Penn
University of Pennsylvania
Human Research Protections Program

Social-Behavioral Research Submission Completion Guidance

What does the IRB look for when reviewing a submission? The following includes the standard completeness checks that administrators will assess about your social-behavioral study prior to exempting, approving, or sending it to a Board or delegated member reviewer. Please review the below information when creating the initial submission in order to ensure that your application is complete prior to submission. ***This can reduce the number of stipulations and questions posed.***

Contents

HS-ERA Application

Basic Info Page

- Protocol Title: Confirm that the full study title in HS-ERA matches the full title in the informed consent form. *Note that most social-behavioral research studies do not require submission of a standalone protocol document unless you think your study may present greater than minimal risk of harm.* If you include a standalone protocol document, the title should match the HS-ERA application and consent form. The IRB must have an accurate study title in the system for reporting purposes.
- Brief description of the protocol: Please provide a brief abstract about the study. *If a standalone protocol exists, you may **not** reference the protocol in this section.*

- Hospital Sites: This section applies to research occurring at Penn Medicine-affiliated hospital sites. If you are not conducting research at a Penn Medicine site, answer "no." If you are conducting research at a Penn Medicine site, answer "yes" and select the applicable site(s). Please confirm that the hospital sites question is answered correctly. This question is important for compliance with PA Department of Health requirements and informs about satellite hospital review requirements.

Personnel Page

- Principal Investigator:
  - For *greater than minimal risk research*: Confirm that the Principal Investigator is a member of Penn faculty. It is Penn policy that the PI must be a member of Penn faculty for greater than minimal risk research.
  - For *minimal risk research*: Confirm that the Principal Investigator is Penn Faculty, or a Penn employed staff member. *Students are not permitted to be listed as the Principal Investigator*. This is to ensure oversight over the research and that access to the protocol will always be available in case a student or an unaffiliated individual moves prior to completion of the protocol.
- Responsible Org: Ensure the responsible org is accurate. This ensures that your research is directed to the correct department chair. ***If this section shows 2100 for the health system, it must be changed as this org has no designated department chair.*** Please contact your administration or business administrator for guidance if you're unsure what to select.
- Disclosure of Significant Financial Interests/ Penn Intellectual Property: Are there any conflicts of interest or Intellectual Property (IP) to be reported? ***If a Conflict of Interest or IP is reported, the IRB will not issue approval until we receive notice from CISC that the protocol may be approved.*** Please ensure your disclosures are submitted to avoid approval delays. Please see https://research.upenn.edu/compliance-and-training/research-integrity for guidance.
- General:
  - Confirm all study team members completed the Human Subjects' Research curriculum in CITI. If some are reflected as having incomplete training, contact them for a copy of their CITI Completion Report to upload in HSERA. You will upload the report on the last page of the application, under the "Additional Documents" field. If they have not completed their training, you may still submit the application, but they will not be approved to participate until their training is complete.
  - Confirm that the individual creating the application is listed as either Principal Investigator, Co-Investigator or a study contact. If not listed in one of these fields, they will not have edit access to the application post-submission.
  - Confirm that all Penn personnel who are listed in the full protocol and informed consent form also listed in the Personnel Page. ***Anyone personnel who meet***

the DHHS definition for 'engagement in research' must be listed on the Personnel Page in HSERA. This includes *anyone with access to identifiable information, anyone consenting participants, and anyone who is intervening or interacting with participants as part of the research protocol.* If you're unsure if someone is engaged in human subjects research, please refer to the Engagement in Research Determination Form for guidance.

- If there are non-Penn personnel engaged in research on the protocol, they should seek IRB approval from their institution of affiliation. If the individual(s) are unaffiliated with an institution or the institution does not have an IRB, please refer to our guidance on Collaborative Research with External Individual Investigators. Please highlight their participation in your cover letter and include copies of their CITI completion reports and signed copies of their individual investigator agreements.

Bio /HRPP Page OR Soc Page

If you are submitting a protocol under one of the exempt categories, you will have to complete the Bio/HRPP page in HS-ERA. Questions on this page are associated with institutional approvals and other federal, state or institutional requirements. This page also sends notifications to ancillary committees and other groups to inform them of your research.

In most cases, you will answer "no" or "not applicable" to most questions on the Bio/HRPP page if you are conducting social-behavioral research. However, a few questions may apply to your protocol. These include:

- Clinical Trial: Carefully review the NIH definition of a clinical trial embedded within the question and confirm the response is answered correctly. IRB staff will assess whether this is answered correctly and whether additional requirements apply. Guidance is available here.
- Cancer Related research not being conducted by an NCI cooperative group: Does this protocol involve cancer-related studies of any of the categories listed in HS-ERA? If Yes: This study will require review by CTSRMC. Please either include the CTSRMC letter of approval and any required changes or confirmation that CTSRMC review is underway in the response submission after IRB review. A reminder of this will be included in the determination letter.
- Medical Information Disclosure: Does your study involve the collection of protected health information (PHI) from the medical record or directly from the participant? Does your study involved the generation/creation of research data under a covered entity such as Penn Medicine or Penn Dental? If yes to any of these questions, HIPAA applies. Answer Yes and reflect your plan for HIPAA authorization.
- Out of State Research: If research activities are occurring at Penn Medicine sites in New Jersey, the IRB needs to assess applicable state laws.

- Primary Focus: If you are conducing survey research, answer "survey." If you are using other methods such as participant observation, interviews, focus groups, or content analysis, answer "sociobehavioral."
- Protocol Interventions: If your study is interventional/experimental, please answer "sociobehavioral" or "survey instrument" depending on your methods. If your work is not interventional/experimental, please answer "none of the above."

If you are submitting a protocol for expedited or full board review, you will see the Soc page rather than the Bio/HRPP page. Some questions on this page are the same as the Bio/HRPP page, and the above instructions apply. However, additional questions on this page are focused on your research methods and data collection instruments.

- Study Instruments: Discuss the particulars of the research instruments, questionnaires, or other evaluation instruments in detail. If you are using validated instruments/scales, please list them and note their format (e.g., how participants will receive, complete, and return them). If you are using more novel are new instruments, please describe their purpose and content. For semi- or unstructured interviews and focus groups, list your topics/phenomena of interest. Be sure to note where your data collection will take place and whether you will audio/video record any interactions, including participant observations. *Please be sure to attach any non-validated data collection instruments, including interview and focus group guides or lists of topics, to the last page of the application*.
- Group Modifications: Will participants be randomly assigned to different intervention, experimental, or treatment groups? If yes, please describe the conditions for each group. Are you using different methods and/or data collection instruments for different populations or sub-groups involved in your research? If yes, please describe these differences. If your methods and procedures are consistent among all participants, you may answer "N/A" to this section.
- Method for Assigning Subjects to Groups: If your research involves randomization, please describe *how* participants will be randomized. If randomization is not involved, you may answer "N/A" to this section.
- Administration of Surveys and/or Processes: For methods such as survey distribution, interviews, focus groups, and participant observations, please describe where and for how long each method will take place. Discuss who will oversee periods of data collection, especially if your research involves populations who may be vulnerable to undue influence like children (note that your answer may simply be "the research team" depending on your specific study and its risk level). If you are reviewing records/content that includes identifiable private information like social media data or classroom records data, please describe where and how you will access information, what identifiers you will collect and retain after retrieval, and how long you will keep those identifiers. Note that if you will keep identifiers for an extended period of time or if you do not intend to destroy them, you should justify your retention plan.

- Data Management: How will you de-identify your data? Where will you store data, including both identifiable and de-identified data? When will you delete identifiers? Will any identifiable data be shared outside the research team? If so, who will may receive these data? Please answer these questions in this section.

Sponsor Page
Questions on this page are reflective of regulatory sponsorship (oversight) and funding.

- Business Administrator: Confirm that the business administrator (internal financial contact) is identified. This is important for discussions regarding any potential IRB billing concerns. *Billing concerns typically only apply to studies that are industry-funded and/or single IRB studies where Penn will serve as the IRB of Record for other sites.*
- Department budget code: Please include your budget code *if the study is industry funded or a single IRB study where Penn is the IRB of Record*. This is used for billing IRB fees. This information should be included at the initial submission, whether the contract is pending or not. As of May 2021, if the IRB billing office is unable to secure a budget code for the charges from the department within two months from the date of billing, they will automatically charge the department's 01XX01 Fund. It will then be the responsibility of the department to reallocate the charges to the correct sponsor project fund.
- Funding Sponsor: Please ensure this section lists the entity funding the research, if applicable.
- Regulatory Sponsor: This applies to FDA-regulated studies rather than social-behavioral research. You may leave it blank.
- IND Sponsor: This applies to FDA-regulated studies rather than social-behavioral research. You may leave it blank.
- Industry Sponsor: If the funding sponsor is not selectable under Funding Sponsor, please add them here for billing purposes. *If you cannot add your funding sponsor*, please select "pending" at the bottom of the page and attach a copy of your grant application (**your grant application should be attached regardless)**. Please include a cover letter that notes that your study is funded and identifies the sponsor.

Centers Page
Questions on this page are to reflect when Penn is the lead of a multicenter study and/or when Penn IRB is the IRB of Record for Multiple sites (i.e., Penn IRB is the sIRB). If Penn will serve as the IRB of Record, please ensure site information for all known relying sites is included in this section. *Please note that Penn cannot serve as the IRB for record for exempted studies*. If you are submitting a protocol for exempt review, all sites should obtain separate approval/exemption for the project.

Protocol Page
The HS-ERA application describes what should be included in each section. Please be sure to provide information that is detailed, but written in plain language. We are

interested in the who, what, when, where, why, and how of your work rather than the methodological tradition to which you subscribe. Tips for certain sections include:

- Primary (and secondary) outcome variables: If you are not conducting experimental research, you may list your research questions/phenomena of interest or you may write "N/A."
- Background: This should be a succinct literature review. Please include enough information to communicate the stakes of your project and why you will conduct it. It is not necessary to copy/paste an extensive literature review from something like a grant application or dissertation proposal.
- Study Design: The "Phase" question likely does not apply to your research (note that the "Phase" question may not appear in an exempt application). Please include *detailed* information about your methods including when, where, and how you will conduct them. Methods like participant observation need as much, if not more, explanation as methods like survey research.

Questions on the Protocol Page will be checked for consistency with a standalone protocol (if applicable) and other documents submitted.

Generally, *if a standalone protocol exists*, references may be made on this page to relevant sections of the approved protocol (e.g., Section 5.1). References should **not** be made to protocol page numbers because they change more frequently with protocol amendments. However, there are some sections where referencing the protocol is not permitted.

- Abstract: May NOT refer to the protocol, as basic information must be contained in the application for documentation purposes, and the review of subsequent submissions without an attached protocol.
- Overall Objectives: May NOT refer to the protocol, as basic information must be contained in the application for documentation purposes, and the review of subsequent submissions without an attached protocol.
- Study Duration: Confirm that the response or reference to protocol includes both 1) the expected duration of a subject's participation (from consenting to completion) as well as 2) the expected duration of the study overall (from approval to closure) is included in the Study Duration section.
- Resources Necessary for human research protection: May NOT refer to a protocol for multicenter research as this requires a local assessment. It is a criterion for approval that the local study team have adequate resources to conduct the study to ensure the safety, rights, and welfare of participants are upheld. Confirm that you have outlined the following:
  a. Briefly describe research staff qualifications and justify that the staff are adequate in number and qualifications to conduct the research and ensure the protection of participants.

b. Describe how you will ensure that all staff assisting with the research are adequately informed about the protocol and their research related duties. Describe plans for site initiation training as well as training if the protocol is amended.

c. As applicable to the research, please describe the facilities available for use in the research.

Populations Page

The HS-ERA application describes what should be included in each section. Please be sure to provide information that is detailed, but written in plain language. When answering questions about recruitment, please explain how you will access contact information prior to using a method like email or direct messaging.

Questions on the Populations Page will be checked for consistency with a standalone protocol (if applicable) and other documents submitted.

Generally, *if a standalone protocol exists*, references may be made on this page to relevant sections of the approved protocol (e.g., Section 5.1). References should **not** be made to protocol page numbers because they change more frequently with protocol amendments. However, there are some sections where referencing the protocol is not permitted.

- Target population: May NOT refer to the protocol, as basic information must be contained in the application for documentation purposes, and the review of subsequent submissions without an attached protocol.
- Subjects enrolled by Penn Researchers: Confirm that this reflects the number of participants prospectively consented; or for secondary research (e.g., chart review, social media analysis), confirm that it reflects the total number of records reviewed.
- Key Inclusion Criteria/ Key Exclusion Criteria: Confirm that the selection criteria have appropriate rationale for their inclusion. Research should not be the sole burden of specific groups of people, and groups should not be excluded without appropriate scientific or safety rationale.
- Vulnerable Populations:
    - **The pregnant person option only applies if your methods may affect the condition of the pregnant person and/or their fetus**. Most social-behavioral research will not affect a pregnancy. Exceptions may include certain types of interventional work that involve physical activity or medical tests. *Pregnant people should not be excluded only because they are pregnant*, especially within studies where the pregnancy is irrelevant.
        - If you will include pregnant people and your methods may affect the pregnant person or their fetus: Please complete and upload a Subpart B form to the

submission. **This form is not required if the study involves secondary data use.**

- Will prisoners be targeted for enrollment?
  - Yes: Please complete and upload a Subpart C form to the submission.
- Will children be targeted for prospective study enrollment? If yes:
  - Please complete and upload a Subpart D form to the submission. **This form is not required if the study involves secondary data use. The form is also not required if you are applying under exempt category 1 (for research in established educational settings**.
  - Please ensure that a parental permission form (if parental permission is not waived) and (if appropriate for the children's age range) assent form are included with the application.

- Populations vulnerable to undue influence or coercion: Please confirm that you have identified any other vulnerable populations that may be targeted for enrollment on the study such as:
  - Penn students or employees,
  - Decisionally impaired individuals,
  - Members of historically marginalized racial or ethnic communities,
  - Members of other historically marginalized groups, such as LGBTQ+ people,
  - Members of the Armed Forces and veterans,
  - Refugees, undocumented immigrants, etc.,
  - Educationally disadvantaged persons,
  - Economically disadvantaged persons,
  - Homeless persons,
  - Institutionalized individuals,
  - Individuals with disabilities,
  - Individuals with mental illness and/or substance use disorders

  The above list may not be exhaustive. Some of these populations may not be considered "vulnerable" within the context of your study. If any other vulnerable populations may be targeted for enrollment, please describe your plans for ensuring enrollment on the study will be free from undue influence.
- Subject Recruitment: A plan should be provided for any studies where there is prospective enrollment of participants. This section may NOT refer to a protocol for

multicenter research. A local recruitment plan is required if recruitment is occurring locally, and the protocol is written by an industry sponsor or another site. *Especially if your study involves the collection of protected health information (PHI)*, please ensure that the recruitment plan aligns with the IRB Guidance entitled, Recruiting Human Research Subjects: Guidance and Requirements.

- Recruitment Materials: Please ensure that the recruitment materials (advertisements, brochures, letters, broadcast materials, etc.) are uploaded and align with the IRB Guidance entitled, Recruiting Human Research Subjects: Guidance and Requirements (linked above). If your materials are not yet completed at time of initial submission (e.g., you want to recruit via flyers but haven't drafted them yet), please note that accordingly in the cover letter. As a reminder, the recruitment materials still cannot be used until submitted to and approved by the IRB.
- Compensation: If applicable to the study:
  - Confirm that you have included the amount, whether compensation will be prorated, the method of compensation and whether social security number is required for payment (e.g., for ClinCards).
  - Confirm HSERA aligns with the consent form.
  - If social security is required for payment, please ensure this is also stated in the consent and include IRS reporting template language, which can be found within our consent templates.

Procedures Page

The HS-ERA application describes what should be included in each section. Please be sure to provide information that is detailed, but written in plain language. We are interested in the who, what, when, where, why, and how of your work rather than the methodological tradition to which you subscribe. Tips for certain sections include:

- Procedures: Research procedures should be detailed. Think of this section like a study timeline, starting with recruitment and ending with any follow-up.
- Analysis Plan: The instructions imply that we are only interest in statistical analysis. This is not the case. Please include a brief explanation of your quantitative, qualitative, or critical/interpretive methods. Note any analysis software you may use (e.g., NVivo, SPSS).
- Subject Confidentiality: How will you de-identify data? Where will you store data? When will you delete identifiers, including any recordings made for the research? This section may NOT refer to a protocol for multicenter research. Confirm that a local plan to protect data confidentiality is detailed if the protocol is written by an industry sponsor or another site. *Especially if your study involves collection for protected health information (PHI)*: please ensure that the confidentiality plan aligns with the IRB Guidance entitled IRB & Penn Medicine Requirements regarding HIPAA PHI Security and Storage.

- Subject Privacy: This section does not refer to HIPAA privacy. *Privacy refers to the subject's ability to control access to their person/body*. Examples include consenting the subject in a private room, enabling features on platforms like Zoom for privacy during interviews, plans for referring confidentiality procedures with focus group participants, etc.
- Data Disclosure: This section may NOT refer to a protocol for multicenter research if the protocol is written by an industry sponsor or another site, as it should discuss sharing of data and specimens *outside of the research team*. Describe disclosures of participant data to any external entities, regardless of level of identifiability. *Confirm an agreement or contract will be executed prior to sharing data and / or specimens*.
- Protected Health Information: This section can be a misnomer for social-behavioral research that does not contain PHI. Please check the boxes next to the categories of information that you will collect.

Questions on the Procedures Page will be checked for consistency with a standalone protocol (if applicable) and other documents submitted.

Generally, i*f a standalone protocol exists*, references may be made on this page to relevant sections of the approved protocol (e.g., Section 5.1). References should **not** be made to protocol page numbers because they change more frequently with protocol amendments. However, there are some sections where referencing the protocol is not permitted.

Note that you will likely answer "No" or "N/A" to biomedically-related questions such as those about tissue samples and genetic testing.

Consent Page
Questions on the Consent Page will be checked for consistency with a standalone protocol (if applicable) and other documents submitted.

Generally, if a standalone protocol exists, references may be made on this page to relevant sections of the approved protocol (e.g., Section 5.1). References should **not** be made to protocol page numbers because they change more frequently with protocol amendments.

- Consent Process, Overview: If you are obtaining prospective consent, confirm HSERA or the referenced protocol describes the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects during the consent discussion, and the method of obtaining consent. Note that you must obtain documented consent (a consent signature) for greater than minimal risk research. For minimal risk research, you may waive documented consent in favor of verbal or electronic consent. *If you are completing an application for exemption,* please note why waiving documentation of

consent is appropriate for your study. *If you are completing an expedited or full application*, please be sure to complete the Waiver of Consent section.

- Children and Adolescents: If you've checked that you are including children on the Populations page, confirm you have covered the following in HSERA or the referenced protocol:
  - Obtaining permission from one or both parents/legal guardian(s) OR waiving consent if your research is a) minimal risk and b) it is not feasible to obtain parent/guardian permission;
  - Obtaining assent from the child based on age/competency. It is generally considered that children aged 7-9 and older are competent to assent; and
  - Any need to re-consent children at age 18 (if long-term participation applies).
- Adult Subjects Not Competent to Give Consent: If you are including participants who may be decisionally impaired, complete the Research Involving Cognitively Impaired Adults Supplemental Form.
- Waiver of Consent:
  - If you are requesting a full waiver of informed consent, confirm you have selected *Waiver or alteration of required elements of consent* and provide rationale for waiving informed consent.
  - If you are requesting a waiver of documentation of consent for verbal or electronic consent processes, confirm you have selected either of the following, as applicable:
    - *Waiver of written documentation of informed consent: the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality.*
    - *Waiver of written documentation of informed consent: the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context*

Risk Benefit Page

Questions on the Risk Benefit Page will be checked for consistency with a standalone protocol (if applicable) and other documents submitted.

Generally, if a standalone protocol exists, references may be made on this page to relevant sections of the approved protocol (e.g., Section 5.1). References should **not** be made to protocol page numbers because they change more frequently with protocol amendments. However, there are some sections where referencing the protocol is not permitted.

- Potential Study Risks: This section may NOT refer to a protocol or a consent form for documentation purposes, and the review of subsequent submissions without an attached protocol. Confirm that the study risks are outlined in this section. It is recommended that this be copied and pasted from the consent form. It should be kept updated with subsequent modifications. For most, but not all, social-behavioral research, the primary risk is breach of confidentiality.
- Potential Study Benefits: This section may NOT refer to a protocol or a consent form for documentation purposes, and the review of subsequent submissions without an attached protocol. Confirm that the potential benefits to participants are outlined in this section. If applicable, note that participants may not directly benefit from your research, but there is prospect of knowledge to be gained.
- Data and Safety Monitoring: If the study is greater than minimal risk, confirm that a Data and Safety Monitoring Plan (DSMP) is outlined in HSERA or the referenced protocol. A DSMP should be designed based on complexity and risk of the protocol.
    - Research that is **minimal risk** usually does not require a DSMP, with most exceptions falling under expedited category 1 involving drugs and devices (note that category 1 is for biomedical research only). For all minimal risk research, there should be clear methods to protect confidentiality and privacy as well as subject safety that are commensurate with the risk.

  For additional guidance, please review the IRB's guidance on Data and Safety Monitoring Plans (DSMP).

Confirmation Page – Document Upload Check
This is where you should upload documents associated with the research study.

Completeness Check	Yes	No	Confirmation
Is the HS-ERA online application meant to serve as the full protocol?	☐	☐	If NO: Confirm a full protocol standalone is uploaded.
Is the study obtaining prospective informed consent?	☐	☐	If YES: ○ ☐ Confirm all study Informed Consent/ Assent/ Parental Permission Forms are uploaded when *consent will be documented.* ○ ☐ Confirm consent script or information sheet is uploaded *if verbal or phone consent is being obtained.* ○ ☐ If the study is being conducted under the Penn Medicine or Penn Dental covered entity, confirm your consent form contains HIPAA Authorization language (*Penn Medicine template authorization is part of the Biomedical Consent Form Template; template Penn Dental authorization language is available on the forms page*)
Are you are requesting a waiver of HIPAA authorization [*for research that involves accessing (using), collecting, and/or disclosing (sharing) protected health information (PHI)*]?	☐	☐	If YES: Confirm you have uploaded the Request for a Waiver of HIPAA Authorization Form. Please note that for the purposes of social-behavioral research, HIPAA applies if you/any members of the research team are affiliated with Penn Medicine or Penn Dental. HIPAA waivers in a social-behavioral context are most often granted to retrospective chart reviews.
Will the study involve any questionnaires, inventories, surveys, diaries, personality tests, quality of life assessments, data collection forms, or interviews?	☒	☐	If YES: ○ If validated and widely recognized/ accepted: confirm the protocol describes their use. ○ If not validated, nor widely recognized/ accepted (i.e., developed for the purposes of the study): confirm they are uploaded. *NOTE: If you have multiple of these types of documents, please consider combining into 1 PDF as opposed to*

Completeness Check	Yes	No	Confirmation
			uploading each document separately to facilitate IRB review.
Will the study involve using recruitment materials (e.g., brochures, flyers, videos, scripts for radio advertisements, etc.)?	☐	☐	If YES: Confirm they are uploaded and align with the IRB Guidance Recruiting Human Research Subjects: Guidance and Requirements.
Will you present any other documentation to participants (participant facing materials)?	☐	☐	If YES: Confirm they are uploaded.
Are you working with a community partner to execute the research?	☐	☐	If YES: ○ Confirm the Community Based Research supplemental form is uploaded. ○ Confirm a letter of support from the site is uploaded.
Is the study funded by any of the following entities: Department of Defense Department of Education Department of Energy Department of Justice Environmental Protection Agency (EPA)	☐	☐	If YES: Confirm the associated supplemental form is uploaded.
Is Penn serving as the IRB of Record for other institutions? Are any non-US sites involved in the research?	☐	☐	If YES: ○ Confirm you have discussed Penn serving as the sIRB with the IRB's Reliance Manager ○ Confirm the Centers page is complete. ○ If the IRB needs to sign an IRB Authorization Agreement, confirm it is uploaded.

Completeness Check	Yes	No	Confirmation
			○ *Penn cannot serve as the IRB of record for international sites*; please upload local site approval.
Review the personnel page. Are any personnel shown as missing CITI training?	☐	☐	If YES: ○ If completed: Obtain their certificate of completion ○ If incomplete: Notify them to complete their training and continue with submission.