have already been collected under another IRB or other collection protocol, please be sure to attach a copy of the IRB approval and approved consent form(s) used to collect the underlying data/specimens to the “Supporting Documents” section in the ESTR SmartForm.***

# XIII. risk assessment

1. Describe the foreseeable risks associated with your study. Please include discussion of any physical risks and non-physical risks, such as economic, psychological, social, and legal harms.
2. Describe the steps that you will take to minimize risks to your participants (for example, using pseudonyms or a coding system, etc.)
3. Are provisions needed for medical and/or psychological support resources (for example, in the event of research-related distress or incidental findings)?

[ ] Yes

[ ] No

1. What steps will you take if a participant becomes distressed during your study or reports intent to harm themselves or others?