Application Instructions for submitting an eFormR on eIRB Projects with PMAP

This document provides step-by-step instructions for each section of the eIRB application for submission of eForm R research requests with PMAP language.

Section 1 – General Information

Q1. Principal Investigator: *Click **Select** to choose PI on the study:*

Q2. Will the PI obtain consent for this study?
Only select Yes if you are obtaining a new consent as part of this eform R and the PI will be a part of the process.

Q3. Is the PI a JHHS RN?
Answer appropriately

Q4. Indicate the PI's primary affiliation:
Answer appropriately

Q5. Title of Study:
Add Title here:

Q6. Provide a BRIEF statement of your research question and plan:
Add project description, research question, and/or plan

Q7. Select the type of review requested: *The majority of registry studies are expedited; Biorepository studies may be convened.*

Q8. Will an external IRB act as the IRB of record for this study?
Answer appropriately

Q9. What kind of study is this?
Answer appropriately. *Single-site study or multi-site; Most PMAP registry studies are single-site*
(***If Multi-site is selected question 10 will appear; if single site, please continue to 11***

Q10. Will your [JHM] IRB act as the single IRB of record for other participating sites?
Please select Yes or No

Q11. Local Site Principal Investigator Click **Select** to choose local PI:

Q12. Does this project ONLY involve a review of records?
*Select "Yes" if this project will **ONLY** involve a review of charts/medical records. Most eForm Rs are designed to create a research resource thus the answer is more often than not NO*

Q13. Is this a quality improvement project?
Select No

Q14. Is the purpose of this protocol to create a research resource (e.g. clinical data, biospecimen, or recruitment registry) that will be maintained by the study team?
Answer appropriately (*The answer is more often than not* YES)

Q15. Is there a component of your proposed project that is a public health surveillance activity? Answer appropriately (*The answer is more often than not* NO)

Q 17-Q 22. Please select Yes or No (*The answer is more often than not* NO)

Q23. Estimated time to complete this study:
List projected overall duration of the study from start to finish, including the estimated length of time to enroll all participants, conduct study activities, analyze data, publication, etc.

Q24. Does the institutional policy on physician consent require that a physician-investigator or mid-level provider obtain informed consent for this research?
Answer appropriately (The answer is more often than not NO) in general, registry studies do not require physician consent
JHM IRB Guidelines Organization Policy on Governing Physician Role in Research Consent Process

Q25. Study Team Members:
*Click **Add** to add new Study Team members. Click **Update** to modify existing Study Team member information.*

Section 2 – Study Team Compliance Training
Ensure that the PI and all study team members have completed the required compliance training courses.
https://www.hopkinsmedicine.org/institutional_review_board/training_requirements/index.html

Section 6 – Protocol Information

2.0 * Clean Protocol:
Click Add to upload a new clean document.

3.0 Track Changes Protocol or Summary of Changes
Click Add to upload a new track change document.

9.0 Additional pilot data or relevant publications
Click Add to upload a new document

10.0 * If your study is occurring at JHH or JHBMC, check all of the below that apply: *(The answer is more often than not "none of the above")*

11.0 Does your study involve organ transplantation from an HIV-positive donor (living or deceased) to an HIV-positive recipient?
Answer appropriately

12.0 Upload a completed HIV+ Organ Transplant Form

13.0 Does this study involve HIV testing in the State of Maryland?
Answer appropriately

14.0 Will any photographic images or recordings (audio or video) of participants be taken solely for research purposes?
Answer appropriately

20.0 Does your study involve Point of Care Testing (POCT)?
When responding to this question please consider all components of your study, including screening, research-related testing, etc.
Answer appropriately

Section 7 – Clinical Trials information
Q1. Select "No"

Section 8 – Conflict of Interest
Answer all questions about COI

Section 9 – Support Information
Q1. Select the type of support, if any, and complete support information.
Q3. Select "No"
Q11. The answer depends on funding

Section 10 – Study Location
Q1. Add all locations and complete all PI contact information
Qs 2 and 3 – Answer appropriately

Section 11 – Sample Size
Q1. If the study will interact with participants (e.g., obtaining consent) mark "yes" in Q1, and complete Q2-5
If Q1 is "no", then complete Q4 and Q5
**Q4 and Q5 should be the same number in a single-site study because Q5 incorrectly populates
Q8. The answer, more often than not, is "no". However, "yes" should be checked if the study plans to use JHHS nursing staff (e.g., a prospective biorepository that plans to collect blood draws, cerebral spinal fluid, etc.).

Section 12 – Participant Information
Q1. Select "Yes"
Q2. Provide age range
Q3. Select one or more of the first 4 options, (not the last 2)
Q4. Only select this option if they will prospectively target for recruitment; If the study will propose a waiver of consent, do not select any options
Q5. Answer appropriately
Q6. Select the appropriate patient population for this registry

Section 13 – Recruitment Information
Q1. Answer appropriately. Selections may result in additional questions populating; complete as appropriate
Q2. Describe the recruitment process if you have selected anything other than "no intervention/interaction with participants" in Q1
Q5. Answer appropriately; complete Q6 and Q7 if Q5 is "yes"
Q8. Answer appropriately
Q10. Provide additional information if applicable
Q11. Please complete and upload a HIPAA Form 4 if you will access and use PHI for research without patient participants' signed authorization. Please note, if you plan to propose a waiver of consent, a waiver of privacy authorization (HIPAA Form 4) will be required.

Section 14 – Consent and Waivers

Q1. Select "Waiver of Consent" if you are using any other sources and consent was not obtained. Describe how each of the 4-5 criteria are met, as follows.
And/or select a form of consent if you plan to consent participants and complete the corresponding application section

Section 20 – Supplemental Documents

Q1. Upload supplemental study document(s) requiring a JHM IRB approval logo *these are rare
Q2. Upload supplemental study document(s) not requiring a JHM IRB approval logo

Section 22 – Devices

Qs 1 and 2 – Select "No".
Qs 1 and 2 – Select "Yes" if there are any devices that will be used or studied in this research.
Mark Q 1 "yes" if you are ***studying*** a device in this research and indicate its FDA status in the Qs that appear. If the device is FDA approved or has 510 K marketing clearance, and it will be used according to the approved indications, list the device in Q 3, providing the details and supporting document(s) where prompted. If the assay is investigational and is not yet FDA approved, list the assay in Q 5 and provide the device details where prompted.
Mark Q 2 "yes" if you will ***use*** any investigational device (not yet approved by FDA or used according to an indication not approved by FDA) in your research.

Section 23 – Human Biological Samples

Q1. Answer appropriately
If the answer is "Yes"
Qs 3-7 - Complete with study-specific information

Section 24 - Institutional Biosafety Committee

Q1. Answer appropriately

Section 34 – SKCCC CRO

Q1. – Answer appropriately

Section 36 – Data Confidentiality

Q1. Complete and upload a Risk Tier Worksheet and select the assigned category
Q2. Answer appropriately
Select "Yes" if any person-level information, including de-identified data, limited data set, personally identifiable information, or protected health information will be sent outside of Johns Hopkins Health System or School of Medicine during the study. Select or provide the name/entity of the receiving party and respond to Q3.
Q4. Answer appropriately
Q6. Answer appropriately
https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/certificates_of_confidential.html
Q7. If **Q6** is "Yes", select "Hopkins Faculty". You need not respond to any of the additional Qs that will appear as a result nor upload any documentation if the study is federally funded.

Section 37 – Application Documents
Section 38 – Approval Documents
Finalize Application