Tips on Completing the IRB Protocol for Human Subjects Research form

The following are some tips on completing the IRB Protocol for Human Subjects Research form. I will start at the beginning of the form and work my way through it. The goal is to have it in the best shape so when the IRB reviews the form, there are no requests for clarification, no requests for revisions thus facilitating approval of the project. Requests for clarification will only slow the process.

Please Note: All sections/questions need a response. If a section/question does not apply, state 'Not applicable'; do not leave it blank.

NOTE: This is for the IRB Protocol form version v2025-02. If you are using an older version of the form, stop and use the current version of the form. Older versions of the form will not be accepted by the IRB. They will be sent back and you will be instructed to complete the current version of the form.

Basic Information	
Title of Study:	
Short Title:	
Principal Investigator Name:	
Principal Investigator's Department/Unit:	

- The short title is required. Do not leave this blank or state 'N/A'. The short title in eIRB should be the same as the short title listed here.
- Principal Investigator's Department/Unit should at minimum be College of Nursing.

1.0 Background (Limit 1,000 words):

Provide the scientific or scholarly background for the proposed Human Research. Discuss relevant prior experience or preliminary data (e.g., existing literature).

A couple of things here. The first is that all acronyms are spelled out the first time used. The second is that it is in lay language, no jargon. If this is copied and pasted from another document and there are references or reference numbers, remember to include the reference list.

2.0 Lay Summary:

Provide a brief description of the proposed research using terms that someone who is not familiar with the science or discipline can understand.

This is a lay summary. It should be fairly short, a paragraph or two, and in lay language. They are asking for a brief description of the proposed research so this should be included.

3.0 Purpose:

Describe the purpose, specific aims, objectives, questions to be answered, hypotheses, and/or primary and secondary study endpoints of this Human Research protocol.

Include a purpose statement. Include specific aims, hypotheses, and/or research questions as applicable.

4.0 Funding Information

Indicate all sources of funding for the project, including gift funds, departmental funds, or other internal funding. For each funder, list the name of the funder, and the institutional proposal number or award number you received from Sponsored Projects. eIRB tip: For externally funded projects, the institutional proposal or award number provided must be linked in the "Study Funding Sources" section in eIRB.

For some projects, there is no funding. If there is no funding and you are giving compensation to participants such as a gift card or raffle for a gift card, the source of the funds needs to be stated or the IRB will ask the source of the funds. If self-funded, suggest checking 'Other' and for 'Name of funding source' state Gift card(s) will be self-funded.
If you have funding, be careful which option is checked, especially if it asks for an institutional proposal or award number and it has not been routed through Sponsored Projects. This will cause a delay when submitted in eIRB.

5.0 Resources Available to Conduct the Human Research:

Describe the resources (facilities, time, emergency resources, etc.) available to recruit, consent, conduct study procedures, and analyze data.

No specific guidelines for this. If you are using survey software such as REDCap or Qualtrics, this can be stated. If you need special software to analyze the data, this can be included. If you are collecting biological samples and need access to a facility to store and analyze the samples, this can be included. You can include who, by job title, will be recruiting, consenting, and collecting data.

6.0 Study Population:

6.1 Select all the categories of participants included in the research:

☐ Healthy adults	☐ Non-English-speaking subjects
☐ Non-healthy adults	☐ UA staff/faculty

☐ Children (under 18 years old) *	☐ UA students
☐ Pregnant women, neonates, and/or fetuses*	☐ Banner employees
☐ Prisoners*	☐ Refugees
☐ Native Americans, Alaskan Native, and Indigenous Populations*	☐ Other – please explain:
☐ Adults unable to consent (i.e., cognitively impaired adults) *	

***Complete and attach the appropriate HSPP Appendices if your subjects include children, pregnant women, neonates, prisoners, cognitively impaired individuals, or Native Americans or Indigenous Populations. eIRB tip: appendices should be uploaded in the "Other Attachments" section in eIRB.**

Include the appropriate appendix if any of the categories with an asterisk (*) is checked.

6.2 For each of the above selected categories, describe the inclusion and exclusion criteria. Indicate age range, gender, and ethnicity.

Inclusion and exclusion criteria should be clearly stated. For ease of reading, this can be formatted as a bulleted list. Age range should be stated. If there are no gender and ethnicity restrictions, it should be stated that all genders and ethnicities will be included or that there are no restrictions on gender and ethnicity. If the study targets specific genders and/or ethnicities, that should be stated.

6.3 Describe the total number of subjects to be enrolled locally under this IRB approval. If obtaining specimens, specify the maximum number of specimens needed for this project.

The total number of subjects anticipated/targeted should be stated. If you are over sampling because of attrition, state this and state the maximum number you will be targeting. For qualitative studies, it is not acceptable to state 'until data saturation'. The IRB will question this. It can be stated, for example, a maximum of 12 participants or until data saturation. Remember the study will be limited to the maximum number stated. If you decide later that additional participants are needed, a study modification may be needed to increase the sample size. So, err on the side of too many participants rather than too few. It is fine to have fewer participants than stated but not always fine to have more.
If obtaining specimens, state the maximum number of specimens needed.

7.0 Recruitment Methods:

7.1 Select the methods used to recruit individuals.

☐ Email	☐ Screening of the Electronic Medical Record (EMR)

☐ Face to face	☐ Social media
☐ Flyers	☐ SONA System
☐ In person presentations	☐ TV, Radio, Print
☐ Online advertisements	☐ Other – please explain:
☐ Phone calls	

Refer to the HSPP Guidance, Recruitment and Advertisements. Provide copies of any materials used to recruit subjects directly (e.g., recruitment scripts, emails, print/audio/visual advertisements, or online notices). Please ensure all recruitment materials state the project has been reviewed and approved by the University of Arizona IRB. eIRB tip: all recruitment material should be uploaded to the "Recruitment Materials" section in eIRB.

7.2 Explain the recruitment process. Describe how potential subjects will be identified, where recruitment will take place, when recruitment will occur, and the methods that will be used to recruit individuals.

Include how participants will be recruited. If by email, state who will send the email. If by flyer, state where it will be posted. If flyers will be handed to potential participants, include who will be handing them out. If participants will be recruited on social media, specify the group/groups you will be posting to and if they are a publicly available group or a private group. If private, include an approval letter or email from the individual running the group stating that you have permission to post the recruitment material. If recruiting face to face or by in person presentations, include a copy of the recruitment script that will be used. If potential participants will be screened, a copy of the screening questions should be included and state if screening information will be retained. If screening information will be retained, potential participants should be consented for screening.

A couple of things to remember. The IRB prohibits 'cold-calling', the solicitation of potential participants who had no prior interaction with the research team. Participants can be contacted via snowball method of recruitment in which potential participants agree to have their name forwarded to a researcher after the potential participant has authorized this.

Remember that all recruitment material (flyers, scripts, emails, etc.) must include the IRB required statement. It may be shortened, but the main concept must remain: An Institutional Review Board responsible for human subjects research at The University of Arizona reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

7.3 Explain how the research plan (recruitment, study population, data collection, etc.) is equitable and represents the demographic makeup for the location in which the research will be conducted.

This might include the demographic makeup of the location of the research. If in Tucson, include the demographic makeup of Tucson and how your proposed study sample will match that.

7.4 Describe whether non-English speaking subjects will be included in the study. If yes, please explain how your research team is prepared to meet the needs of the population. If not, please explain why non-English speakers will be excluded from the study population.

This should address non-English speaking participants. If they will be included, state how you will meet their needs in terms of recruiters/recruitment, translated documents, and the ability of study personnel to speak the language.
If non-English speaking participants will not be included, state why they will not be included.

7.5 What methods will you use to collect demographic information from participants? If you will not collect demographic information, please explain why not.

State the method that will be used to collect demographic information, for example a Demographic Questionnaire.
If demographic information will not be collected, explain why it will not be collected.

8.0 Consenting Process:

8.1 Indicate the informed consent process(es) and/or document(s) for the study. Check all that apply.

Written Consent
☐ Informed Consent (ICF) – written or electronically signed form
☐ Parental Permission – written or electronically signed form
☐ Assent (participants under 18) – written or electronically signed form
☐ Combined ICF/PHI Authorization – written or electronically signed form
☐ Standalone Protected Health Information (PHI) HIPAA Authorization – written or electronically signed
☐ Translated Consent/Assent – written or electronically signed form(s)
☐ Short Consent Form – written or electronically signed form (see guidance on **Short Form process**)
☐ Debriefing Script or Form – document used to properly inform subjects of the study's purpose when intentionally deceived

Oral/Online/Unsigned Consent (Appendix for Alteration/Waiver of Consent or PHI is Required for upload into eIRB)
☐ Informed Consent – oral script/online/unsigned
☐ Parental Permission – oral script/online/unsigned
☐ Assent – oral script/online/unsigned
☐ Translated Consent/Assent – oral script/online/unsigned

Waivers of Informed Consent and/or PHI Authorization
☐ Waiver of Consent
☐ Full Waiver of PHI Authorization
☐ Partial Waiver of PHI for Screening Purposes

Word versions of all consenting documents are required. Use HSPP template consent forms.
eIRB tip: all consent forms should be uploaded in the "Consent Forms" section in eIRB.

Remember the Appendix for Alteration/Waiver of Consent or PHI is required if you are requesting a waiver of a signature or waiver of consent. This is to be uploaded in the 'Other attachments' section in eIRB

8.2 Describe in detail the consent processes checked above, including any waiting period for subjects to sign the consent, steps to minimize the possibility of coercion or undue influence, and the language used by those obtaining consent.

Describe the consent process. If using a Disclosure form, include when/how it will be presented to participants and if it will be paper or online. If using a Consent form, include when/how it will be presented to participants and if it will be paper or online. If the person will sign the consent form, include if this will be an electronic signature or a physical/wet signature. If participants do not speak or read English, then documents must be translated into a language they understand or an alternative process available. Include if a translated consent document will be available to participants if they do not speak English and how the translation was verified.

8.3 Where will the original signed consent and PHI authorization documents be stored?

Remember that signed consent documents must be stored at the University of Arizona (University of Arizona policy). One option for storage is the Office of Research & Scholarship. Consent documents signed online should be stored in an approved secure location such as REDCap.
If using a Disclosure form, state this or state that there will be no signed consent documents or state Not applicable.

8.4 Acknowledgement of consent form storage.

☐ I will store original signed consent and/or PHI authorization documents for at least 6 years past the time the study is concluded.
☐ For studies involving minors, I will store original signed consent and/or PHI authorization documents for at least 6 years after the youngest participant turns 18.
☐ Not applicable – I am not collecting signed documents.

9.0 Research and Data Collection Procedures:

9.1 Select the methods of data collection that will be used in this study (select all that apply):

☐ Anthropometric measures (e.g., height, weight, waist circumference, etc.)	☐ Participant observation
☐ Audio/video recording	☐ Screening data
☐ Benign interventions	☐ Self-health monitoring (e.g., pedometers, food diaries, etc.)
☐ Biological specimens – blood draws	☐ Surveys – paper
☐ Biological specimens – clinically discarded blood or specimens	☐ Surveys – internet (including online and email-based data collection)
☐ Biological specimens (urine/feces, tissue, saliva, skin, hair, nails, nasal swab)	☐ Surveys – telephone
☐ Clinical Data Warehouse (CDW)	☐ Randomization with control and experimental groups
☐ Cognitive or behavioral measures, including daily diaries	☐ Records – billing
☐ Data collected using other communication/electronic devices (e.g., cell phones, pagers, and texting devices)	☐ Records – educational
☐ Data previously collected for research purposes	☐ Records – employee
☐ Deception	☐ Records – lab, pathology and/or radiology results
☐ Instrumentation, equipment, or software not approved by the FDA	☐ Records – mental health
☐ Interviews – focus groups	☐ Records – substance abuse
☐ Interviews – in person	☐ Research imaging protocols
☐ Interviews – virtual/online	☐ Recombinant DNA
☐ Medical records review	☐ Social networking sites
☐ MRI/ultrasound with contrast	☐ Stem cells
☐ MRI/ultrasound without contrast	☐ Radiation Scans (X-Ray, CT Scans, etc.)

☐ Non-invasive instruments (e.g., external sensors applied to the body)	☐ Other activities or interventions – describe:

Attach all surveys, scripts, and data collection forms. eIRB tip: data collection tools should be uploaded in the "Other Attachments" section in eIRB.

9.2 Description of research procedures.

Provide details of EACH research procedure in chronological order using simple language. Be clear when identifying which procedures are specifically for research, and which study population will be completing each study procedure. Include a description of all procedures already being performed on subjects for diagnostic or treatment purposes.

If there are plans for long-term follow-up (once all research related procedures are complete), describe what data will be collected during this period. For projects investigating drugs/devices or treatment plans, describe the tests and procedures that will be done to accomplish this. If applicable, discuss the randomization ratio, the dosages of drugs being used, and the investigational treatment plan.

If this is a multisite study where UArizona IRB will oversee an outside site, please briefly summarize what participating sites will be involved and what their role(s) will be.

Include a detailed description of the study procedures. The recruitment and consent process has already been stated so they should not be included here. If different groups of participants will be doing different things, for example intervention and control group, state what each group will be doing in a separate paragraph. If there are different phases of the study, they should be clearly labeled. If participants will be randomized, state the randomization procedure and the odds of being assigned to each group.

If this is a multi-site study and the University of Arizona IRB will be the IRB of record, include what research procedures will be conducted at each site. If no research procedures will be conducted at a site, state the role of that participating site.

9.3 Specify the total estimated time commitment for subject participation, and the estimated time commitment for each activity.

The estimated time commitment should be stated. If this is a longitudinal study, state the total time commitment, for example 300 hours over 4 months. Then it should be broken down, for example 1 hour for baseline data collection, 30 minutes daily for the intervention activity (specify the activity) for 8 weeks, 30 minutes for time 2 data collection, 20 minutes daily for the intervention activity (specify the activity) for 4 weeks, 30 minutes for time 3 data collection, and 1 hour for time 4 data collection. There should be agreement between what is stated in recruitment material, the consent document, study procedures and what is stated here.

9.4 If any biological specimens (blood, urine, tissue, etc.) are being collected for research, state the amount (ml/tsps./tbsp, etc.), method, frequency, and type of specimen to be collected and what the specimen will be used for.

If no biological specimens will be collected, state this or state Not applicable.
If biological specimens will be collected, state the type of specimen to be collected, method of specimen collection, amount to be collected, frequency of collection, and what the specimen will be used for. I recommend stating if the specimen will be used up in the analysis. If there will be any left after analysis, include what will happen to it, for example if it will be discarded, kept for additional analysis, or for future research. This should also be stated in the consent document.

9.5 If the study is a clinical trial, confirm registration with https://clinicaltrials.gov/ has been completed:

This study is not a clinical trial: ☐
Registration complete: ☐
Registration pending: ☐

b) If the Principal Investigator (PI) does not possess a medical license, describe the scope and nature of the PI's previous clinical trial experience, including other studies they have led or participated in as Co-Investigator. If applicable, describe the previous clinical trial experience for the appointed Responsible Physician.

Note: Completion of the Collaborative Institutional Training Initiative (CITI) course on Good Clinical Practice for Clinical Trials involving Investigational Drugs and Medical Devices is mandatory for non-MD/DO PIs overseeing clinical trials.
In addition, all research coordinators listed on protocols overseen by non-MD/DOs supervising clinical trials must complete the *Clinical Research Coordinator* CITI training course. The HSPP will confirm completion of this training for all members of the study team that will be directly involved with research participants.

If this is not a clinical trial, state Not applicable. If this is a clinical trial, describe your previous clinical trial experience as PI or Co-Investigator. If a Responsible Physician is included as a study team member, describe their previous clinical trial experience. Please note the additional training requirements for study personnel.

10.0 Potential Benefits to Subjects:

10.1 Describe the anticipated benefits of this study to society, academic knowledge, or both.

The broader benefits to society, the discipline, or both should be stated. The broader benefits stated here should also be stated in the consent document.

10.2 Describe any benefits that individuals may reasonably expect from participation (not including compensation, which cannot be considered a benefit of participation).

If there are no direct benefits, state this. If there are direct benefits, state them. The benefits stated here should also be stated in the consent document.

11.0 Risks to Subjects:

11.1 Describe all physical, psychological, social, legal, and/or economic risks that could be associated with participation in this research.
Risks not directly related to the research need not be included in this section. However, nearly all human research has some minimal level of risk, such as a loss of confidentiality when identifiable data is collected.

If there are risks, state them. If there are no risks, state no risks. As stated in the red text, the risk of loss of confidentiality should be considered. However, if the data will be anonymous and no identifiers will be collected, this may not be a risk. Risks stated here should also be stated in the consent document.

11.2 Discuss what steps will be taken to minimize risks to subjects/data.

For each of the risks listed, state the steps to minimize that risk. Steps to minimize the risks should also be stated in the consent document.
If there are no risks, state no risks.

12.0 Costs, Compensation, and Injury:

12.1 Describe any costs, monetary and non-monetary, that subjects may incur. This includes time.

If there are costs for participation, they should be stated. For example, if participants are asked to come to the College of Nursing for data collection, they may, for example, need to pay for travel to the University but parking will be paid by the study.
For the cost of time, the total time required should be stated. There should be agreement between what is stated in recruitment material, the consent document, and what is stated here.

12.2 Discuss the amount of compensation (monetary and/or non-monetary) subjects may receive. Describe if compensation will be prorated.

If there is no compensation, state this or state Not applicable.
If compensation is offered, the amount of compensation should be stated. If compensation is offered for completion of each part of the study, for example $10 for each data collection completed, this should be stated. The amount of compensation should be fair for the time and effort required, but not excessive. There should be

agreement between what is stated in recruitment material, the consent document, and what is stated here.

13.0 Privacy of Subjects and Confidentiality of Data:

13.1 Describe steps, if any, to protect the privacy of the subjects throughout their participation (e.g., during the recruitment process, consent process, and/or research procedures).

This may include, for example, where recruitment, consenting and data collection will take place. This should be in a private setting without distraction. Confidentiality of data may be addressed here as well.

13.2 Will data be kept for future research, including unspecified future research and genetics?

Yes ☐ No☐

If data will be kept for future research, this should be stated in the consent document. If data will not be kept for future research, this should be stated in the consent document. There should be agreement in the statements across documents.

13.3 If yes to the above question, describe future use plans here, including unspecified research, any storage in a repository (if applicable), and what data will be retained/reused.

If data will not be kept for future research, state this or state Not applicable. If data will not be kept for future research, this should be stated in the consent document.
If data will be kept for future research, describe plans for future use. This should also be stated in the consent document. There should be agreement in the statements across documents.
If data will be stored in a repository, state this and if the data and/or specimens stored will be identifiable or de-identified. Include the name of the repository if the name of the repository is known.

13.4 Discuss how study results will be shared with subjects, families, and/or the institution, both immediately and long-term.

If data will not be shared with participants, state this or state Not applicable.
If results will be shared with participants, state what will be shared and how it will be shared. Generally, results are not shared with participants. If they are, generally this is in aggregate form. There may be instances where data will be shared with participants. This should be clearly stated and should also be stated in the consent document.

13.5 Indicate if the research team will be accessing any of the following records.

☐ Substance abuse records (HIPAA and 42 CFR Part 2)
☐ Medical records (HIPAA)
☐ Educational records (FERPA)*
☐ Employee records (ABOR Policy 6-912)*
☐ Other, specify:

***Access to information from a University of Arizona employee record or FERPA information requires the written permission of the participants.**

13.6 For each record source selected above, list the data elements to be accessed, who will access them, and how the information will be obtained.

If none will be accessed, state Not applicable.
If any will be accessed, state the specific data elements that will be obtained; who will obtain the information from the records, for example someone from the study or will the information be supplied by someone else; and how the information will be obtained. It should be clearly stated what identifiers will be included. If the identifiers are not needed, they should not be obtained.

13.7 Indicate where data will be stored:

☐ Box@UA	☐ OnCore
☐ Box@UA Health	☐ PACS medical imaging software
☐ Clinical Data Warehouse (CDW)	☐ Password Protected Drive
☐ Cloud Server	☐ REDCap
☐ Department Drive	☐ Transmitting/receiving subject data to/from an outside group
☐ Department Office	☐ UA Records Management & Archives
☐ Encrypted Drive	☐ Banner Server/Platform, specify:
☐ External Drive (hard drive, USB, disk)	☐Soteria
☐ Google Suite for Education	
☐HIPAA Research Computing Service	☐Other, specify:

13.8 For EACH of the storage locations checked above, discuss the type of data to be stored, including if the data will be identifiable, coded, or de-identified upon storage.

If data will be coded, specify who will maintain the code, where it will be stored, and when it will be destroyed. If data will be de-identified, explain if there is any possibility that the data could be re-identified.

Definitions:

- **Identifiable: The identity of the subject is or may be readily ascertained.**
- **Coded: Data are separated from personal identifiers through use of a code. As long as a link to identifiers exists, data is considered identifiable and not de-identified.**
- **De-identified: A record in which all identifying information is removed.**

This asks for multiple pieces of information. First it asks the type of data to be stored, including if data will be identifiable, coded, or de-identified upon storage. If only anonymous surveys are being collected and stored in Box@UA, this should be stated. If coded questionnaires (link between a study number and identifying information) and/or coded specimens are being collected, with questionnaire data stored in Box@UA Health and specimens stored in the Biological Laboratory, this should be stated. If data will be coded, include who will maintain the code, where it will be stored and when it will be destroyed. It is best that the list is destroyed at the conclusion of the study. If data will be de-identified, explain if there is any possibility the data could be re-identified.
If the study includes audio and/or video recorded interviews/focus groups, include that the recordings will be deleted once transcription is complete and the transcripts have been checked for accuracy. This should also be stated in the consent document. If there is a reason to retain the recordings after transcription, this will need to be justified.

13.9 If collecting biological specimens, please describe the storage location for the specimens, including if they will be identifiable, coded, or de-identified upon storage.

If biological specimens will not be collected, state this or state Not applicable.
If biological specimens will be collected, state the type of specimens that will be collected, where they will be stored, and if they will be identifiable, coded, or de-identified upon storage.

13.10 Storage of research records (research records should be maintained for whichever of the following time periods is the longest, select one):

☐ I will store research records for at least 6 years past the time the study is concluded.
☐ For studies involving minors, I will store research records for at least 6 years after the youngest participant turns 18.
☐ I will store research records for the length of time required by law or study sponsor, please specify:

13.11 Describe what security controls (e.g., administrative, physical, technical) are in place to make sure data/specimens are secure.

This may include secure locations where data/specimens will be stored, encryption of data especially if it will be transmitted to or from an outside group.

13.12 Indicate how data/specimens will be shared with collaborating entities:

☐ Data and/or specimens will not be shared between UA and any outside group or collaborating entity.

☐ Data/or specimens will be transmitted and/or disclosed to an outside group or a collaborating entity.
☐ Data and/or specimens will be received from an outside group or a collaborating entity.
☐ PHI will be transmitted to or received from an outside group or a collaborating entity. *
☐ A Limited Data Set will be transmitted or received from an outside group or a collaborating entity. *
☐ Data/specimens will be sold to pharmaceutical companies.

***If you will be transmitting or receiving any PHI, or a Limited Data Set, as a part of your project, please go to the following link to review the Data Use Agreement (DUA) from the HIPAA Privacy Program.**

Please note: a Data Use Agreement is needed if PHI or a Limited Data Set will be transmitted or received.

13.13 Describe what information will be shared, who it will be shared with, and how it will be shared (e.g., secure file transfer, REDCap, etc.). Also include information about future use sharing and repositories. Specify if the shared data will be identifiable, coded, a limited data set, or de-identified.

If data will not be shared with an outside group or collaborating entity, state Not applicable. If data will be shared, include a description of the data that will be shared; if the data shared will be identifiable, coded or de-identified; who it will be shared with; and how it will be shared, for example, if it will be in a central location with all having access to it or encrypted and sent. If any identifiable information will be shared, this should be clearly stated. If a transcription service is being used to transcribe interviews or focus group data, include the name of the transcription service. Also include information about future use sharing and repositories.

14.0 Additional Questions (complete as applicable):

If any of the questions are not applicable, state Not applicable.

14.1 Subject Injury: If the research involves more than minimal risk to subjects, describe the provisions for medical care and available compensation in the event of research related injury. If the Human Research has a clinical trial agreement, this language should reflect what is stated in the agreement.

For most projects, this is not applicable. If this does not apply, state Not applicable.

14.2 Withdrawal of Subjects: Discuss how, when, and why subjects may be removed from the study. If abrupt withdrawal is necessary, discuss how subjects will be withdrawn so that they

are not put at increased risk. Discuss what happens if a subject is withdrawn from one part of the study but asked to continue with other parts, such as ongoing follow-up.

This should be addressed. Most of the time participants will not be withdrawn from the study by the PI rather participants will withdraw from the study. If participants will be withdrawn, state why and state if data collected to that point will be retained or deleted. If participants request to be withdrawn from the study, address if data collected to that point will be retained or deleted. This should also be stated in the consent document.

14.3 Monitoring for Subject Safety: Provide a brief lay discussion of your plan to monitor for subject safety. Describe what safety information will be collected, including serious adverse events, how safety information will be collected, and the frequency of collection including a timeline of when the data and review(s) will occur, who will review the information, and the plan for reporting findings.
If there will not be a way to monitor for subject safety, please explain.

There should be a response. It may be restating the risks and steps to minimize risks, but this involves those risks/events that are not anticipated, the adverse events. If there will not be a way to monitor for participant safety, provide an explanation.

14.4 Data Management Plan: Please discuss the data management plan, if required by your funder. For additional resources, reference the HSPP Data Management webpage. If your sponsor/funding agency requires a Data Management Plan, please upload the approved copy in eIRB. This section and the informed consent form should contain all pertinent information including:

- **What data/metadata will be shared (imaging, survey; raw data or derived; protocol, data form; etc.)**
- **What repository will be used (if known)**
- **How will data be stored (in a de-identified or identifiable format)**

If this does not apply, state Not applicable. If the project is funded and the funding agency requires a data management plan, outline the data management plan. Upload a copy of the data management plan in the "Other attachments" section in eIRB.

14.5 International Research: Describe site-specific regulations or customs affecting the research, local scientific and/or ethical review structures that differ, and if community advisory boards are involved. If so, describe their composition and involvement. For research being conducted outside of the US, please explain any local laws, regulations, or customs the IRB needs to be aware of.

Authorization from sites where research will take place is required with the application. Permission to conduct research outside of the country requires review by the UA Travel Registry.

If this does not apply, state Not applicable. If the study is international, this needs to be fully addressed.

Additional items needed for review:

- Word version of applicable subject material: Consent document(s), PHI Authorization Form(s), Recruitment Material, Data Collection Material, Participant Material
- Appendix for Alteration/Waiver of Consent or PHI, if using a Disclosure form
- Current PI CVs or biosketch
- Advisor approval (Advisor Attestation if the PI is a student or medical resident)
- Department/Center/Section Review approval
- Scientific/Scholarly review approval
- Responsible physician approval and CV (if the PI is conducting medical procedures for which he/she is not clinically certified to perform)
- Additional approvals, as needed (e.g., RAP/Banner feasibility, Export Control, Radiation, COI, CATS, Cancer Center SRC, school district approval, tribal approval, etc.)
- The appropriate appendices if children, pregnant women, neonates, prisoners, cognitively impaired individuals, or Native Americans or Indigenous Populations will be enrolled

Other items as applicable:

- HSPP Appendices
- Data Monitoring Plan or Data Management Plan
- Drug/Device information
    - Applicable Drug or Device Appendix
    - Investigator's Brochure, drug product sheet, device manual, user's manual, instructions for use, package insert, IND/IDE documentation, FDA 1572 form, 510k indication, FDA exemption, sponsor determination of device risk, etc.
- Sponsor Protocol and MOPs that are used in the study