***This instructional template provides guidance and template language that can be used to develop an eForm S protocol for projects that will involve analysis of a data projection from an existing resource protocol [eForm R]. The eForm S template should be downloaded from the Forms page of the IRB website. This tool serves as a guide for completing that form.***

**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.**

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

*Instructional text appears throughout the document in blue italics. It should be deleted before submission. This text is intended to provide guidance as to what content should be supplied in response to the questions in the eForm S.*

*Sample text appears in italics and is highlighted in yellow. This text can be used to build project-specific text in several sections of the form. Please remove the yellow highlighting before submitting your protocol to the IRB.*

1. **Research Question** (include all primary and secondary objectives)

*Please provide a description of your research question and explain how the use of secondary data will assist with answering that research question. Please include a description of your primary and secondary objectives.*

1. **Background** (briefly describe relevant information to justify the research)

*Please briefly describe the background and purpose of the research and the importance of the research questions outlined above.*

1. **Methods**
2. 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.

*As this template should be used for projects seeking to utilize data projected from an existing resource, please identify the data sources from which data and/or biospecimens will be projected for this project. Please list the applicable protocol numbers for the protocols that will provide source data for this project.*

*The primary source of the data for this study will be from (Registry name and IRB number).*

*For data projected from existing resource protocols, please describe how you have worked with the CCDA or the resource data manager to develop a data specification document and ensure that document is uploaded in Section 20, Item 2 of your eIRB application. If you combine data from multiple sources, please be sure to specify each data source that will be used for this study.*

*We worked with the CCDA* *certified registry data manager to define the inclusion/exclusion criteria, all data sources, and specific data elements from each data source for my project and have uploaded the CCDA specification document to Section 20, Item 2 of the eIRB application.*

*Inclusion Criteria:*

*[Who? Adult or pediatrics? Sensitive populations?]*

*[Where seen? – as outpatient or inpatients? At specific clinics?]*

*[When seen? – date/time range]*

*[What disease, what lab results, what meds, what other conditions?]*

*Exclusion Criteria:*

*[Deceased? Other comorbidities? Other exclusions?]*

*Please 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.

*Complete if applicable*

1. Clarify whether there was an ethical review process for the 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.

*The resource protocol from which this data is obtained underwent a separate IRB review. The protocol number for the resource is XXXX.*

1. If biological materials are involved, please describe all the experimental procedures and analyses in which they will be used.

 *N/A*

1. Specify the estimated 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 [Core for Clinical Research Data Acquisition (CCDA)](https://ictr.johnshopkins.edu/programs_resources/programs-resources/i2c/center-for-clinical-data-analysis-ccda/) or the PMCoE CCDA-certified registry data manager to help you to determine the target cohort.

*The targeted number of the cohort does not require a precise count. It is acceptable to provide a size range (1-499 unique cases, 500-1,000 unique cases, 1,001-10,000 cases, Over 10,000, etc.)however the maximum possible for inclusion should be listed and must match the number entered in the eIRB application. Include the method by which a targeted count was obtained (working directly with the CCDA, the BEAD Core, using SlicerDicer or TriNetX, etc.)*

*The maximum number of individuals whose records may be accessed is XXXX. This estimate was reached by working with CCDA/CCDA-certified registry data manager (choose one) to define the inclusion/exclusion criteria.*

1. 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 the identification of an honest broker.

*Below are specific examples of data extraction methods (Choose one of the examples below or describe your method)*

*Example 1- Data will be provisioned via a query performed by the CCDA and delivered as a PMAP SQL database projection. In rare cases, we may need to conduct a manual chart review in Epic to clarify specific data elements or to extract information not available in PMAP. Medical record numbers and other direct PHI for a subset of patients will be stored on the study team’s secure SAFE desktop folder and will not be moved from that location.*

*Example 2 - Data will be provisioned via a query performed by a CCDA-certified registry data manager and delivered to the study team’s: SAFE folder or PMAP SQL in the form of flat files to analyze with and use Python/R/ STATA/ SAS/Etc. (choose the appropriate option, as discussed with the CCDA)*

 *Below is a specific example for conducting analysis on text documents:*

*We will work with CCDA/SOM/WSE/APL NLP Expert \_\_\_\_\_\_\_\_\_\_\_ to perform Natural Language Processing in the PMAP, Phoenix, or SAFE environment. Only \_\_\_\_\_ will have access to the notes for NLP processing.*

*If the study is using an NLP tool that requires annotation of documents as part of the NLP process, include the following sentence: (Choose one of the examples below or describe your method)*

*Example 1- The NLP tool requires annotation of documents as part of the NLP process. The following people will have access to a limited set of notes in order to annotate the documents: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Example2- The results of the analysis, including extracted elements (named entity recognition), will be returned to the larger study team for use in the study. Access to notes will be limited to 30 days.*

*If the NLP expert has a primary appointment outside the JHM covered entity, include a statement that possesses the individual's special expertise required for this research, and describes what that special expertise is.

If the disclosure is not consented, upload a completed HIPAA form 4 describing the special expertise, and indicating any constraints on obtaining such expertise within the JHM covered entity. See* [*Access to Patient Data for Research: Frequently Asked Questions*](https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/access_to_patient_data_for_research_faqs.html)*.)*

1. Explain how your data are being recorded (paper, laptop, etc.).

*This is mostly applicable for people who are recording their data manually versus receiving a PMAP projection. If this does not apply enter N/A*

*Below are specific examples for recording data collected by manual chart review: (Choose one of the examples below or describe your method)*

*Example 1- We will conduct manual chart abstraction and enter supplementary data into REDCap, Excel, and use* Python/R/ STATA/ SAS/Etc. (choose the appropriate tool) *for analysis on the SAFE desktop. Data will not leave the study team’s SAFE desktop folder.*

*Example 2- We will conduct manual chart abstraction and enter supplementary data into REDCap, export results to the SAFE desktop, and use* Python/R/ STATA/SAS/Etc. (choose the appropriate tool) *for analysis. Data will not leave the study team’s SAFE desktop folder.*

1. Explain how the data are being moved to the final storage location.

*The CCDA-certified registry data manager or the CCDA core team will deliver the local projection into a PMAP SQL database separate from the registry (system projection) or to the study team’s SAFE desktop folder.*

 *(Please choose one)*

1. Provide the name and location of the server where the data will be housed.

*The working data sets will be stored in the PMAP Research Analytics Platform or on the study team’s SAFE desktop folder. (Please choose one)*

1. Provide the name of the study team member responsible for data management and security.
2. 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.

*Below are specific examples for describing data de-identification: (Choose one of the examples below or describe your method)*

*Example 1 - We are requesting direct PHI (MRN, patient name, [other direct identifiers]) [insert justification]. We will maintain separate raw data and analytic files, with a mapping file linking PHI identifiers to an anonymized study ID in the analytic file. Access to a linking table containing PHI will be limited to the study team members with access only given to the data manager. Data analysts will work with a* [*HIPAA limited dataset*](https://www.hopkinsmedicine.org/institutional_review_board/hipaa_research/limited_data_set.html)*. The files containing PHI will be stored in a separate location from the analytic file.*

*Example 2 - We are requesting a HIPAA limited dataset that will contain no direct PHI (MRNs, patient names) but will contain relevant clinical dates and patient dates of birth.*

*Example 3 - We are requesting a Safe Harbor fully de-identified dataset that will not contain PHI. The data de-identification method has been approved by the CCDA.*

1. Explain how access to the data will be controlled and whether the access is logged.

*Access to the data will be restricted, housed on the SAFE desktop /PMAP Research Analytics environment (choose which). Only study team members will be given access to the SAFE virtual desktop and/or PMAP Research Analytics environment. If not using PMAP the files with PHI identifiers will be further password protected and restricted. The PMAP Research Analytics environment logs all data access. SAFE logs access to files.*

1. List the computer programs being used to store and analyze the data.

*Storage examples include SAFE virtual desktop, PMAP SQL Server database, PMAP ADLS. Analytic tools include Stata, R, Python, Data Bricks, PMAP (SQL Server, CrunchR, ADLS), Excel, and MATLAB.*

1. If you are using data from several sources explain what variables will be used to merge files.

*CCDA will be doing the merging, some examples of variables used to merge data sources include medical record number (EMRN) plus patient name, date of birth, and gender or other demographic data that can be used to uniquely identify a patient (Medicare ID, Social Security Number)*

 *The study team will be doing the merging (Insert variables here)*

1. Will, the data set include any sensitive information (e.g., HIV status, psychiatric diagnosis)?

[Sensitive Information](https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/research_using_pmap.html)

*Below are specific examples to describe the inclusion of sensitive information: (Choose one of the examples below or describe your method)*

 *Example 1 - The data set will or will not include any sensitive information.*

*Example 2 - I am working with the CCDA to define which variables if any are considered to be sensitive information. Please see attached specification document for detailed information.*

*Example 3 - Yes, the dataset will include notes from a mental health professional or substance abuse professional/mental health, substance abuse, or HIV diagnoses/* *medications used exclusively for Mental health, substance abuse, or HIV/HIV test results/ (select applicable choices)*

1. Will, the data set include any genomic data?

*The data set will or will not include any genomic data.*

1. 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 (ORA) for details related to Data Use Agreements (DUA): <https://www.hopkinsmedicine.org/research/resources/offices-policies/ora/>)

*No, the data provisioned for this study will not leave the JHM covered entity.*

1. Provide an estimate of how long it will take you to complete the study, including the time for data analysis.
2. **Study Statistics**
3. Primary outcome variable.

*Describe primary outcome*

1. Secondary outcome variables.

*Describe secondary outcomes if applicable*.

1. A statistical plan including sample size justification and any plans for interim data analysis.
2. **Risks**
3. Address the risk of loss of confidentiality.

*Risks include loss of confidentiality if there were a lapse in security practices. Included below is a sample of a description of the risk of loss of confidentiality.*

*Despite efforts to secure the data, there is a risk of loss of confidentiality should an accidental breach occur. We will make our best efforts to minimize this risk using the mitigation strategies outlined below.*

1. Discuss the steps you are taking to minimize this risk.

*We will follow all Federal and state laws and Johns Hopkins policies regarding patient privacy and HIPAA.  All study team members have completed all clinical training modules and research modules regarding patient privacy and HIPAA. Students of JHU schools outside the JHM covered entity will complete HIPAA training as required by the* [*Privacy Office*](https://intranet.insidehopkinsmedicine.org/privacy_office/quick_links/learn_what_training_you_need.html)*. The data will exist only on the Precision Medicine Platform. Please refer to section 6.b of the PMAP umbrella protocol (IRB123456789) for a description of risk minimization.*

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.

*Unanticipated problems or study deviations will be reported to the IRB within 10 days of the PI becoming aware of such problems or deviations in accordance with the IRB policy on prompt reporting.*

1. **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.)
2. **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>).

*N/A This instructional template is to be used for studies that involve the secondary use of data only.*

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 completed Biospecimen Transfer Information Form <https://www.hopkinsmedicine.org/institutional_review_board/forms/biospecimen_transfer_information_form.docx>
	2. Confirmation of a submitted “Material Transfer Agreement Request Form for Outbound Material” <https://ventures.jhu.edu/technology-transfer/material-transfer-agreements/>. This confirmation can be supplied by providing the COEUS/Fibi PD/My RAP/JAWSnumber.
	3. Confirmation of a submitted Data Use Agreement for data leaving Hopkins. This confirmation is also supplied by providing the COEUS/Fibi PD/My RAP/JAWSnumber.
	4. Approval documents from recipient site, if applicable.
	5. Copy of the consent form(s) associated with the IRB protocol under which the biospecimens were, or will be 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/guidelines-policies/guidelines/transferring-human-biospecimens-to-outside-organizations>.