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| **Always ensure that you have reviewed the most current guidance** for this category on the [HRP website](http://www.hrpo.pitt.edu/) (see “Exempt” review) and that you are using the most current version of this exempt form. | |
|  | |
| Name of Principal Investigator: | |
| Study Title: | |
| Study Number: | |
|  | |
| 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,  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 |
| 1. Will any information from this project be submitted to the FDA or held for inspection by the FDA?   If Yes  and contact [askirb@pitt.edu](mailto:askirb@pitt.edu) for assistance | Yes  No |
| 1. Will de-identified frozen specimens (and if applicable, data) be obtained exclusively from the PBC / Pitt Biospecimen Core (formerly called the HSTB)?   If Yes,  Submit directly to the PBC using their application instead of submitting a protocol in PittPRO. | Yes  No |
| 1. What materials will you obtain for research?   Data  Specimens  Both data and specimens  \*Note that specimens can only be included under options i or ii below, or if a “no human subjects” determination is deemed appropriate. Otherwise the protocol should be submitted for expedited review. If obtaining specimens, be sure to select “specimens” in the study scope section, item 3. | |
| 1. Are the following statements true or false? 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)  True  False   b. No identifiable private information will be reviewed or recorded by the study team:  True  False  \*select “false” to item b if this is a medical record review and the study team will directly access charts. | |
| 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  This includes materials that are truly public. It does not include medical records, clinical specimens, private identifiable information, etc. CMS data should be included under criterion iii, option 2. | Yes  No |
| 1. Name each source of data/specimens:  2. 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:  3. How will data/specimens be obtained?  4. Who will access the data/specimens from their current source and what is their right to do so?  5. 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 and/or specimens obtained from a bank, repository, registry, research study, or other source.   * Study team members may access identifiable private information, but cannot record / obtain data in a way in which it could be linked back to identifiers, even temporarily. * Any individuals accessing the identifiable data must already have access to that information (e.g. by means of their involvement with the original collection). * Medical Record Reviews should not be included here – they should be included under criterion iii. * Materials from the Pitt Biospecimen Core should not be included here – they should be under criterion iii, option 1 | Yes  No |
| 1. If the materials will be obtained from a research source, address the following:  a. Title of each research bank/repository/registry/study or other source of materials:  b. PI name(s):  c. IRB number(s):  d. Describe all data, including source(s), types, and specific variables (including all direct or indirect identifiers), and all specimens, that will be used for this research:  e. Who will access the data/specimens from their current source(s) and what is their right to do so?:  f. 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:  Yes; Explain why it is necessary to access potentially identifiable information and/or identifiable specimens, and this study team’s right to access these materials:  g. Did the consent form(s) signed by the subjects restrict use of their data/specimens in any way?  No;  Yes; describe the restrictions:  h. Attach the bank/repository/study consent form(s) on the Supporting Documents page. If not applicable/available, explain:    2. If the materials will be obtained from a non-research source, please address the following:   a. What was the purpose of the original collection of these materials?:        b. Under whose possession are the materials currently?:        c. How will the materials be obtained from this source?:  d. Describe all data, including source(s), types, and specific variables (including all direct or indirect identifiers), and all specimens, that will be used for this research:  e. Who will access the data/specimens from their current source(s) and what is their right to do so?:  f. 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:  Yes; Explain why it is necessary to access potentially identifiable information and/or identifiable specimens, and this study team’s right to access these materials: | |
| Criterion iii – Data subject to HIPAA regulations  Two acceptable strategies for collection of these date are listed below:   * Option 1: Honest broker provides data, or * Option 2: Direct access to identifiable medical records by the researcher team / Waiver of HIPAA Authorization is required   Information about HIPAA can be found in [A-Z guidance](http://www.hrpo.pitt.edu/guidance) at [www.hrpo.pitt.edu](file:///C:\Users\pao100\Desktop\www.hrpo.pitt.edu). | No exempt form needed – see instructions under each of the two options below. |
| *Option 1: Data/specimens obtained from clinical sources by an honest broker, and provided without any identifiers or linkage codes*  *\* 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 based on information provided in the protocol.*  *Be sure to that your PittPRO protocol includes, but is not limited to, the following:*  *Study Scope section:  2 - Do NOT choose the “Waiver/Alteration of HIPAA”.*  *3 - If using a Pitt/UPMC certified honest broker system, choose “Honest Broker to provide data/specimens” and upload a signed honest broker assurance in the Honest Broker section of the PittPRO protocol. A certified honest broker is typically required – note that there are certified honest broker systems available andable to access most sources of clinical data/specimens), A blank form can be found in A-Z guidance of our web site (*[*https://www.hrpo.pitt.edu*](https://www.hrpo.pitt.edu)*).  Be sure to select “specimens” if applicable.*  *4 - Select the source of the medical records / specimens*  *Research Activities section:*  *Name each clinical source of data/specimens.  Explain how data/specimens will be obtained.*  *If you are not using a Pitt/UPMC certified honest broker system, be sure that you explain why it is not possible to utilize a certified honest broker. Also address the right and ability of the individual providing honest broker services to access the necessary data/specimens including their current access to the data/specimens, their qualifications, and that they are providing this service but are not otherwise considered to be a member of the study team.*  *Specify in what format will the medical record information be provided to this study team. The two options are:*  *A. The study team will obtain a Safe Harbor De-identified data set as defined by HIPAA. None of the 18 HIPAA identifiers will be received, or  B. The study team will obtain a Limited data set (includes dates and certain geographic information). If choosing this option, be sure to*  *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,*  *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 the UPMC version of this form, click* [*here*](file:///C:\Users\infin\AppData\Local\Temp\here)*. For a copy of the Pitt form, contact* [*askirb@pitt.edu*](mailto:askirb@pitt.edu)*.*  *Medical Records section:*  *This section should list / describe all variables to be obtained – Reduce duplication by only listing this information here.* | |
| *OR* | |
| *Option 2: Data obtained from UPMC/Pitt clinical sources by member(s) of this study team*  *\*Specimens cannot be included under this option. \*Choose this option for CMS data, as their policy requires that a waiver of HIPAA Authorization be granted.*  *Be sure to that your PittPRO protocol includes, but is not limited to, the following:*  *Study Scope Section:*  *2 - Choose “Waiver/Alteration of HIPAA”. Include a study-specific justification for each waiver criterion in the related section later in the protocol.*  *4 – Select the source of the medical records*  *Research Activities Section:*  *Name each clinical source of data,*  *Explain how will data be obtained,*  *Specify whether any identifiers be recorded by the study team, even temporarily. If so, explain briefly why this is necessary. Note that if you do not record identifiers or linkage codes, 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.*  *Medical Records section:*  *This section should list / describe all variables to be obtained – Reduce duplication by only listing this information here.* | |
| 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.:  2. Describe all data, including source(s), types, and specific variables (including all direct or indirect identifiers) that will be used for this research: | |
| Other / None of the option listed above (recommended to contact [askirb@pitt.edu](mailto: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. Describe all data, including source(s), types, and specific variables (including all direct or indirect identifiers), and all speciemns, that will be used for this research:  3. How will data/specimens be obtained?  4. Who will access the data/specimens from their current source(s) and what is their right to do so?  5. 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,  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** (unless using criterion iii).
* The Research Activities section of the protocols should also summarize the materials and the collection and use of the materials.
* If specimens/data will come from, or will be sent to, another institution, you must consult with the University of Pittsburgh [Office of Research](http://www.research.pitt.edu/) regarding any necessary transfer agreements.
* Note: Exempt studies are exempt from the requirement to obtain a regulatory-compliant consent. No waivers of consent or waivers to document consent are applicable to exempt studies.