PittPRO | Pitt Protocol Review Online

Form: Exemption 45 CFR 46.104(d)(4) Secondary Research with Data and/or Specimens Request for Exempt or No Human Subject Involvement Determination

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Always ensure that you have reviewed the most current guidance for this category on the HRPO website (see "Exempt" review) and that you are using the most current version of this exempt form.

Name of Principal Investigator: _____

Study Title: _____

Study Number: STUDY_____

1. Is this research limited solely to the use of an FDA-regulated in-vitro device (IVD) study with leftover human specimens (or specimens from an IRB-approved repository) that are not individually identifiable? If Yes, STOP and instead submit the "Request for an Exception to Informed Consent Requirements: Studies Using In Vitro Diagnostic Devices with Specimens Not Individually Identifiable" Exempt form	☐ Yes ☒ No
2. Will any information from this project be submitted to the FDA or held for inspection by the FDA? If Yes STOP and contact askirb@pitt.edu for assistance	☐ Yes ☒ No
3. Will de-identified frozen specimens (and if applicable, data) be obtained exclusively from the Health Sciences Tissue Bank (HSTB)? If Yes, STOP Submit directly to the HSTB using their application instead of submitting a protocol in PittPRO.	☐ Yes ☒ No

4. What materials will you obtain for research?
   ☐ Data ☐ Specimens ☒ Both data and specimens

*Note that specimens can only be included if publicly available, or if a "no human subjects" determination is deemed appropriate. Otherwise the protocol should be submitted for expedited review.

5. Describe all data and/or specimens, including source(s), types, and specific variables (including all direct or indirect identifiers) that will be used for this research: **Samples from the MOMI Biobank linked to de-identified clinical and demographic data.**

6. Briefly describe how the data/specimens will be used: _____

7. Specify the inclusion/exclusion criteria for the selection of data/specimens used in this study: _____

8. Does your study meet the following conditions?
   a. No member of the research team has interacted or intervened, for research purposes, with the individuals whose data/specimens will be studied (note: if any members of this study team are/were affiliated with a project from which data/specimens will be obtained, you may not qualify for this determination) ☒ Yes ☐ No
   b. No identifiable private information will be reviewed or recorded by the study team: ☒ Yes ☐ No

Each source of materials should only be listed in one section based on the current location of materials
(Do not fill in the follow-up items in any section if the initial "yes" box is unchecked.)

Criterion i: Publicly Available data/specimens	☐ Yes ☒ No

1. Name each source of data/specimens: _____
2. How will data/specimens be obtained? _____
3. Who will access the data/specimens from their current source and what is their right to do so? _____
4. Will the data/specimens that will be received include any identifiers and/or codes that could be used by the study team to link data/specimens to identifiers?
   ☐ No; Explain the de-identification process: _____
   ☐ Yes; Explain why it is necessary to receive identifiable information, and the study team's right to access the potentially identifiable information: _____

Criterion ii - Non-public data **Data obtained from a tissue bank, repository, registry, or research study**	☒ Yes ☐ No

*An exempt determination cannot be made for a study using specimens under this option, but the study may qualify for a "no human subjects" determination.

1. Title of each research bank/repository/registry/study: **MOMI Biobank**
2. PI name(s): **Arun Jeyabalan, MD**
3. IRB number(s): **STUDY19100240**
4. Who will access the data/specimens from their current source(s) and what is their right to do so? **MOMI Biobank staff who handle the specimens as part of their duties.**
5. Will the data/specimens that will be accessed by this study team include any identifiers and/or codes that could be used by this study team to link data/specimens to identifiers?

☒ No; An honest broker will be used. Explain the de-identification process: **HB051 will cover any linkages to clinical data and provide data and specimens de-identified.**

☐ Yes; Explain why it is necessary to access potentially identifiable information, and this study team's right to access the potentially identifiable information: _____

6. Attach the bank/repository/study consent form(s) on the **Supporting Documents page**. If not applicable/available, explain: _____
7. Did the consent form(s) signed by the subjects restrict use of their data/specimens in any way?
   ☒ No;
   ☐ Yes; describe the restrictions: _____

Criterion iii – Data subject to HIPAA regulations
Two acceptable strategies for collection of these date are listed below:
- Honest broker provides data, **or**
- Direct access to identifiable medical records by the researcher team / Waiver of HIPAA Authorization is required

☐ Yes ☒ No
*Also select "Yes" to one of the 2 options below

Data/specimens obtained from clinical sources by an honest broker, and provided without any identifiers or linkage codes ☐ Yes ☐ No

* Clinical data/specimens are subject to HIPAA regulations, but Do **NOT** choose "Waiver/Alteration of HIPAA Authorization" on the Study Scope page. Information about HIPAA can be found in A-Z guidance at www.hrpo.pitt.edu.
* The honest broker cannot, under any circumstances, be a member of the study team.
* An exempt determination cannot be made for a study using specimens under this option, but the study may qualify for a "no human subjects" determination.

1. Name each clinical source of data/specimens: _____
2. How will data/specimens be obtained? _____
3. In what format will the medical record information be provided to this study team?
   ☐ De-identified (HIPAA safe harbor; none of the 18 HIPAA identifiers included)
   ☐ Limited data set (includes dates and certain geographic information)
      i. Justify why dates and/or geographic information from medical record are needed for this study: _____
      ii. Justify the need for the requested medical record data elements that you have listed **on the Medical Records page, item 1 and/or 2**: _____
      iii. For UPMC and/or University of Pittsburgh medical records: A completed Data Use Agreement for Limited Data Sets must be uploaded on the **Supporting Documents page**. Note: This application cannot be processed without this form, signed by the recipient. For a copy of this form, contact askirb@pitt.edu.
4. Will a UPMC/Pitt certified honest broker be utilized?
   ☐ No; Explain why it is not possible to utilize a certified honest broker, and address the right and ability of the individual providing honest broker services to access the necessary data/specimens including access to the data/specimens and qualifications: _____
   ☐ Yes; (typically required – note that there are certified honest broker systems available and able to access most sources of clinical data/specimens): _____
5. Complete and upload a signed Honest Broker Assurance form (found in A-Z guidance at www.hrpo.pitt.edu). This is required prior to submitting your application in PittPRO.
6. If paraffin tissue blocks from UPMC will be studied, provide the name of the pathologist who has reviewed this project and approved the allocation of tissue:
   Name: _____ E-mail: _____

OR

Data obtained from UPMC/Pitt clinical sources by member(s) of this study team ☐ Yes ☐ No

*Specimens cannot be included under this option.

1. Name each clinical source of data: _____
2. How will data be obtained? _____
3. List the specific date range of records to be studied (Required – include full date, not only months/years): starting _____ through _____

4. Specify the approximate number of individuals about whom data will be requested: _____
5. Will any identifiers be recorded by the study team, even temporarily?
   ☐ No; Note that once the data have been extracted from the clinical source, it will not be possible for this study team to go back to that source to add other patient-specific data, to verify data, to link multiple sources of data, or for any other reason.
   ☐ Yes; Explain why it is necessary to record identifiers: _____
6. If paraffin tissue blocks from UPMC will be studied, provide the name of the pathologist who has reviewed this project and approved the allocation of tissue:
   Name: _____ E-mail: _____

* For this criterion, you must select "Waiver/Alteration of HIPAA" on the **Study Scope page, item 2**. The Waiver must be fully justified (for all included subjects, for the time frame indicated) in order for the research to be approved. Information about HIPAA can be found in A-Z guidance at www.hrpo.pitt.edu.

Criterion iv – Research conducted on behalf of Federal Agencies ☐ Yes ☒ No

1. Will identifiable private information be obtained?
   ☐ No; A "no human subjects" determination will be given, if appropriate.
   ☐ Yes; Describe how information is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.: _____

Other / None of the option listed above (recommended to contact askirb@pitt.edu before proceeding

*An exempt determination cannot be made for a study using specimens under this option, but the study may qualify for a "no human subjects" determination.

1. Name each source of data/specimens: _____
2. How will data/specimens be obtained? _____
3. Who will access the data/specimens from their current source(s) and what is their right to do so? _____
4. Will the data/specimens that will be received by the study team include any identifiers and/or codes that could be used by the study team to link data/specimens to identifiers?
   ☐ No; Explain the de-identification process:
   ☐ Yes, STOP and contact mailto:askirb@pitt.edu for assistance.

General

Additional information, clarification, or comments for IRB review: _____

Reminders:

- After completing this document, save it to your computer and then upload into PittPRO, **Basic Information page, item 8**.
- If accessing medical records directly or via an honest broker, choose which medical records are being accessed (Pitt, UPMC, and/or Other) on the **Study Scope page, item 4**. **Then ensure that you describe all variables to be obtained from medical records on the Medical records page.**
- If an IRB-approved Honest Broker system will be used to provide de-identified specimens/data, choose "Honest Broker to provide data/specimens" on the **Study Scope page, item 3**. Also upload the **completed and signed Honest Broker Assurance Form** available in the PittPRO Library under the General tab.
- If an individual other than an IRB-approved Honest Broker will de-identify specimens/data prior to providing it to the study team, it is recommended to contact mailto:askirb@pitt.edu before proceeding. In this case, you would not choose "Honest Broker" under the Study Scope page, but instead you would describe this person and their access to the data/specimens in the Research Activities section. Also upload the completed and signed Honest Broker Assurance Form available in the PittPRO Library under the General tab on the **Supporting Documents page**.
  Note that this person must be independent from the study team.
- If specimens/data will come from, or will be sent to, another institution, you must consult with the University of Pittsburgh Office of Research regarding any necessary transfer agreements.
  - If you intend to share electronic data, this must be addressed in PittPRO, **Electronic Data Management page**.
  - If you intend to share data in a paper format, this must be addressed in PittPRO, **Data Safety and Monitoring page**.