

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 is no request for clarification, no request for revisions thus facilitating approval of the project. Requests for clarification only slow the process.

NOTE: This is for the IRB Protocol form version v2023-12. 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. If you are using a more recent version of the form, some of this may not apply or additional information may be requested.

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

- The short title is required when submitting to the University of Arizona IRB through the eIRB system. 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. I generally do not check the word count unless it is pages long. I have not seen the IRB request anyone shorten this because it exceeded the word count. If this is copied and pasted from another document and there are reference numbers included, I generally ask that the numbers be removed unless the reference list is included.

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.

Again, 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. If only specific aims, hypotheses, and/or research questions are included, I will ask that the purpose statement be added. The research procedures should address the purpose and specific aims. If they do not, I generally question this.

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 most student 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. Here is a suggestion, if self-funded you can check ‘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 need special software to analyze the data, this should be included. If you are collecting biological samples and need access to a facility to store and analyze the samples, this should 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:

<input type="checkbox"/> Healthy adults	<input type="checkbox"/> Non-English-speaking subjects
<input type="checkbox"/> Non-healthy adults	<input type="checkbox"/> UA staff/faculty

<input type="checkbox"/> Children (under 18 years old) *	<input type="checkbox"/> UA students
<input type="checkbox"/> Pregnant women, neonates, and/or fetuses*	<input type="checkbox"/> Banner employees
<input type="checkbox"/> Prisoners*	<input type="checkbox"/> Refugees
<input type="checkbox"/> Native Americans, Alaskan Native, and Indigenous Populations*	<input type="checkbox"/> Other – please explain:
<input type="checkbox"/> 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, then 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 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. It is not acceptable to state ‘until data saturation’ for qualitative studies. 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 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 anticipated/stated but not always fine to have more.

7.0 Recruitment Methods:

7.1 Select the methods used to recruit individuals.

<input type="checkbox"/> Email	<input type="checkbox"/> Screening of the Electronic Medical Record (EMR)
<input type="checkbox"/> Face to face	<input type="checkbox"/> Social media
<input type="checkbox"/> Flyers	<input type="checkbox"/> SONA System

<input type="checkbox"/> In person presentations	<input type="checkbox"/> TV, Radio, Print
<input type="checkbox"/> Online advertisements	<input type="checkbox"/> Other – please explain:
<input type="checkbox"/> 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 include 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. A copy of all recruitment material should be included. If potential participants will be screened, a copy of the screening questions should be included and state if screening information will be retained. If the 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. Subjects can be contacted via snowball method of recruitment in which potential participants agree to have their name forwarded to a researcher.

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.

8.0 Diversity, Equity, and Inclusion

8.1 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. Include how you propose to recruit so you can reach your proposed study sample.

8.2 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. 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 they will not be included, state why they will not be included.

8.3 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.

9.0 Consenting Process:

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

Written Consent
<input type="checkbox"/> Informed Consent (ICF) – written or electronically signed form
<input type="checkbox"/> Parental Permission – written or electronically signed form
<input type="checkbox"/> Assent (participants under 18) – written or electronically signed form
<input type="checkbox"/> Combined ICF/PHI Authorization – written or electronically signed form
<input type="checkbox"/> Standalone Protected Health Information (PHI) HIPAA Authorization – written or electronically signed
<input type="checkbox"/> Translated Consent/Assent – written or electronically signed form(s)
<input type="checkbox"/> Short Consent Form – written or electronically signed form (see guidance on Short Form process)
<input type="checkbox"/> 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)
<input type="checkbox"/> Informed Consent – oral script/online/unsigned
<input type="checkbox"/> Parental Permission – oral script/online/unsigned
<input type="checkbox"/> Assent – oral script/online/unsigned
<input type="checkbox"/> Translated Consent/Assent – oral script/online/unsigned

Waivers of Informed Consent and/or PHI Authorization
<input type="checkbox"/> Waiver of Consent
<input type="checkbox"/> Full Waiver of PHI Authorization
<input type="checkbox"/> 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.

A template for a Disclosure form (unsigned consent form) is available on the College of Nursing website.

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

9.2 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. 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 potential participants if they do not speak English and how the translation was verified.

9.3 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, College of Nursing Room 410. Consent documents signed online should be stored in an approved secure location such as REDCap. If using a Disclosure form, you can leave this blank.

9.4 Acknowledgement of consent form storage.

<input type="checkbox"/> I will store original signed consent and/or PHI authorization documents for at least 6 years past the time the study is concluded.
<input type="checkbox"/> 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.
<input type="checkbox"/> Not applicable – I am not collecting signed documents.

10.0 Research and Data Collection Procedures:

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

<input type="checkbox"/> Anthropometric measures (e.g., height, weight, waist circumference, etc.)	<input type="checkbox"/> Participant observation
<input type="checkbox"/> Audio/video recording	<input type="checkbox"/> Screening data
<input type="checkbox"/> Benign interventions	<input type="checkbox"/> Self-health monitoring (e.g., pedometers, food diaries, etc.)
<input type="checkbox"/> Biological specimens – blood draws	<input type="checkbox"/> Surveys – paper
<input type="checkbox"/> Biological specimens – clinically discarded blood or specimens	<input type="checkbox"/> Surveys – internet (including online and email-based data collection)
<input type="checkbox"/> Biological specimens (urine/feces, tissue, saliva, skin, hair, nails, nasal swab)	<input type="checkbox"/> Surveys – telephone
<input type="checkbox"/> Clinical Data Warehouse (CDW)	<input type="checkbox"/> Randomization with control and experimental groups
<input type="checkbox"/> Cognitive or behavioral measures, including daily diaries	<input type="checkbox"/> Records – billing
<input type="checkbox"/> Data collected using other communication/electronic devices (e.g., cell phones, pagers, and texting devices)	<input type="checkbox"/> Records – educational
<input type="checkbox"/> Data previously collected for research purposes	<input type="checkbox"/> Records – employee
<input type="checkbox"/> Deception	<input type="checkbox"/> Records – lab, pathology and/or radiology results
<input type="checkbox"/> Instrumentation, equipment, or software not approved by the FDA	<input type="checkbox"/> Records – mental health
<input type="checkbox"/> Interviews – focus groups	<input type="checkbox"/> Records – substance abuse
<input type="checkbox"/> Interviews – in person	<input type="checkbox"/> Research imaging protocols
<input type="checkbox"/> Interviews – virtual/online	<input type="checkbox"/> Recombinant DNA
<input type="checkbox"/> Medical records review	<input type="checkbox"/> Social networking sites

<input type="checkbox"/> MRI/ultrasound with contrast	<input type="checkbox"/> Stem cells
<input type="checkbox"/> MRI/ultrasound without contrast	<input type="checkbox"/> Radiation Scans (X-Ray, CT Scans, etc.)
<input type="checkbox"/> Non-invasive instruments (e.g., external sensors applied to the body)	<input type="checkbox"/> 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.

If the study involves an investigational drug or device, complete and attach the Appendix for Drugs or the Appendix for Devices. Note: Drugs and devices may be used in research but may not be the purpose of the investigation (e.g., as an adjunct to a standard procedure or test for screening). Information about these drugs or devices must be included in this section so an assessment of risk and safety to subjects can be made. eIRB tip: under the “Study Scope” section in eIRB, if you are investigating drugs, biologics, food and dietary supplements, mark Question 1 “Does the study specify the use of an approved drug or biologic..?” as YES to ensure the appropriate Smart Form populates.

10.2 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 the 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 the study is longitudinal with multiple data collection periods, included how data for each participant will be matched.

If 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.

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

This should be stated. If this is a longitudinal study, state the total time commitment, for example 8 hours over 4 months. Then it should be broken down, for example 1 hour for baseline data collection, 30 minutes each week for 8 weeks, 30 minutes for time 2 data collection, 20 minutes each week 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.

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

If no biological samples are being collected, you can leave this blank.

If biological samples will be collected, state the amount, frequency, type of specimen, and what the specimen will be used for. I recommend stating if the sample will be used up in the analysis, if there will be any sample left after analysis, and what will happen to any sample that is left. Include if it will be discarded or kept for additional analysis. This should also be stated in the consent document.

10.5 If the study is a [clinical trial](https://clinicaltrials.gov/), confirm registration with <https://clinicaltrials.gov/> has been completed:

This study is not a clinical trial:

Registration complete:

Registration pending:

11.0 Potential Benefits to Subjects:

11.1 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. What is stated here should agree with what is stated in the consent document.

11.2 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, this should be stated. If there are direct benefits, state them. What is stated here should agree with what is stated in the consent document.

12.0 Risks to Subjects:

12.1 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 are anonymous and no identifiers are being collected, this may not be a risk. Risks stated here should agree with what is stated in the consent document.

12.2 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.

13.0 Costs, Compensation, and Injury:

13.1 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.

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

If compensation is offered, the amount of the compensation should be stated. If compensation is offered for completion of each part of the study, for example \$10 for completion of each survey, 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.

14.0 Privacy of Subjects and Confidentiality of Data:

14.1 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.

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

Yes No

If data or specimens 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.

14.3 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 or specimens 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 stored will be identifiable or de-identified. Include the name of the repository if the name of the repository is known.

If data will not be kept for future research, this can be left blank.

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

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.

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

<input type="checkbox"/> Substance abuse records (HIPAA and 42 CFR Part 2)
<input type="checkbox"/> Medical records (HIPAA)
<input type="checkbox"/> Educational records (FERPA)*
<input type="checkbox"/> Employee records (ABOR Policy 6-912)*
<input type="checkbox"/> Other, specify:

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

If none of these are being accessed, it is fine that none are checked. Nothing additional needs to be stated.

14.6 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 are being accessed, this can be left blank. 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, minimum necessary.

14.7 Indicate where data will be stored:

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

14.8 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 is 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 the study includes 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.

It also asks who may have access to the data. Many times, this is not included. If everyone on the study team will have access to the data, this should be stated. If only the PI and the Advisor/Co-I will have access to the data, this should be stated.

It asks how long data will be kept. University of Arizona policy is that data be kept for at least 6 years after the conclusion of the study or if the study involves children, at least 6 years after the youngest child reaches age 18. If data will be kept for future research, this should be stated.

14.9 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 specimens will be collected, state the type of specimen that will be collected, where it will be stored, and if it will be coded, or de-identified upon storage. For example, if coded blood samples will be collected and stored in the Biological Laboratory, this should be stated.

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

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

14.11 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 will be stored, encryption of data especially if it will be transmitted to or from an outside group.

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

<input type="checkbox"/> Data and/or specimens will not be shared between UA and any outside group or collaborating entity.
<input type="checkbox"/> Data/or specimens will be transmitted and/or disclosed to an outside group or a collaborating entity.

<input type="checkbox"/> Data and/or specimens will be received from an outside group or a collaborating entity.
<input type="checkbox"/> PHI will be transmitted to or received from an outside group or a collaborating entity. *
<input type="checkbox"/> A Limited Data Set will be transmitted or received from an outside group or a collaborating entity. *
<input type="checkbox"/> 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.**

For most student projects, 'Data and/or specimens will not be shared between UA and any outside group or collaborating entity' will be checked. If a transcription service is being used to transcribe interviews or focus group data, 'Data/or specimens will be transmitted and/or disclosed to an outside group or a collaborating entity' should be checked. If PHI or a Limited Data Set will be transmitted or received, a Data Use Agreement is needed.

14.13 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, this can be left blank. If it 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.

15.0 Additional Questions (complete as applicable):

15.1 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 student projects, this is not applicable and can be left blank.

15.2 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 be stated in the consent document. If the surveys/questionnaires are anonymous, it will not be possible to delete data collected to that point.

15.3 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 were not anticipated, the adverse events. If this is an anonymous, online survey, there may be no way to monitor participant safety. If so, that should be stated.

15.4 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)**

For most student projects, this can be left blank. If the project is funded and the funding agency required a data management plan, outline the data management plan and upload a copy of the data management plan in the "Other Attachments" section in eIRB.

15.5 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](#).

For most projects, this can be left blank. If the study is international, this needs to be fully addressed.

Additional items needed for review:

- Word version of applicable subject materials: Consents, PHI Authorization Form(s), Recruitment Materials, Data Collection Materials, Participant Materials
- Appendix for Alteration/Waiver of Consent or PHI, if using a Disclosure form
- Current PI CVs or biosketch
- Advisor approval (if the PI is a student or medical resident)
- Department/Center/Section Review approval
- [Scientific/Scholarly review](#) approval
- Responsible physician approval (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