**JHM IRB - eForm R –Research Resource Protocol**

**This form is intended to describe the creation or set-up of a research resource. Common examples of research resources are a database, biospecimen repository and a recruitment database. Generally, the purpose of a research resource is to help support current and future research rather than to answer a particular research question.**

* **PLEASE NOTE: If you intend to create a research resource, a separate IRB application is required for the creation of the resource itself. Use this form to describe the resource you are creating, how it will be managed and how it will be accessed for future research use.**
* **IRB protocols for registries and repositories that are designed to be used as a research resource should not also include specific hypotheses and planned analyses.**
* **Each research project utilizing your research resource must be submitted as a separate eIRB application.**
* **Investigators overseeing a research resource are required to track and report to the IRB annually a summary of any studies that have utilized the resource.**
* **Please provide complete information for each item below. If an item is inapplicable to your research resource, explain why.**
* **When submitting JHM IRB eForm R (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. **Objective & Rationale for the Resource**
2. Explain the goal(s) of the resource.

1. Provide a justification for the establishment of this research resource. Explain how this resource addresses an unmet need, [e.g. why is this new resource needed? What value will it provide?]
2. **Description**
	1. Identify the type of resource [biospecimen repository, data repository, recruitment registry, etc.]
	2. Specify the data/material sources from which this research resource will be compiled.
	3. Describe the specific INCLUSION and EXCLUSION criteria for data/biospecimens to be included in the resource.
	4. Explain whether this resource will be static, comprised of only currently existing data/specimens or dynamic, prospectively adding new data/specimens. Explain whether you will be accumulating new data/specimens for patients already included in the database.
3. **Data Acquisition**
4. Will the data/biospecimens to be included in this resource come from consented participants or are you requesting a waiver of consent? Provide a justification for a waiver of consent. If there is any intent to use the registry/resource for future patient contact, consent is required.

1. If participants will be consented, describe the method that will be used to recruit and consent participants. Upload these materials into the application.
2. If you will be including data/biospecimens from patients consented under other research studies, please list the IRB numbers for those studies.
3. 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 4 in the application will need to be answered “Yes” and “Hopkins Faculty” should be selected in question 7. No other documents are required.
4. Will the data include new information provided by participants? If so, provide copies of forms/materials participants will complete. This includes any information gathered via apps.
5. If collecting data from medical records upload your data collection forms(s) and describe:
	1. The process for identifying patient records to be included,
	2. The estimated number of patient records to be included,
	3. The process for extracting the data (e.g. manual chart review, automated data extraction, CCDA, etc.),
	4. The process for updating the resource: At what interval are you entering new cases or updating existing cases? How is this managed?
	5. Whether complete records will be copied and placed in this file (e.g., copies of image files, copies of medical notes, etc.) If so, please provide a justification. If the project will include storing copies of original documents from EPIC, you will need to identify an honest broker (contact the CCDA: <https://ictr.johnshopkins.edu/programs_resources/programs-resources/i2c/center-for-clinical-data-analysis-ccda/>)
	6. Identify the individual(s) who will be conducting the data extraction.
6. **Data Storage**
7. Explain in what format the data/ will be stored (REDCap, SQL, etc.).
8. Provide specific details as to where the data/ will be stored.
9. Identify the individual who will oversee data security and safe management of the resource.

Where will the working datasets be stored (The IRB prefers research data to be stored on a SAFE desktop. See here for details: [SAFE Desktop – Institute for Clinical and Translational Research (johnshopkins.edu)](https://ictr.johnshopkins.edu/service/informatics/safe-desktop/))

Where will any coding linkage data to reidentify data, if applicable, be stored

If any data is collected on portable devices via an app, will any PHI be stored locally on the app device?

For patient provided information via apps, will they use a study code number or their own personal identifiers?

1. Will communication to and from portable devices be encrypted?
2. **Biospecimen Storage**
3. Explain how/where biospecimens will be stored
4. **Data Management**
5. Please identify who is going to manage access to the data/specimens contained in the resource.
6. Explain how individual researchers will request access to this resource.

1. What are the requirements for granting access to the resource?

1. How will separate IRB approval for any use of the resource be verified before access is granted?
2. Explain how other researchers will access the resource. Will they be granted access to the entire resource and able to extract any data they require or will the overseers of the resource provide researchers with access only to data/specimens needed for their specific research plan?
3. Will the data be used in collaborative efforts with other institutions? Describe the nature of the collaboration.

If data will be shared as part of this collaboration, please describe the following:

1. The data that will be shared (e.g. individual-level data; summary-level data; aggregate data)
2. The purpose of the data sharing
3. How the sharing will be accomplished
4. The security measures in place for the transfer of data to collaborators

*Note that best practices for sharing/transfer include JHOneDrive and SFTP [*[*https://researchit.jh.edu/faqs/#hfaq-post-417*](https://researchit.jh.edu/faqs/#hfaq-post-417)*]. Data Use Agreements are also required for sharing of datasets outside of Hopkins regardless of the level of identifiability of the dataset.*

*(Please contact the Office of Research Administration for details related to Data Use Agreements:* [*https://www.hopkinsmedicine.org/research/resources/offices-policies/ora/*](https://www.hopkinsmedicine.org/research/resources/offices-policies/ora/)*)*

1. If researchers are provided with a data file, will they be given an actual file or will they need to conduct their analysis within the same data framework that supports this resource?

1. Will files include identifiable data or be a limited or de-identified data set?
2. What is the time period that researchers may use any data/specimens they are provided?
3. What are the procedures once researchers have completed their analyses, i.e. do they return the data, is access terminated, is data deleted?
4. Is there a requirement that projects utilizing the resource contribute data/results back to the resource?
5. If this data source will also be a resource for research recruitment, please explain what the requirements are for researchers to receive patient contact information. Explain how this contact information would be shared and any time limit for its use.
6. Explain your process for keeping records of access to this resource and for reporting the use of this resource yearly to the IRB.
7. If you will be disseminating data from this protocol (e.g., as a requirement of funding), please describe the data that will be disseminated (including any tools needed to interpret it) and any methods that will be used to prepare the data for dissemination. If there are no plans nor requirements for individual-level sharing and data dissemination will consist of aggregate or summary-level data in publication, please state so.

*Note: If you have submitted a formal Data Management and Sharing Plan for funding purposes, please reference the plan. These plans should be uploaded in Section 9 Item 4 of your eIRB application.*

1. Each protocol that utilizes data from your resource must include any individual-level dissemination plans in their eFormS protocols. It is your responsibility to ensure that any investigators who use data from this resource adhere to and align with the approved data management and sharing plan you have in place. Please describe how you will ensure that this occurs for this study.

*Note: Please consult the IRB’s guidance on* [*Sharing of Individual Level Research Data.*](https://jhura.jhu.edu/wp-content/uploads/2023/01/JHUIRBs_DataSharingGuidance_Jan122023.pdf)

1. For resources involving JHM clinical data and/or biospecimens collected at JHM, please confirm the registry adheres to the following institutional guidelines: <https://hpo.johnshopkins.edu/enterprise/policies/1099/39500/policy_39500.pdf>
2. **Risks**
3. Describe any risks related to this resource [including potential legal or financial risks].
4. Explain the steps taken to minimize the risks.
5. Describe your plan for reporting unanticipated problems and study deviations in accordance with the IRB’s [prompt reporting policy](https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/organization_policies/prompt_reporting_policy.html).
6. **Resources/Support**
7. Provide information on the financial support for this data resource. (If this is departmental, please upload a letter of support).
8. What resources exist to enable the study team to maintain/manage the resource as proposed [describe relevant resources including personnel, technology, etc.]?