**JHM IRB - eForm S–Secondary Research Protocol**

What is secondary research? Secondary research is re-using information and/or biospecimens that are collected for some other ‘‘primary’’ or ‘‘initial’’ activity (HHS 2017). For example, use of data from medical records, leftover tissue/samples from a hospital’s pathology specimen repository or collected via a prior research protocol, or excess blood drawn for clinical purposes. Secondary research does not involve any prospective research data collection [e.g. via surveys, interviews, or collection of new samples by the investigator (that would have a primary research purpose)].

* **This form should be used for secondary research using identifiable private information and/or identifiable biospecimens. Data or samples are not required to be in existence at the time of the submission to the IRB. Some of these projects may be considered “exempt” and some may qualify for expedited review.**
* **In certain cases, the identifiability of the data/biospecimens may be unclear. However, this form should be used to describe all secondary research projects.**
* **Examples of the types of projects that should utilize this form are:**
* **Projects that involve the use of identifiable private information or identifiable biospecimens that are publically available;**
* **Projects that involve the secondary use of identifiable private information or identifiable biospecimens where the information is recorded in an unidentifiable manner; or**
* **Projects that involve the secondary use of identifiable private information or identifiable biospecimens where the information is recorded in an identifiable manner [including those projects that involve protected health information[PHI]]; or**
* **Projects that involve the secondary use of information or biospecimens where the identifiability of the information/biospecimens may be unclear or where identifiers have been removed.**
* **Please provide complete information for each item below. If an item is inapplicable to your study, explain why.**
* **When submitting JHM IRB eForm S (new or revised), enter the date submitted, the name of the PI, and the eIRB application number in the header at the top of the form.**

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1. **Research Question** (include all primary and secondary objectives)
2. **Background** (briefly describe relevant information to justify the research)
3. **Methods**
4. Describe the study design and the database(s) that will be utilized, including the specific sources from which you will collect data or samples. Include in your description whether you will use JHM clinical data (e.g., EPIC) or a research resource (provide IRB protocol number) Provide your inclusion/exclusion criteria and describe your method of case/patient/sample identification.

1. If your study involves data/biospecimens from participants enrolled under other research studies with a written consent or under a waiver of consent, please list the IRB application numbers for those studies.  Please note:  Certificate of Confidentiality (CoC) protections applied to the data in source studies funded by NIH or CDC will extend to this new study if the funding was active in 2016.  If this situation applies, Section 36, question 6 in the application will need to be answered “Yes” and “Hopkins Faculty” should be selected in question 7. No other documents are required.
2. Clarify whether there was an ethical review process for initial collection/derivation of data/biospecimens. If applicable, provide the determination of the ethics committee or IRB study number. Indicate whether consent was obtained and whether the consent covered the use as proposed in this research.
3. If biological materials are involved please describe all the experimental procedures and analyses in which they will be used.
4. Specify the targeted number of individuals from whom you plan to include data/samples in this secondary use. Please be sure to specify the initial/largest cohort of eligible cases from which you will identify the final sample. Where applicable, please include an estimate of the time period that will be covered (e.g., will you include data within a certain range of dates?) (You should contact the Johns Hopkins Center for Clinical Data Analysis (CCDA) if you need help to determine the number of individuals for whom your desired data is available. <https://ictrweb.johnshopkins.edu/ictr/connection/> )
5. Explain how your data are being extracted (manual chart review, bulk query). If you are planning to collect data from text documents (e.g., pathology/radiology reports) specify exactly how this will be accomplished. Are you planning to download text documents themselves? Storing copies of original documents from EPIC requires consultation with the CCDA and identification of an honest broker.
6. Explain how your data are being recorded (paper, laptop, etc.).
7. Explain how the data are being moved to the final storage location.
8. Provide the name and location of the server where the data will be housed.
9. Provide the name of the study team member responsible for data management and security.
10. Provide any plans for de-identification of the dataset. Identifiers (MRN, Name) should be stored in a separate file with the data file using unique IDs.
11. Explain how access to the data will be controlled and whether the access is logged.
12. List the computer programs being used to store and to analyze the data.
13. If you are using data from several sources explain what variables will be used to merge files.
14. Will the data set include any sensitive information (e.g., HIV status, psychiatric diagnosis)?
15. Will the data set include any genomic data?
16. Will the data be used in collaborative efforts with other institutions? If yes, will data leave Hopkins? If so, how will this be accomplished? What security measures are in place for the transfer? (Please contact the Office of Research Administration for details related to Data Use Agreements: <https://www.hopkinsmedicine.org/research/resources/offices-policies/ora/>)
17. Provide an estimate of how long it will take you to complete the study, including the time for data analysis.
18. **Study Statistics**
19. Primary outcome variable.
20. Secondary outcome variables.
21. Statistical plan including sample size justification and any plans for interim data analysis.
22. **Risks**
23. Address the risk of loss of confidentiality.
24. Discuss the steps you are taking to minimize this risk.

1. Identify whether there are any additional risks and how you will minimize these risks.
2. Discuss your plan for reporting unanticipated problems or study deviations.
3. **Requested Variables** (Upload your data collection form in Section 20, Q 2 of the application. Do not use general terms, i.e. medical history. Be specific about what you plan to collect and indicate any coding scheme that will be used, e.g.  yes/no.)
4. **Transfer of Materials**

Transfer of biospecimens from Johns Hopkins to another organization for research purposes and receipt of biospecimens from an outside organization for your research must adhere to JHU policies for material transfer (<https://ventures.jhu.edu/faculty-inventors/forms-policies/>) and biospecimen transfer (<https://hpo.johnshopkins.edu/enterprise/policies/176/39187/policy_39187.pdf?_=0.622324232879>).

Please complete this section if your research involves transfer or receipt of biospecimens.

1. Will you **receive** biospecimens from an external entity for this research? [Yes/No].

 If “Yes”, please confirm you will secure an MTA/research agreement from the appropriate office (JHTV/ORA) prior to transfer.

 See: <https://ventures.jhu.edu/technology-transfer/material-transfer-agreements/> .

1. Will you **transfer** biospecimens to an external entity as part of this research? [Yes/No]

 If “Yes”, please address each of the following:

1. Describe the nature of the research collaboration with the external entity and the rationale for the transfer. (Include an explanation of your intellectual contribution to the design of the research study, resulting data and sharing, and participation in the planned publications.)
2. Please confirm you will secure an MTA through the appropriate office (JHTV or ORA) prior to transfer.

(See: <https://ventures.jhu.edu/technology-transfer/material-transfer-agreements/>.)

1. If the biospecimens you intend to transfer were obtained through clinical or research procedures at Johns Hopkins and “Other” is selected in Item 4, Section 23, please submit the following items in that Section:
	1. A pdf version of a completed JHTV Online “Material Transfer Agreement Request Form for Outbound Material” <https://ventures.jhu.edu/technology-transfer/material-transfer-agreements/> **OR** a copy of the COEUS PD (Proposal Development Summary).
	2. A completed Biospecimen Transfer Information Sheet <https://www.hopkinsmedicine.org/institutional_review_board/forms/>.
	3. A signed and dated “De-identified Human Subject Certification” <https://www.hopkinsmedicine.org/institutional_review_board/forms/>
	4. Approval documents from recipient site, if applicable.
	5. Copies of the consent forms associated with the IRB protocols under which the biospecimens were collected, with language appropriate to this transfer highlighted.
	6. The name of the specialist you are working with in ORA to complete a contract/MTA.

Please see the following website for more information about transferring human biospecimens to outside entities: <https://www.hopkinsmedicine.org/institutional_review_board/news/announcement_transfer_human_biospecimens_outside_entities.html/> .