How Your New Biomedical Study Will Be Screened

The following includes the standard questions that administrators will ask about your greater-than-minimal-risk, biomedical study prior to sending it to the Board for final review. Please review the below questions when creating the initial submission in order to ensure that your application is complete prior to submission. This can also reduce the number of administrative stipulations and pre-meeting questions to be addressed prior to the meeting.

**HS-ERA Application:**

**Basic Info Tab:**
- Confirm that the study title in HS-ERA matches the title in both the study protocol and the informed consent form.
  - If Unmet: Please revise the title in HS-ERA to match either the full or short title used across study documentation.
- Is the HS-ERA online application meant to serve as the full protocol? If not, is a full protocol uploaded to the application?
  - If Unmet: Please upload the full protocol to the HS-ERA application.
- Does the submission reference or contain a reference for an IRB Authorization Agreement? If so, is it for Penn/CHOP or another type of reliance agreement?
  - If Reliance Agreement is Being Sought: Please reference the “Reliance Agreements” section of the “How to Submit” tab on our website here to include all necessary documentation and considerations.

**Personnel Tab:**
- Is the Principal Investigator a member of Penn faculty?
  - If Unmet: It is Penn policy that the PI must be a member of Penn faculty in order for a research study to be conducted. (This is to ensure that access to the protocol will always be available in case a student or an unaffiliated individual moves prior to completion of the protocol.) Please revise the application to assign a Penn faculty member as the Principal Investigator, being sure to inform them of all necessary duties of the submission (e.g. signing off on all HS-ERA applications prior to submission, etc.).
- Have all study team members completed the human subjects’ research course in CITI Training?
  - If Unmet: Please contact those individuals to receive their completed CITI Training reports of completion and upload those reports to the application.
- Is the research staff member who created the HS-ERA application listed as a Study Contact in the Personnel tab?
  - If Unmet: Only study contacts and the principal investigator can submit applications in HS-ERA for the protocol. Please add the drafter of this submission to the Study Contacts section (if the Principal Investigator is not creating the submission personally) to ensure that all designated individuals can update the protocol as needed.
- Are all personnel who are listed in the full protocol or informed consent form also listed in the Personnel tab?
  - If Unmet: Please revise the Personnel tab to include all individuals who are listed in the protocol/informed consent form & participating in human subjects research. If the person is not affiliated with the University of Pennsylvania and therefore not selectable in HS-ERA, please state that accordingly in the cover letter.
Are there any conflicts of interest reported?

- If a Conflict of Interest is reported: Please note that IRB approval is contingent on CISC review. Please submit a disclosure through FIDES and provide documentation of the CISC management plan. Please also update the informed consent form to note that an investigator on the protocol has a conflict of interest.

Bio Tab:

- Is this an investigator-initiated trial?
  - If Yes: Please be sure to reflect that this is investigator-initiated and click “Yes” to the corresponding question in HS-ERA.

- Are drugs/biologicals/investigational products and/or devices being used?
  - If Yes: Please be sure to reflect the use of such products/devices in the HS-ERA application. Please also include:
    - IND/IDE/exemption letter
    - A plan of how these products/device(s) will be managed (e.g. provided by IDS, etc.)
    - Investigator’s Brochure / Package Insert (as applicable)
    - Device Manual (if device is being used)

- Are research subjects receiving radiation exposure (e.g. X-rays, CTs, etc.) that they would not receive if not enrolled in the protocol?
  - If Yes: This study will require EHRS/RRSC review to review the language & procedures surrounding radiation. If you click yes and submit the protocol via HS-ERA, they will automatically be notified about your protocol. If the ancillary committee requests any revisions to any study documentation prior to approval, please submit a modification including these requested revisions (including tracked and clean copies) to the IRB.

- Does this research involve gene transfer (including vectors) to human subjects?
  - If Yes: This study will require review and approval by the Institutional Biosafety Committee. Please note that IRB approval is contingent upon IBC review, meaning that the IRB will not be able to approve this study until IBC approves it. A reminder of this will be included in the determination letter.

- 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.

- Does the application correctly reflect whether any medical information will be disclosed?
  - If Not: Please revise the HS-ERA application to reflect whether any medical information will be disclosed and, if so, the plan for obtaining HIPAA authorization (typically via a combined informed consent & HIPAA authorization form).

- Does this protocol involve the use of CTRC resources?
  - If Yes: This study will be reviewed by IRB #3. Please also be sure that this information is correctly reflected in the HS-ERA application.

- Are any other responses on the Bio tab incorrect?
If Any Responses in the Bio tab Do Not Appear to Reflect the Procedures Outlined: Please revise this section in the Bio tab to correctly reflect the type of research being conducted. This is important in order to properly notify any ancillary committees that review is needed.

Sponsor Tab:
- Is this study funded by a grant?
  - If Yes: If the study is investigator-initiated and federally funded, please upload a copy of the grant application to the HS-ERA submission. Please also be sure accurately reflect the funding sponsor in the Sponsor tab of HS-ERA. Note that, if the study is funded by the Department of the Navy, it will be reviewed by IRB #3.

- Is the study funded by an industry sponsor?
  - If Yes: Please be sure the sponsor is accurately reflected as the funding and regulatory sponsor in HS-ERA, including the complete address information.

Also, if the study is industry-sponsored, this means that the IRB will check the injury language in the informed consent form to be sure it accurately reflects the agreed contract between the university and the sponsor. As a result:
- If the sponsor has a master agreement with Penn: the injury language will be assessed at time of initial submission, since the contract is already finalized. You may be asked to make additional edits to this section as an administrative stipulation to align with contract language.
- If the sponsor does not have a master agreement with Penn: the IRB cannot check the injury language until the contract is negotiated and finalized. Therefore, you will receive a reminder note in the letter that a stamped informed consent form cannot be provided until this occurs. Please also note that OCR is responsible for these contract negotiations and will notify the IRB at time of finalization.

- Is the business administrator identified in the Sponsor tab?
  - If Unmet: Please update the Sponsor tab with the name and contact information of the department business administrator. This is important for discussions regarding any potential billing concerns.

- Is the IND sponsor also the PI, a member of the study team, or Penn faculty?
  - If Yes: This will be flagged accordingly for the IRB, who will let you know if any additional actions need to be taken.

Protocol Tab:
The following items in the Protocol tab will be checked for consistency with the protocol. If you have a full clinical protocol and the information is already covered within that document, please simply reference the corresponding sections in the HS-ERA application (e.g. “See Section 4.1 for Key Inclusion Criteria”).
- Background Section
- Study Design

- Is both the expected duration of a subject’s participation (from consenting to completion) and also the expected duration of the protocol overall (from approval to closure) included in the Study Duration section?
  - If Unmet: Please update this section to include both pieces of information as it applies to the Penn site specifically.

- Do the resources necessary for human subjects’ protection align with the design of the study?
  - If Unmet: Please provide further detail regarding the resources used specifically at Penn to ensure the protection of human subjects during this study within the Protocol tab.

Populations Tab:
The following items in the Populations tab will be checked for consistency with the protocol. If you have a full clinical protocol and the information is already covered within that document, please simply reference the corresponding sections in the HS-ERA application (e.g. “See Section 4.1 for Key Inclusion Criteria”).
- Target Population
- Accrual
- Key Inclusion Criteria
- Key Exclusion Criteria

▪ Do the eligibility criteria reference infectious disease testing?
  ➔ If Yes: Please be sure that the necessary reporting language is included in the informed consent form.

▪ Do the eligibility criteria reference pregnancy testing?
  ➔ If Yes: Please be sure that the required method of pregnancy testing (i.e. urine or serum) is consistent across both the full protocol and the informed consent form.

▪ Do the eligibility criteria reference contraception requirements?
  ➔ If Yes: Please be sure that required methods for contraception are consistent between the full protocol and informed consent form.

▪ Will pregnant women, fetuses, or neonates be targeted for enrollment?
  ➔ If Yes: Please complete and upload a Subpart B form to the submission.

▪ Will prisoners be targeted for enrollment?
  ➔ If Yes: Please complete and upload a Subpart C form to the submission.

▪ Will children be targeted for enrollment?
  ➔ If Yes: Please complete and upload a Subpart D form to the submission; please also ensure that an assent form and a parental permission form (as applicable with further explanation on these circumstances provided in the Subpart D form) are uploaded, as well as a plan for the assent and permission process.

▪ Will data be collected in the event of an incidental pregnancy?
  ➔ If Yes: Please clarify whether the study team will seek to collect data on only enrolled subjects or also on pregnant partners of male subjects. Please also be sure to include the following:
  - A statement confirming that all the below required materials will be submitted as a modification in the event of an incidental pregnancy prior to the collection of data.
  - The submission of all required materials for collection of incidental pregnancy up-front during time of initial review; this includes:
    - A specification of the type of data to be collected for pregnancy follow-up
    - A description of how this data collection will occur
    - A pregnant partner informed consent form
    - A statement in the informed consent form that the study team will request to collect data on the subject or the pregnant partner of a male subject in the event of an incidental pregnancy

▪ Is the information provided to address “populations vulnerable to undue influence or coercion” complete and appropriate given the nature of the protocol? (Note: This must include a statement affirming that any Penn affiliates will be informed that their decision of whether or not to participate will not in any way impact their standing with the University.)
  ➔ If Unmet: Please update this section to thoroughly denote any subjects who might be uniquely vulnerable in this population (e.g. subjects who are unable to provide independent consent, Penn affiliates, etc.).

▪ Is the plan for recruitment sufficiently outlined to describe the efforts that will be undertaken for the study?
  ➔ If Unmet: Please update the description to provide a thorough outline as to how subjects will be recruited for this protocol.
If any recruitment materials (e.g. advertisements, brochures, letters, broadcast materials, etc.) will be used for the protocol, are they both listed in the HS-ERA application & uploaded to the submission? Are they also appropriate per Penn recruitment policy?

- **If Unmet:** Please be sure that all documentation is consistent with the planned recruitment materials as desired. Please also review the guidance document provided on the IRB website to be sure the materials align with Penn policy.

  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.

- Are both the compensation method and amount specified, and are they consistent with the protocol?

- **If Unmet:** Please align the compensation methods with those outlined in the protocol and ensure that both the method and the amount are included in both the HS-ERA application and the informed consent form.

### Procedures Tab:

The following items in the Procedures tab will be checked for consistency with the protocol. If you have a full clinical protocol and the information is already covered within that document, please simply reference the corresponding sections in the HS-ERA application (e.g. “See Section 4.1 for Key Inclusion Criteria”).

- Procedures
- Analysis Plan

- **Is the confidentiality plan appropriate as described and in alignment with the protocol?**

  - **If Unmet:** Please review the companion guide on data security (available [here](#)) and update the confidentiality section to thoroughly note how data confidentiality will be maintained. (Note: confidentiality refers to the maintenance of the security of data collected throughout the study.)

- **Is the privacy plan appropriate as described and in alignment with the protocol?**

  - **If Unmet:** Please update the privacy section to clearly describe how subject privacy will be protected throughout participation. (Note: privacy refers to the subject’s ability to control access to their data; examples include consenting the subject in a private room, etc.)

- **Is the list of protected health information in the HS-ERA application consistent with the one listed in the informed consent form?**

  - **If Unmet:** Please revise the informed consent form and/or the HS-ERA application to ensure the list of protected health information collected during the study is consistent.

- **Is the genetic information section consistent, complete, and appropriate per the procedures outlined in the protocol?**

  - **If Unmet:** Please update the HS-ERA application accordingly to detail how genetic testing will be performed as part of the protocol. Please also include the required template GINA language in the informed consent form (available on our Forms page [here](#)).

- **Are the monitoring provisions checked in the HS-ERA application supported by the provisions outlined in the protocol?**

  - **If Unmet:** Please detail all monitoring parties that will be overseeing the conduct of the study, including but not limited to a Data Safety Monitoring Board, a medical monitor, CTSRMC, etc.

### Informed Consent Form

The following are the required elements of consent that must be present in any consent form in order for it to receive IRB approval. Please ensure that these are included and, if they are not, the IRB will request revisions accordingly.

- A statement noting that the study involves research
- A description of the reasonably foreseeable discomforts/risks (including potential risks of all research-related procedures)
- A description of the benefits to subjects or others (including both direct & indirect benefits)
- Disclosure of alternative procedures or courses of treatment (e.g. if you can receive the standard of care treatment without participating in the research, palliative care, etc.)
- A statement describing how confidentiality will be maintained (e.g. use of secured UPHS servers, use of unique subject identifiers, etc.)
- An explanation of any compensation to be provided and description of injury coverage
- An explanation of whom to contact with questions/concerns (noting that the contact information for both a member of the study team and also someone outside of the study must be included)
- A statement to indicate that participation is voluntary and refusal to participate will not involve loss of benefits

The following are the required elements of HIPAA authorization that must be present in either a separate form or, more typically, the consent form in order for a study collected protected health information to receive IRB approval. Please ensure that these are included and, if they are not, the IRB will request revisions accordingly.
- A list of the protected health information collected/used
- A description of who may use/disclose the information
- A description of who may receive the information
- A statement to indicate that the duration of authorization does not expire
- A statement to indicate that a subject has the right to revoke authorization, and how to do this
- A statement to indicate information disclosed outside the covered entity may not be protected

- Do the signature lines align with the eligibility criteria (e.g. is there a signature line for an LAR when only subjects who can independently consent are included, etc.)?
  ➤ If Unmet: Please update the signature lines provided to align with the eligibility criteria as detailed in the protocol.

- Are you requesting a waiver of consent, an alteration of the consent process, or a waiver of documentation of consent?
  ➤ If Yes: Please be sure to include all appropriate waiver of consent documentation (available on our Forms page here) as well as a rationale for why this is necessary for conduct of the study.

- Does the research include a screening consent form?
  ➤ If Yes: Please detail how the screening will be conducted (e.g. via phone, in-person, etc.) and provide both a screening script and a template document/letter to track the data.

**Supporting Documents:**
- Will the study involve any questionnaires, inventories, surveys, diaries, personality tests, quality of life assessments, data collection forms, or interviews?
  ➤ If Yes: Please upload this documentation to the HS-ERA application as long as they are not widely recognized, accepted, standard tests.