Post-Approval Monitoring &

Education

Self-Evaluation Tool (PAM&E SET)

The Post-Approval Monitoring & Education Self-Evaluation Tool (PAM&E SET) is designed as a tool for human research investigators and staff to aid in:

* Preparing for a Continuing Review or VCU/Sponsor/Regulatory Agency site visit
* A routine quality improvement exercise
* Training new research personnel

Due to the comprehensive nature of this tool, certain sections may not apply to your research. Please skip those sections and make a note of the reason it does not apply.

For a description of the **Post-Approval Monitoring & Education program**, please visit:

<https://research.vcu.edu/human-research/hrppirb/other-submissions-and-monitoring/>

A **Study Conduct Toolkit** with templates and organizational tools is available at:

<https://research.vcu.edu/human-research/hrppirb/hrpp-policies-and-guidance/#d.en.404017>

If this form is being completed as part of a PAM&E study review, please email the completed Self-Evaluation Tool to [pame@vcu.edu](mailto:pame@vcu.edu) by the submission deadline provided in the PAM&E notification email.

If this form is being completed to prepare for a site visit or for quality improvement, feel free to forward it to [pame@vcu.edu](mailto:pame@vcu.edu) for feedback.

In most cases, the information needed to answer each question should be readily available by using study regulatory binders and/or selected research records. When reviewing research records, do not directly identify research participants on the study evaluation form (i.e., use the subject identifier/code).

**Questions**

If you have questions or concerns while completing the PAM&E SET, please contact [pame@vcu.edu](mailto:pame@vcu.edu).

PAM&E SET

***SECTION NAVIGATION:*** *(click on the heading below to go directly to the section)*

1. [**Regulatory Documentation**](#bookmark=id.gjdgxs)
2. [**IRB Documentation**](#bookmark=id.30j0zll)
3. [**Subject Selection Criteria**](#bookmark=id.1fob9te)
4. [**Subject Recruitment Procedures**](#bookmark=id.3znysh7)
5. [**Informed Consent Process**](#bookmark=id.2et92p0)
6. [**Risk/Benefit**](#bookmark=id.tyjcwt)
7. [**Unanticipated Problem, Adverse Event, Serious Adverse Event Reporting**](#bookmark=id.3dy6vkm)
8. [**Protocol Deviation Reporting**](#bookmark=id.1t3h5sf)
9. [**Registry/Repository**](#bookmark=id.4d34og8)
10. [**Genetic Data**](#bookmark=id.2s8eyo1)
11. [**Drug/Device Accountability**](#bookmark=id.17dp8vu)
12. [**Record Keeping/Data Security**](#bookmark=id.3rdcrjn)
13. [**Special Conditions**](#bookmark=id.lnxbz9)

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| --- | --- | --- | --- | --- |
| PAM&E SET Completion Details | | | | |
| Name of person completing this form: | | | | Click or tap here to enter text. |
| Role on the research team (e.g., PI, Coordinator, Project Manager, etc.): | | | | Click or tap here to enter text. |
| Date study received IRB approval: | | | | Click or tap here to enter text. |
| Date first subject was enrolled: | | | | Click or tap here to enter text. |
| Date Self-Evaluation Tool completed: | | | | Click or tap here to enter text. |
| Study Information (please add other personnel and their contact information as needed) | | | | |
| Study Title: | Click or tap here to enter text. | | | |
| VCU IRB #: | Click or tap here to enter text. | | | |
| PI name: Click or tap here to enter text. | | | Contact info: Click or tap here to enter text. | |
| Study Coordinator name: Click or tap here to enter text. | | | Contact info: Click or tap here to enter text. | |
| Student name (if applicable): Click or tap here to enter text. | | | Contact info: Click or tap here to enter text. | |
| This research study is: | | | ☐ Biomedical  ☐ Social Behavioral  ☐ Both Biomedical & Social Behavioral  ☐ Other: Click or tap here to enter text. | |
| IRB used: | | | ☐ VCU IRB  ☐ WCG IRB  ☐ Other: Click or tap here to enter text. | |
| Funding sources: | | | ☐ Industry  ☐ Federal  ☐ Foundation  ☐ Internal/Departmental (or not funded)  ☐ Other: Click or tap here to enter text. | |
| Monitoring sources: | | | ☐ Sponsor  ☐ Federal  ☐ Foundation  ☐ Internal/Departmental  ☐ CRC  ☐ CRO  ☐ Massey  ☐ Foundation  ☐ Other: Click or tap here to enter text. | |
| Date of last monitoring visit and by whom: | | | Click or tap here to enter text.  Please email all monitoring reports to the PAM&E Self-Evaluation email address provided. | |
| Are the regulatory and study records available electronically or on paper? | | | | |
| Study Population | | | | |
| # of total participants enrolled\* | | Click or tap here to enter text. | | |
| # of participants enrolled since the last review\*\* | | Click or tap here to enter text. | | |
| *\*Enrolled refers to a person who has signed an informed consent document. Later, the individual may fail screening tests and/or decline further participation (or otherwise withdrawal from participation).*  *\*\*Enrolled since the last review refers to the number of participants enrolled since the last study renewal or status update.* | | | | |
| Vulnerable Populations | | | | |
| Please indicate if any of the following study populations are represented by enrolled persons:  \*Vulnerable populations with additional *regulatory* requirements | | ☐ Children\*  ☐ Pregnant Women, Fetuses, or Neonates\*  ☐ Prisoners\*  ☐ Decisionally Impaired Adults  ☐ Persons with Limited English Proficiency  ☐ Students/Residents  ☐ None of the above | | |
| Does your approval letter specify approval for all of those populations noted above? | | ☐ Yes  ☐ No: Click or tap here to enter text. are not listed. | | |
|  | | | | |
| **Please use this section to provide any additional study-specific information:**  Click or tap here to enter text. | | | | |

**1.** **REGULATORY DOCUMENTATION**

Reminder: if a problem has been identified, be sure to review the terms of approval (in your IRB approval letter) and search the new HRPP policies under the HRPP toolkit <https://research.vcu.edu/human-research/hrppirb/hrpp-policies-and-guidance/> to determine reporting requirements to the VCU IRB.

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Protocol Version | | | | | | | | | ***YES*** | | ***NO*** | | ***N/A*** |
| 1.1 | | | | Is the most recent version of the research plan/protocol on RAMS-IRB?   * If applicable, ask for the IRB Submission and Review Tracking Log | | | | | ☐ | | ☐ | | ☐ |
| 1.1.2 | | | | Are there previous versions of the research plan/protocol? ***(If no, go to 1.2)*** | | | | | ☐ | | ☐ | | ☐ |
| 1.1.3 | | | | If yes, are they on RAMS-IRB? | | | | | ☐ | | ☐ | | ☐ |
| 1.1.4 | | | | Are you able to identify each version and date of the protocol? | | | | | ☐ | | ☐ | | ☐ |
| 1.1.5 | | | | Are you tracking the version numbers and dates in a submission log? | | | | | ☐ | | ☐ | | ☐ |
| Regulatory Binder | | | | | | | | | ***YES*** | | ***NO*** | | ***N/A*** |
| 1.2 | | | | Are you keeping a Regulatory Binder to organize the study?   * If applicable, ask for the [Regulatory Binder Contents](https://research.vcu.edu/media/office-of-research-and-innovation/humanresearch/toolkitdocs/regulatory_binder.docx) | | | | | ☐ | | ☐ | | ☐ |
| FDA-Regulated Research | | | | | | | | | ***YES*** | | ***NO*** | | ***N/A*** |
| 1.3 | | | | Is this an FDA-regulated study? ***(If no, go to 1.4)*** | | | | | ☐ | | ☐ | | ☐ |
| 1.3.1 | | | | If yes, is there a signed 1572 uploaded to RAMS-IRB? | | | | | ☐ | | ☐ | | ☐ |
| 1.3.2 | | | | Is the Clinical Investigator Financial Disclosure form (FDA 3455 or 3454) uploaded to RAMS-IRB for each investigator? | | | | | ☐ | | ☐ | | ☐ |
| 1.3.3 | | | | Is all the correspondence to and from the sponsor on file? | | | | | ☐ | | ☐ | | ☐ |
| 1.3.4 | | | | Is study being conducted according to Good Clinical Practices standards?   * <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/good-clinical-practice> * [GCP Research Study Document Checklist](https://research.vcu.edu/media/office-of-research-and-innovation/humanresearch/toolkitdocs/GCP_research_study_document_checklist.docx) | | | | | ☐ | | ☐ | | ☐ |
| 1.3.5 | | | | What is the expected closure date on the FDA Letter of Agreement? | | | Click or tap here to enter text. | | | | | | |
| Federally-Sponsored Research | | | | | | | | | ***YES*** | | ***NO*** | | ***N/A*** |
| 1.4 | | | | Is this research activity federally sponsored or submitted for federal sponsorship? ***(If no, go to 1.5)*** | | | | | ☐ | | ☐ | | ☐ |
| 1.4.1 | | | | Is the protocol as originally submitted to the IRB congruent with the federal application? | | | | | ☐ | | ☐ | | ☐ |
| PI Sponsor-Investigator | | | | | | | | | ***YES*** | | ***NO*** | | ***N/A*** |
| 1.5 | | | | Is the PI the sponsor-investigator (i.e. IND/IDE holder)? ***(If no, go to 1.6)*** | | | | | ☐ | | ☐ | | ☐ |
| 1.5.1 | | | | Does the PI hold the IND/IDE? | | | | | ☐ | | ☐ | | ☐ |
| 1.5.2 | | | | If yes, is there a signed FDA 1571 on file (IND only)? | | | | | ☐ | | ☐ | | ☐ |
| 1.5.3 | | | | Have you submitted a copy to the IRB? | | | | | ☐ | | ☐ | | ☐ |
| 1.5.4 | | | | If yes, are there 1571s on file for the following:  Original application? | | | | | ☐ | | ☐ | | ☐ |
| 1.5.5 | | | | All amendments? | | | | | ☐ | | ☐ | | ☐ |
| 1.5.6 | | | | Annual Reports? | | | | | ☐ | | ☐ | | ☐ |
| 1.5.7 | | | | Who (organization or individual) is listed as the monitor in Section 14 of the 1571? | | Click or tap here to enter text. | | | | | | | |
| Training and Experience | | | | | | | | ***YES*** | | ***NO*** | | ***N/A*** | |
| 1.6 | | | Have all key study personnel (including PI, Sub/Co-PIs, and all other staff who interact/intervene with research participants or their identifiable data) completed the Basic CITI course in Biomedical Research and/or Social Behavioral Research?   * <https://about.citiprogram.org/en/homepage/> | | | | | ☐ | | ☐ | | ☐ | |
| 1.6.1 | | | If applicable, is the CITI Refresher up to date? | | | | | ☐ | | ☐ | | ☐ | |
| 1.6.2 | | | Are all current CITI Certificates on file? | | | | | ☐ | | ☐ | | ☐ | |
| 1.6.3 | | | If applicable, has the IRB approved an alternative research ethics training program?  Please explain below. | | | | | ☐ | | ☐ | | ☐ | |
| 1.6.4 | | | Is the study personnel roster up to date? | | | | | ☐ | | ☐ | | ☐ | |
| 1.6.5 | | | Have all key personnel received appropriate training on execution of the protocol? Please explain below. | | | | | ☐ | | ☐ | | ☐ | |
| 1.6.6 | | | Are there CVs of PI/CO-PI and all study staff on file? ***(If no, go to 1.6.7)*** | | | | | ☐ | | ☐ | | ☐ | |
| 1.6.6.1 | | | Are filed CVs updated within the past two years and signed and dated? | | | | | ☐ | | ☐ | | ☐ | |
| 1.6.7 | | | Is the study being conducted on a clinical inpatient or outpatient unit? ***(If no, go to 1.6.8)*** | | | | | ☐ | | ☐ | | ☐ | |
| 1.6.7.1 | | | If yes, has the unit staff been informed and trained on the protocol? | | | | | ☐ | | ☐ | | ☐ | |
| 1.6.8 | | | Does the study team have the time and resources available to do the work?  If no, please indicate what is needed below. | | | | | ☐ | | ☐ | | ☐ | |
| 1.6.9 | | | Does the study team attend educational events?  Please note areas of further training that would be helpful below. | | | | | ☐ | | ☐ | | ☐ | |
| Enrollment | | | | | | | | ***YES*** | | ***NO*** | | ***N/A*** | |
| 1.7 | | | Is there a subject screening/enrollment log? ***(If no, go to 1.8)*** | | | | | ☐ | | ☐ | | ☐ | |
| 1.7.1 | | | If yes, is the subject enrollment log up to date? | | | | | ☐ | | ☐ | | ☐ | |
| Monitoring | | | | | | | | ***YES*** | | ***NO*** | | ***N/A*** | |
| 1.8 | | | Is the study site *externally* monitored (by sponsor or DSMB)? ***(If no, go to 1.9)*** | | | | | ☐ | | ☐ | | ☐ | |
| 1.8.1 | | | If yes, is there a monitoring log? | | | | | ☐ | | ☐ | | ☐ | |
| 1.8.2 | | | Is the monitoring log up to date? | | | | | ☐ | | ☐ | | ☐ | |
| 1.8.3 | | | How frequently is the site monitored? | | Click or tap here to enter text. | | | | | | | | |
| Staff Signature Log | | | | | | | | ***YES*** | | ***NO*** | | ***N/A*** | |
| 1.9 | | | Is there a staff signature log? ***(If no, go to 1.10)*** | | | | | ☐ | | ☐ | | ☐ | |
| 1.9.1 | | | If yes, is the staff signature log up to date? | | | | | ☐ | | ☐ | | ☐ | |
| 1.9.2 | | | Does the staff signature log include information regarding delegation of responsibility? | | | | | ☐ | | ☐ | | ☐ | |
| Investigational Drugs, Devices, Biologics | | | | | | | | ***YES*** | | ***NO*** | | ***N/A*** | |
| 1.10 | | Is this an investigational drug or device study? ***(If no, go to 1.11)*** | | | | | | ☐ | | ☐ | | ☐ | |
|  | | Is there an updated accountability log? | | | | | | ☐ | | ☐ | | ☐ | |
| 1.10.1 | | If yes, are all versions of the Investigator Brochure, Labeling, or Device Manual on file? | | | | | | ☐ | | ☐ | | ☐ | |
| 1.10.2 | | Is there package insert/product information on file? Other labeling? | | | | | | ☐ | | ☐ | | ☐ | |
| Laboratory Records | | | | | | | | ***YES*** | | ***NO*** | | ***N/A*** | |
| 1.11 | | Are lab tests required? ***(If no, go to 1.12)*** | | | | | | ☐ | | ☐ | | ☐ | |
| 1.11.1 | | Is a copy of the normal lab values on file? | | | | | | ☐ | | ☐ | | ☐ | |
| 1.11.2 | | Is lab certification on file, (e.g. CLIA)? If this is an IND study, documentation for all laboratories listed on the FDA form 1572 must be on file. | | | | | | ☐ | | ☐ | | ☐ | |
| 1.11.3 | | Does this study use a CLIA certified Lab? | | | | | | ☐ | | ☐ | | ☐ | |
| 1.11.4 | | Is the lab director’s CV on file (signed and dated)?  This should be updated every 2 years. | | | | | | ☐ | | ☐ | | ☐ | |
| Data Safety Monitoring | | | | | | | | ***YES*** | | ***NO*** | | ***N/A*** | |
| 1.12 | Is there a data safety monitoring plan (DSMP) for this study? | | | | | | | ☐ | | ☐ | | ☐ | |
| 1.12.1 | If yes, does the plan involve a Data Safety Monitoring Board (DSMB)? | | | | | | | ☐ | | ☐ | | ☐ | |
| 1.12.2 | If yes, has the DSMB met in accordance with the IRB approved protocol?  Please note how frequently below. | | | | | | | ☐ | | ☐ | | ☐ | |
| 1.12.3 | Are appropriate DSMB reports or indication of DSMB reviews and recommendations on file?  Provide the number of DSMB reviews and dates below. | | | | | | | ☐ | | ☐ | | ☐ | |
| Incidental Findings | | | | | | | | ***YES*** | | ***NO*** | | ***N/A*** | |
| 1.13 | Do you have a plan for communicating potentially clinically significant incidental findings to subjects? | | | | | | | ☐ | | ☐ | | ☐ | |
| 1.13.1 | If yes, is the plan described in the RAMS-IRB submission and Informed Consent Document? | | | | | | | ☐ | | ☐ | | ☐ | |
| 1.13.2 | Have you read the President’s Bioethics Commission report? [Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to-Consumer Contexts (Dec, 2013)](https://bioethicsarchive.georgetown.edu/pcsbi/sites/default/files/FINALAnticipateCommunicate_PCSBI_0.pdf) | | | | | | | ☐ | | ☐ | | ☐ | |
|  | | | | | | | | | | | | | |
| **Please describe any areas of concern identified, action(s) to take or taken, and other notes:**  Click or tap here to enter text. | | | | | | | | | | | | | |

**2.** **IRB DOCUMENTATION**

Reminder: if a problem has been identified, be sure to review the terms of approval (in your IRB approval letter) and search search the new HRPP toolkit policies here <https://research.vcu.edu/human-research/hrppirb/hrpp-policies-and-guidance/> to determine reporting requirements to the VCU IRB.

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| General IRB Correspondence | | | | | | ***YES*** | | ***NO*** | ***N/A*** |
| 2.1 | Is all correspondence (signed/dated applications, responses, approvals) to the IRB on file (if paper copies)? | | | | | ☐ | | ☐ | ☐ |
| 2.1.1 | Is other correspondence (e.g., emails) to and from the IRB available? | | | | | ☐ | | ☐ | ☐ |
| Initial Review | | | | | | ***YES*** | | ***NO*** | ***N/A*** |
| 2.2 | Is the initial IRB approval letter on file? | | | | | ☐ | | ☐ | ☐ |
| Continuing Review | | | | | | ***YES*** | | ***NO*** | ***N/A*** |
| 2.3 | Has a continuing review occurred? ***(If no, go to section 2.4)*** | | | | | ☐ | | ☐ | ☐ |
| 2.3.1 | Total number of continuing review submissions, thus far? | | | #: Click or tap here to enter text. | | | | | |
| 2.3.2 | Please describe the most recent continuing review history (according to your records) ***by profiling the last 3 cycles of continuing review below:*** | | | |  | |  | | |
| ***Cycle 1*** | | | | | | | | | |
| Date Continuing Review submitted: | | Click or tap here to enter text. | | | | | | | |
| Date approved by the IRB: | | Click or tap here to enter text. | | | | | | | |
| Is the IRB approval letter on file? | | ☐ YES | ☐ NO | | | | | | |
| Number of enrolled subjects reported: | | ***#*** Click or tap here to enter text. | | | | | | | |
| *Notes:* Click or tap here to enter text. | | | | | | | | | |
| ***Cycle 2*** | | | | | | | | | |
| Date Continuing Review submitted: | | Click or tap here to enter text. | | | | | | | |
| Date approved by the IRB: | | Click or tap here to enter text. | | | | | | | |
| Is the IRB approval letter on file? | | ☐ YES | ☐ NO | | | | | | |
| Number of enrolled subjects reported: | | ***#*** Click or tap here to enter text. | | | | | | | |
| *Notes:* Click or tap here to enter text. | | | | | | | | | |
| ***Cycle 3*** | | | | | | | | | |
| Date Continuing Review submitted: | | Click or tap here to enter text. | | | | | | | |
| Date approved by the IRB: | | Click or tap here to enter text. | | | | | | | |
| Is the IRB approval letter on file? | | ☐ YES | ☐ NO | | | | | | |
| Number of enrolled subjects reported: | | ***#*** Click or tap here to enter text. | | | | | | | |
| *Notes:* Click or tap here to enter text. | | | | | | | | | |

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| ***Continuing Review (cont.)*** | | | | | | | ***YES*** | | ***NO*** | ***N/A*** |
| 2.3.3 | Was each Continuing Review submitted by the IRB due date? | | | | | | ☐ | | ☐ | ☐ |
| 2.3.4 | Was there any lapsed period(s) between expiration date and Continuing Review approval date? ***(If no, go to 2.4)*** | | | | | | ☐ | | ☐ | ☐ |
| 2.3.5 | Were any subjects enrolled during this lapse period? | | | | | | ☐ | | ☐ | ☐ |
| 2.3.6 | If yes, was a protocol violation reported to the VCU IRB? | | | | | | ☐ | | ☐ | ☐ |
| 2.3.7 | Was any study procedure conducted during the lapse period? ***(If no, go to 2.4)***  Please explain below. | | | | | | ☐ | | ☐ | ☐ |
| 2.3.8 | If yes, were they justified in writing in order to ensure the safety/well-being of the research subject (and approved by the VCU IRB)? | | | | | | ☐ | | ☐ | ☐ |
| Changes in Research (Amendments) | | | | | | | YES | | ***NO*** | ***N/A*** |
| 2.4 | Have there been **any** changes to the study since your initial approval? ***(If no, got to 3.1)*** | | | | | | ☐ | | ☐ | ☐ |
| 2.4.1 | If there have been changes to the study, were the amendments approved by the IRB prior to implementation (unless necessary to ensure the safety of the research subjects)? | | | | | | ☐ | | ☐ | ☐ |
| 2.4.2 | Were there any changes to the study that were not IRB-approved?  Describe below. | | | | | | ☐ | | ☐ | ☐ |
| 2.4.3 | How many amendments have been submitted to the IRB since the date of initial IRB approval (or, if approval extends beyond 3 years ago, identify the number of amendments submitted in the past 3 years)? | | | | | ***#:*** Click or tap here to enter text. | | | | |
| 2.4.4 | Use the following grid to summarize the amendment history. | | | | |  | |  | | |
| ***Amendment***  ***Summary*** | | **Date Submitted** | | ***Date Approved*** | **What document(s) were submitted?** | ***IRB approval letter on file?*** | | | | |
|  | | |  |  |  | | ***YES*** | | ***NO*** | ***N/A*** |
| ***Total number of amendments to date:***  Click or tap here to enter text. | | | Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | | ☐ | | ☐ | ☐ |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | | ☐ | | ☐ | ☐ |
| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | | ☐ | | ☐ | ☐ |
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| Click or tap here to enter text. | Click or tap here to enter text. | Click or tap here to enter text. | | ☐ | | ☐ | ☐ |
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| **Please describe any areas of concern identified, action(s) to take or taken, and other notes:**  Click or tap here to enter text. | | | | | | | | | | |

**3.** **SUBJECT SELECTION CRITERIA**

To complete the optional exercise in section 3.2, use the subject study files chosen for review in section 5.1 (below) to complete the following questions pertaining to subject selection criteria. Add additional space as necessary to accommodate the number of chosen subjects. If a NO response is given in this section, you may have identified a potential compliance problem. Reminder: if a problem has been identified, be sure to review the terms of approval (in your IRB approval letter) and search the new HRPP toolkit policies here [https://research.vcu.edu/human-research/hrppirb/hrpp-policies-and-guidance/](https://research.vcu.edu/human-research/hrppirb/hrpp-policies-and-guidance/%20) to determine reporting requirements to the VCU IRB.

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| --- | --- | --- | --- | --- | --- |
| Subject Selection | | | ***YES*** | ***NO*** | ***N/A*** |
| 3.1 | Is there an eligibility screening log containing inclusion/exclusion criterion? ***(If no, skip to 3.3)*** | | ☐ | ☐ | ☐ |
| 3.2 | (**Optional Exercise**) Does each subject file indicate whether the subject was included/excluded appropriately? (An eligibility checklist is typically completed and then signed/initialed by the research staff member who is determining eligibility.) | |  |  |  |
|  | | ***YES*** | ***NO*** | ***N/A*** |
| Subject #1: | | ☐ | ☐ | ☐ |
| Subject #2: | | ☐ | ☐ | ☐ |
| Subject #3: | | ☐ | ☐ | ☐ |
| Subject #4: | | ☐ | ☐ | ☐ |
| Subject #5: | | ☐ | ☐ | ☐ |
| 3.3 | Are there any enrollment issues (such as slow enrollment)? | | ☐ | ☐ | ☐ |
| 3.4 | According to your enrollment goal (described in the RAMS-IRB submission), are you on target for your enrollment goal? | | ☐ | ☐ | ☐ |
| 3.4.1 | If any subjects did not meet the eligibility criteria (and were enrolled), was this reported to the IRB (as a protocol deviation or violation)? | | ☐ | ☐ | ☐ |
| 3.5 | Do the subjects enrolled reflect equitability, allowing for distribution of the research risk among persons (race, gender, etc.) who have a potential for future benefit? | | ☐ | ☐ | ☐ |
| 3.6 | Does the current distribution of subjects (by race, gender, etc.) meet expectations (outlined within the protocol or at the time of IRB submission)? | | ☐ | ☐ | ☐ |
| **3.7** | **Number of subjects excluded:** | ***#:*** Click or tap here to enter text. | | | |
| **3.8** | **Number of subjects who withdrew:** | ***#:*** Click or tap here to enter text. | | | |
| 3.9 | If enrollment is low relative to goal, is there a plan to meet the goal?  Please describe plan below. | | ☐ | ☐ | ☐ |
| 3.9.1 | Do you plan to continue recruitment/enrollment/interventions? | | ☐ | ☐ | ☐ |
| 3.10 | If compensation provided, is it consistent with protocol and IRB approval? | | ☐ | ☐ | ☐ |
| 3.10.1 | Is amount and type of compensation still appropriate? | | ☐ | ☐ | ☐ |
|  | | | | | |
| **Please describe any areas of concern identified, action(s) to take or taken, and other notes:**  Click or tap here to enter text. | | | | | |

**4.** **SUBJECT RECRUITMENT PROCEDURES**

If a problem has been identified, be sure to review the terms of approval (in your IRB approval letter) and search <https://research.vcu.edu/human-research/hrppirb/hrpp-policies-and-guidance/> to determine reporting requirements to the VCU IRB.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Recruitment | | | | |
| 4.1 | How are potential subjects identified?  *(check all recruitment methods that apply)* | ☐ Clinical practice  ☐ Investigator(s)  ☐ Database  ☐ Medical record review  ☐ Treating physician or PCP  ☐ Subject response to recruitment materials  ☐ Subject response to direct mail  ☐ Other: Click or tap here to enter text. | | |
|  | | ***YES*** | ***NO*** | ***N/A*** |
| 4.2 | Are recruitment ***methods*** (identified above) stated in the IRB approved protocol? | ☐ | ☐ | ☐ |
| 4.3 | Is initial contact made in compliance with the IRB-approved protocol? | ☐ | ☐ | ☐ |
| 4.4 | Is this a community-based study? | ☐ | ☐ | ☐ |
| 4.4.1 | Have there been community forums to explain the study?  If so, # Click or tap here to enter text. | ☐ | ☐ | ☐ |
| 4.4.2 | Are community members/leaders involved in your study? | ☐ | ☐ | ☐ |
| 4.5 | If recruitment ***materials*** have been used, please check all that apply: | ☐ None Used ***(Go to 4.7)***  ☐ Print Advertisements (print or postings)  ☐ Televised or Radio Advertisements  ☐ Flyers  ☐ Email/Web postings  ☐ Letters  ☐ Pre-screening forms  ☐ Other: Click or tap here to enter text. | | |
|  | | ***YES*** | ***NO*** | ***N/A*** |
| 4.5.1 | Have all recruitment materials (identified above) been approved by the IRB? | ☐ | ☐ | ☐ |
| 4.5.2 | Are all approved recruitment materials (identified above) uploaded to RAMS-IRB? | ☐ | ☐ | ☐ |
| 4.5.3 | Were changes made to recruitment materials since last continuing review?  If you are dropping use of some recruitment materials, please note below. ***(If no, go to section 4.7)*** | ☐ | ☐ | ☐ |
| 4.5.4 | If yes, was an amendment submitted to the IRB? | ☐ | ☐ | ☐ |
| 4.6 | Is a pre-screening telephone interview conducted?  ***(If no, go to 4.7)*** | ☐ | ☐ | ☐ |
| 4.6.1 | If yes, is the script stamped with an approval by the VCU IRB? | ☐ | ☐ | ☐ |
| 4.7 | Is recruitment/enrollment at the expected level for this study? | ☐ | ☐ | ☐ |
| 4.7.1 | What is the rate of recruitment (per month)? | Click or tap here to enter text. | | |
| 4.8 | Estimated closure date for this study: | Click or tap here to enter text. | | |
|  | | | | |
| **Please use this space to describe any areas of concern, action(s) to take or taken, and other notes:**  Click or tap here to enter text. | | | | |

**5.** **INFORMED CONSENT PROCESS**

This section pertains to the documentation of procedures used for the informed consent process.

Reminder: if a problem has been identified, be sure to review the terms of approval (in your IRB approval letter) and search the new HRPP toolkit policies <https://research.vcu.edu/human-research/hrppirb/hrpp-policies-and-guidance/> to determine reporting requirements to the VCU IRB.

For consent templates and guidance see: <http://www.research.vcu.edu/human_research/guidance.htm#informed_consent>.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Informed Consent | | | | | | |
| 5.1 | Please identify all consent/assent documents **currently in use** by the date approved by the VCU IRB. *NOTE: Date of IRB stamp on a current consent document should NOT exceed 365 days.* | | | | | |
|  | | ***Version ID (your code):*** | ***Valid/IRB Approval Date:*** | | | |
| 5.1.1 | | Click or tap here to enter text. | Click or tap here to enter text. | | | |
| 5.1.2 | | Click or tap here to enter text. | Click or tap here to enter text. | | | |
| 5.1.3 | | Click or tap here to enter text. | Click or tap here to enter text. | | | |
| 5.1.4 | | Click or tap here to enter text. | Click or tap here to enter text. | | | |
| 5.1.5 | | Click or tap here to enter text. | Click or tap here to enter text. | | | |
|  | | | | ***YES*** | ***NO*** | ***N/A*** |
| 5.2 | Are you keeping an Informed Consent Revision log? | | | ☐ | ☐ | ☐ |
| 5.3 | Are all-prior IRB-approved versions of the IRB approved consent forms available? | | | ☐ | ☐ | ☐ |
| 5.4 | Does the place where you obtain informed consent allow the participants to preserve their privacy? | | | ☐ | ☐ | ☐ |
| 5.5 | Is the consent form read to the subject and discussed/left with them? | | | ☐ | ☐ | ☐ |
| 5.5.1 | Are subjects given a copy to take home? | | | ☐ | ☐ | ☐ |
| 5.5.2 | Is this noted in the subject’s research file or subject log? | | | ☐ | ☐ | ☐ |
| 5.5.3 | Is consent a continuous process? If yes, when does this begin after the initial consent and the frequency thereafter?  Please note below. | | | ☐ | ☐ | ☐ |
| 5.6 | Do you provide educational materials to subject? | | | ☐ | ☐ | ☐ |
| 5.6.1 | Are the educational materials uploaded to RAMS-IRB? | | | ☐ | ☐ | ☐ |
| 5.7 | Will there be re-contacting for any reason? | | | ☐ | ☐ | ☐ |
| 5.7.1 | Is information on re-contacting the subject in the consent form? | | | ☐ | ☐ | ☐ |
|  | | | | | | |
| **Please describe any areas of concern identified, action(s) to take or taken, and other notes:**  Click or tap here to enter text. | | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ***Informed Consent – File Review Exercise*** | | | | | | | | | | |
| 5.8 | Randomly choose 5 or more subject files for review. Using each subject file, complete the information below. Be sure to identify subjects by codes (combined letters and numbers that cannot be linked to the subject) that cannot be easily linked to individuals by those outside of the research staff. Add additional space as necessary to accommodate the number of subject files chosen. NOTE: you may want to keep these files handy in order to answer questions in sections 5 and 6 also. ***(If no subjects have been enrolled, go directly to section 6.)***  ***REMINDER: Signed informed consent documents contain identifiers and should be carefully guarded to respect the privacy of the research volunteer.*** | | | | | | | | |
| ***Subject***  ***Code*** | | ***Did the subject or LAR sign the consent/assent document?*** | | ***What date did the subject or LAR sign the consent/assent document?*** | ***Indicate the VCU IRB approval stamp date for the consent/assent form signed by the subject or LAR:*** | ***Did the PI sign the consent document?*** | | ***Is it documented in the study files that the subject received a copy of the signed/dated consent document?*** | | |
| ***Code Only*** | | ***YES*** | ***NO*** | ***DATE*** | ***DATE*** | ***YES*** | ***NO*** | ***YES*** | ***NO*** | |
| Click or tap here to enter text. | | ☐ | ☐ | Click or tap here to enter text. | Click or tap here to enter text. | ☐ | ☐ | ☐ | ☐ | |
| Click or tap here to enter text. | | ☐ | ☐ | Click or tap here to enter text. | Click or tap here to enter text. | ☐ | ☐ | ☐ | ☐ | |
| Click or tap here to enter text. | | ☐ | ☐ | Click or tap here to enter text. | Click or tap here to enter text. | ☐ | ☐ | ☐ | ☐ | |
| Click or tap here to enter text. | | ☐ | ☐ | Click or tap here to enter text. | Click or tap here to enter text. | ☐ | ☐ | ☐ | ☐ | |
| Click or tap here to enter text. | | ☐ | ☐ | Click or tap here to enter text. | Click or tap here to enter text. | ☐ | ☐ | ☐ | ☐ | |
|  | | | | | | | | | | |
| **Please describe any areas of concern identified, action(s) to take or taken, and other notes:**  Click or tap here to enter text. | | | | | | | | | | |

***6.*** **RISK/BENEFIT**

Reminder: if a problem has been identified, be sure to review the terms of approval (in your IRB approval letter) and search the new HRPP toolkit policies [here https://research.vcu.edu/human-research/hrppirb/hrpp-policies-and-guidance/](file:///C:\Users\olversonl\Downloads\here%20https:\research.vcu.edu\human-research\hrppirb\hrpp-policies-and-guidance\) to determine reporting requirements to the VCU IRB.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Risk/Benefit | | ***YES*** | ***NO*** | ***N/A*** |
| 6.1 | Have risk/benefits changed since last submission?  If so, please provide details below. | ☐ | ☐ | ☐ |
| 6.2 | Have participants experienced any benefits? | ☐ | ☐ | ☐ |
| 6.3 | Is there any new relevant risk related information regarding this research? | ☐ | ☐ | ☐ |
| 6.3.1 | If yes, has the RAMS-IRB submission been amended? | ☐ | ☐ | ☐ |
| 6.3.2 | If yes, have the Informed Consent document been updated? | ☐ | ☐ | ☐ |
| 6.4 | Please complete the Risk Evaluation/Mitigation Table and email it to the PAM&E email address provided. | | | |
| 6.5 | If there is any risk that participation in the study will be upsetting to the subject, is there a plan for managing the situation? | ☐ | ☐ | ☐ |
| 6.6 | If the study involves “deception”, is there a plan to inform/debrief subjects after their participation in the study? | ☐ | ☐ | ☐ |
| 6.6.1 | Do you have a script for the debriefing session? | ☐ | ☐ | ☐ |
| 6.7 | Will you be recording subjects in any manner (audio and/or video)? | ☐ | ☐ | ☐ |
| 6.7.1 | Will people be identifiable on the recordings? | ☐ | ☐ | ☐ |
| 6.7.2 | Do you have extra security protections in place for storage of the recordings? | ☐ | ☐ | ☐ |
|  | | | | |
| **Please use this space to describe any areas of concern, action(s) to take or taken, and other notes:**  Click or tap here to enter text. | | | | |

**7.** **UNANTICIPATED PROBLEM, ADVERSE EVENT, SERIOUS ADVERSE EVENT REPORTING**

If there have been no problem reports, ***go to section 8***. Reminder: if a problem has been identified, be sure to review the terms of approval (in your IRB approval letter) and search the new HRPP toolkit policies here <https://research.vcu.edu/human-research/hrppirb/hrpp-policies-and-guidance/> to determine reporting requirements to the VCU IRB.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Refer to the VCU IRB Reporting guidelines above as you answer the following: | | ***YES*** | ***NO*** | | ***N/A*** | |
| 7.1 | Have all Unanticipated Problems (UPs) been reported according to the  VCU IRB guidelines? | ☐ | ☐ | | ☐ | |
| 7.2 | Number of Unanticipated Problems (UPs) in history of study?  If there have been UPs, please describe the problem(s) and the actions  taken to resolve the problems in the space below. | | ***#:*** Click or tap here to enter text. | | | |
| 7.3 | Have there been any complaints from subjects?  If so, explain below. | ☐ | ☐ | | ☐ | |
| 7.4 | In this review, have there been any UPs (including unanticipated AEs/SAEs)  identified that have not been reported to the VCU IRB? | ☐ | ☐ | | ☐ | |
| 7.5 | Have all UPs (including unanticipated AEs/SAEs) been reported to the sponsor and/or  FDA (as applicable)? *Note: Some sponsors may require the submission of*  *expected adverse events. Device studies require the submission of all adverse*  *events and unanticipated problems. If the investigator is the holder of the IND,*  *direct submission to regulatory agencies is required.* | ☐ | ☐ | | ☐ | |
| 7.6 | How many RAMS-IRB reports are pending follow-up (review and action still in  progress since initial reporting to the VCU IRB)? | | ***#:*** Click or tap here to enter text. | | | |
| 7.7 | Is the UP/AE/SAE reporting requirement to the VCU IRB clear?  If no, note question or concern below. | ☐ | | ☐ | | ☐ |
| 7.8 | Is the UP/AE/SAE reporting requirement to the sponsor or regulatory agencies  clear?  If no, note question or concern below. | ☐ | | ☐ | | ☐ |
|  | | | | | | |
| **Please describe any areas of concern identified, action(s) to take or taken, and other notes:**  Click or tap here to enter text. | | | | | | |

**8.** **PROTOCOL DEVIATION REPORTING**

Please use the following checklist to evaluate the documented management of protocol violations and/or deviations and their reporting to the VCU IRB. Reminder: if a problem has been identified, be sure to review the terms of approval (in your IRB approval letter) and search the new HRPP Toolkit policies here [https://research.vcu.edu/human-research/hrppirb/hrpp-policies-and-guidance/](https://research.vcu.edu/human-research/hrppirb/hrpp-policies-and-guidance/%20) to determine reporting requirements to the VCU IRB.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Protocol Deviations | | | ***YES*** | ***NO*** | ***N/A*** | |
| 8.1 | Does your study have a plan for documenting protocol deviations? | | ☐ | ☐ | ☐ | |
| 8.2 | Have there been protocol deviations? If so please describe the kind of deviations, the number of deviations and steps taken to prevent further deviation | | ☐ | ☐ | ☐ | |
| 8.2.1 | Have all protocol deviations been reported to the VCU IRB if they involved increased risk to research participants or others?  *Note: Withdrawal from a research protocol or missed dosing (unless the action of withdrawal or missed dose leads to potential added risk) is not necessarily a protocol deviation or violation.* | | ☐ | ☐ | ☐ | |
| 8.2.2 | Have all deviations been approved by or reported to the sponsor (as appropriate/required)? | | ☐ | ☐ | ☐ | |
| 8.3 | How many protocol deviations have been reported to the VCU IRB in the past 12 months, if any? | ***#:*** Click or tap here to enter text. | | | | |
| 8.4 | Do you keep a log of Problem Reports? (see links at 7.1) | | ☐ | ☐ | ☐ | |
| 8.4.1 | If yes, is it up to date? | | ☐ | ☐ | ☐ | |
|  | | | | | |
| **Please describe any areas of concern identified, action(s) to take or taken, and other notes:**  Click or tap here to enter text. | | | | | |

**9.** **REGISTRY/REPOSITORY**

Please use the following checklist to evaluate the registry/repository. ***If this study does not involve a registry, go to section 10.*** If a NO response is given in this section, you may have identified a potential compliance problem. Reminder: if a problem has been identified, be sure to review the terms of approval (in your IRB approval letter) and search the new HRPP Toolkit policies here [https://research.vcu.edu/human-research/hrppirb/hrpp-policies-and-guidance/](https://research.vcu.edu/human-research/hrppirb/hrpp-policies-and-guidance/%20) to determine reporting requirements to the VCU IRB.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Registry/Repository | | | | | | |
| 9.1 | Is this a: | | ☐ Registry  ☐ Repository  ☐ Registry & Repository  ☐ Other: Click or tap here to enter text. | | | |
| 9.2 | Who is responsible for: | Click or tap here to enter text. | ☐ Receiving and sending data/specimens  ☐ Storage and data maintenance  ☐ Website maintenance (if applicable)  ☐ Cleaning data and coordinating incoming  data/specimens  ☐ Other: Click or tap here to enter text. | | | |
| Click or tap here to enter text. |
| Click or tap here to enter text. |
| Click or tap here to enter text. |
| Click or tap here to enter text. |
| 9.3 | If the data/specimens are coded, who will maintain the key? | | ☐ Investigator  ☐ Research Nurse  ☐ Coordinator  ☐ Other: Click or tap here to enter text. | | | |
| 9.4 | Who will be using the data/specimens now and in the future? *(check all that apply)* | | ☐ Investigators on the registry/repository roster  ☐ Other researchers at VCU/VCUHS  ☐ Researchers outside VCU/VCUHS  ☐ International Researchers –  Locations: Click or tap here to enter text. | | | |
| 9.5 | Registry/Repository database will include: | | ☐ Identifiers  ☐ HIPAA data  ☐ Private Personal Data  ☐ Sensitive Data (drug, alcohol use, mental health, criminal activity, illnesses, community information, etc.  ☐ Coded data/Specimens  ☐ Other: Click or tap here to enter text. | | | |
| 9.6 | Data/Specimens shared with investigators will include: | | ☐ Identifiers  ☐ HIPAA data  ☐ Private Personal Data  ☐ Sensitive Data (drug, alcohol use, mental health, criminal activity, illnesses, community information, etc.  ☐ Coded data/Specimens  ☐ Other: Click or tap here to enter text. | | | |
| ***Registry/Repository (cont.)*** | | | | ***YES*** | ***NO*** | ***N/A*** |
| 9.7 | Are there written policies and procedures that explain how the registry/repository functions and the organizational structure? | | | ☐ | ☐ | ☐ |
| 9.8 | Are other PIs able to apply to use data/specimens? | | | ☐ | ☐ | ☐ |
| 9.9 | Are other PIs able to apply to donate data/specimens? | | | ☐ | ☐ | ☐ |
| 9.9.1 | Are there forms for these PIs to fill out to make these requests? | | | ☐ | ☐ | ☐ |
| 9.9.2 | Is there a committee of non-affiliated experts to vet these requests and PIs? | | | ☐ | ☐ | ☐ |
| 9.10 | Do you require applicant PIs to provide IRB approval letters for their study? | | | ☐ | ☐ | ☐ |
| 9.11 | Do you require applicant PIs to provide proof their Informed Consent document allows for their data/specimens to be used for the proposed area of research? | | | ☐ | ☐ | ☐ |
| 9.11.1 | Does the consent allow the subject to agree to the data being used for future research? | | | ☐ | ☐ | ☐ |
| 9.12 | Will shared data/specimens contain identifiers? | | | ☐ | ☐ | ☐ |
| 9.13 | Are you charging for PIs for receipt of data/specimens? | | | ☐ | ☐ | ☐ |
| 9.14 | Do you use a data use or data security for any data (with identifiers) that is going outside the VCU/VCUHS system? | | | ☐ | ☐ | ☐ |
| 9.15 | Is the registry/repository housed at VCU/VCUHS?  If not, provide the name and contact information for the registry/repository below. | | | ☐ | ☐ | ☐ |
| 9.16 | Has this registry/repository been approved with a waiver of consent or waiver of documentation of consent? | | | ☐ | ☐ | ☐ |
| 9.17 | Is there any possibility you will need to recontact subjects? | | | ☐ | ☐ | ☐ |
| 9.17.1 | If subjects cannot be reached with current contact information, what methods will you employ to reach subjects? | | Click or tap here to enter text. | | | |
|  | | | | | | |
| **Please describe any areas of concern identified, action(s) to take or taken, and other notes:**  Click or tap here to enter text. | | | | | | |

**10.** **GENETIC DATA**

Please use the following checklist to evaluate the documented management of collection of genetic material, storage and use. ***If this study does not involve genetic material, go to section 11.*** If a NO response is given in this section, you may have identified a potential compliance problem. Reminder: if a problem has been identified, be sure to review the terms of approval (in your IRB approval letter) and search the new HRPP Toolkit policies here <https://research.vcu.edu/human-research/hrppirb/hrpp-policies-and-guidance/> to determine reporting requirements to the VCU IRB.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Genetic Data | | | ***YES*** | ***NO*** | ***N/A*** |
| 10.1 | Do participants have the option to decline donation of their genetic material and still become/remain a subject in the study? | | ☐ | ☐ | ☐ |
| 10.2 | Will you be storing/maintaining the genetic material long enough that tests may be developed/run on the samples that could produce “incidental findings” that may be clinically significant? | | ☐ | ☐ | ☐ |
| 10.2.1 | If yes, do you have a plan for communicating potentially clinically significant incidental findings to subjects? | | ☐ | ☐ | ☐ |
| 10.2.2 | If yes, is the plan described in the RAMS-IRB submission and Informed Consent Document? | | ☐ | ☐ | ☐ |
| 10.2.3 | Do subjects have the option to decline receiving clinically significant incidental findings? | | ☐ | ☐ | ☐ |
| 10.2.4 | Have you read the President’s Bioethics Commission report: [Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to-Consumer Contexts (Dec, 2013)](https://bioethicsarchive.georgetown.edu/pcsbi/sites/default/files/FINALAnticipateCommunicate_PCSBI_0.pdf) | | ☐ | ☐ | ☐ |
| 10.3 | Will you be submitting any genetic data to NIH GWAS? | | ☐ | ☐ | ☐ |
| 10.4 | Do subjects have the option to have their samples withdrawn from the study? | | ☐ | ☐ | ☐ |
| 10.4.1 | Is there a point when subjects can no longer withdraw their genetic data? | | ☐ | ☐ | ☐ |
| 10.5 | Is there appropriate documentation for the return or destruction of the genetic sample if requested by the subject? | | ☐ | ☐ | ☐ |
| 10.6 | Have any subjects requested withdrawal or destruction of their genetic material/data? | | ☐ | ☐ | ☐ |
| 10.7 | Is the genetic material/data stored in a secure location?  Please note location below. | | ☐ | ☐ | ☐ |
| 10.8 | Are all freezer storage units (where genetic samples are stored) locked? | | ☐ | ☐ | ☐ |
| 10.9 | Are temperature/humidity logs maintained for all stored material? | | ☐ | ☐ | ☐ |
| 10.10 | Is a dispensing and accountability log being maintained? | | ☐ | ☐ | ☐ |
| 10.11 | Who is responsible for collecting and storing? | ☐ Investigator  ☐ Study Staff  ☐ Other: Click or tap here to enter text. | | | |
| 10.12 | Who is the person authorized to release genetic material/data? | ☐ Investigator  ☐ Research Nurse  ☐ Coordinator  ☐ Other: Click or tap here to enter text. | | | |
|  | | | | | |
| **Please describe any areas of concern identified, action(s) to take or taken, and other notes:**  Click or tap here to enter text. | | | | | |

**11.** **DRUG/DEVICE ACCOUNTABILITY**

Please use the following checklist to evaluate the documented management of drug/device storage and dispensing accountability. ***If this is not a drug/device study, go to section 12.*** If a NO response is given in this section, you may have identified a potential compliance problem. Reminder: if a problem has been identified, be sure to review the terms of approval (in your IRB approval letter) and search the new HRPP Toolkit policies here [https://research.vcu.edu/human-research/hrppirb/hrpp-policies-and-guidance/](https://research.vcu.edu/human-research/hrppirb/hrpp-policies-and-guidance/%20) to determine reporting requirements to the VCU IRB.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Drug/Device | | | | | |
| 11.1 | Who is responsible for shipping/receiving? | ☐ Investigator  ☐ Investigational Drug Pharmacy  ☐ Study Staff  ☐ Other: Click or tap here to enter text. | | | |
| 11.2 | Who is the person authorized to dispense and/or administer the drug/device to the subject? | ☐ Investigator  ☐ Research Nurse  ☐ Coordinator  ☐ Other: Click or tap here to enter text. | | | |
|  | | | ***YES*** | ***NO*** | ***N/A*** |
| 11.3 | Has the persons(s) authorized person(s) received appropriate training for dispensing/administration of the drug/device? | | ☐ | ☐ | ☐ |
| 11.4 | Is the drug/device stored in a secure location?  Please note location below. | | ☐ | ☐ | ☐ |
| 11.5 | Is there documentation of drug/device use for each subject? | | ☐ | ☐ | ☐ |
| 11.6 | Are VA Board of Pharmacy regulations followed in dispensing and administering a controlled substance? | | ☐ | ☐ | ☐ |
| 11.6.1 | Is there a shipping receipt? | | ☐ | ☐ | ☐ |
| 11.7 | Is there appropriate documentation for the return or destruction of the drug/device? | | ☐ | ☐ | ☐ |
| 11.8 | Have all drug/device errors (if any) been properly handled and reported? | | ☐ | ☐ | ☐ |
| 11.9 | Is a dispensing and accountability log being maintained? | | ☐ | ☐ | ☐ |
| 11.10 | Are all refrigerated storage units locked? | | ☐ | ☐ | ☐ |
| 11.11 | Are temperature/humidity logs maintained for all investigational products stored outside the Investigational Drug Pharmacy? | | ☐ | ☐ | ☐ |
| 11.12 | Who is responsible for instructing subject on how to use the medication or device | ☐ Investigator  ☐ Research Nurse  ☐ Coordinator  ☐ Other: Click or tap here to enter text. | | | |
| 11.12.1 | How much time is spent on subject instruction (per subject)? | Click or tap here to enter text. | | | |
|  | | | | | |
| **Please describe any areas of concern identified, action(s) to take or taken, and other notes:**  *The exception would be if it involved an off-site clinic (such as research being conducted a couple miles away from campus), where it is not practical for the pharmacy to be the dispensing unit. For these exceptions, on a case-by-case basis, the pharmacy would review a drug management plan and approve, and then audit the site periodically to ensure they are in compliance with the approved plan.*  Click or tap here to enter text. | | | | | |

**12.** **RECORD KEEPING/DATA SECURITY**

\*Questions below may relate to electronic storage. Reminder: if a problem has been identified, be sure to review the terms of approval (in your IRB approval letter) and search the new HRPP Toolkit policies here <https://research.vcu.edu/human-research/hrppirb/hrpp-policies-and-guidance/> to determine reporting requirements to the VCU IRB.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ***Records/Data*** | | ***YES*** | ***NO*** | ***N/A*** |
| 12.1 | Do you keep a binder/folder for all regulatory documents (IRB approved documents, etc.)? | ☐ | ☐ | ☐ |
| 12.2 | Do you keep a binder/folder/section for IRB correspondence? | ☐ | ☐ | ☐ |
| 12.3 | Do you keep a study file for each subject? | ☐ | ☐ | ☐ |
| 12.4 | Are the study files stored separately from consent documents?\* | ☐ | ☐ | ☐ |
| 12.4.1 | Are the subject study files coded (by a unique number/letter combination), with the code key stored in a secure location?\* | ☐ | ☐ | ☐ |
| 12.5 | Are any Personal Health Information or Private Personal data kept in electronic files? | ☐ | ☐ | ☐ |
| 12.5.1 | Are data in storage de-identified? | ☐ | ☐ | ☐ |
| 12.6 | Is there a data maintenance and destruction plan for the end of the study? | ☐ | ☐ | ☐ |
| 12.7 | Have you completed a data management plan in the VCU Data Management System (applicable for studies using Category 1 data)? | ☐ | ☐ | ☐ |
| ***Tools Used for Storage of Project Data*** | | ***YES*** | ***NO*** | ***N/A*** |
| 12.8.1 | VCU issued computer, encrypted. | ☐ | ☐ | ☐ |
| 12.8.2 | VCU issued computer, non-encrypted. | ☐ | ☐ | ☐ |
| 12.8.3 | Personal computer and/or tablet/phone, encrypted. | ☐ | ☐ | ☐ |
| 12.8.4 | Personal computer and/or tablet/phone, non-encrypted. | ☐ | ☐ | ☐ |
| 12.8.5 | School or Department file share (e.g. T: drive, S: drive). | ☐ | ☐ | ☐ |
| 12.8.6 | VCU managed Google Drive for faculty/staff in MCV campus unit. | ☐ | ☐ | ☐ |
| 12.8.7 | VCU managed Google Drive for faculty/staff in Monroe Park campus unit. | ☐ | ☐ | ☐ |
| 12.8.8 | VCU managed Google Drive for students. | ☐ | ☐ | ☐ |
| 12.8.9 | VCUHS managed Microsoft OneDrive. | ☐ | ☐ | ☐ |
| 12.8.10 | VCU FileLocker (temporary storage). | ☐ | ☐ | ☐ |
| 12.8.11 | VCU or VCUHS managed email system. | ☐ | ☐ | ☐ |
| 12.8.12 | Paper format, locked in secure location. | ☐ | ☐ | ☐ |
| 12.8.13 | Paper format, in unsecure location. | ☐ | ☐ | ☐ |
| 12.8.14 | Flash drive or external drive/CD/DVD, encrypted. | ☐ | ☐ | ☐ |
| 12.8.15 | Flash drive or external drive/CD/DVD, non-encrypted. | ☐ | ☐ | ☐ |
| 12.8.16 | VCU/VCUHS issued encrypted USB drive. | ☐ | ☐ | ☐ |
| 12.8.17 | REDCap. | ☐ | ☐ | ☐ |
| 12.8.18 | VCUHS Cerner (electronic medical record system). | ☐ | ☐ | ☐ |
| 12.8.19 | VCU OnCore. | ☐ | ☐ | ☐ |
| 12.8.20 | I am not storing any project data. | ☐ | ☐ | ☐ |
| 12.8.21 | Other. If other, please describe the systems below. | ☐ | ☐ | ☐ |
| ***Communication Mechanism(s) for Transferring Project Data:*** | | ***YES*** | ***NO*** | ***N/A*** |
| 12.9.1 | VCU provided Google email for faculty/staff in MCV campus unit. | ☐ | ☐ | ☐ |
| 12.9.2 | VCU provided Google email for faculty/staff in Monroe Park campus unit. | ☐ | ☐ | ☐ |
| 12.9.3 | VCU provided Google email for students. | ☐ | ☐ | ☐ |
| 12.9.4 | VCUHS provided Microsoft email. | ☐ | ☐ | ☐ |
| 12.9.5 | VCU FileLocker (temporary file transfer). | ☐ | ☐ | ☐ |
| 12.9.6 | Share data using VCU managed Google Drive for faculty/staff in MCV campus unit. | ☐ | ☐ | ☐ |
| 12.9.7 | Share data using VCU managed Google Drive for faculty/staff in Monroe Park Campus unit. | ☐ | ☐ | ☐ |
| 12.9.8 | Share data using VCU managed Google Drive for students. | ☐ | ☐ | ☐ |
| 12.9.9 | Share data using VCUHS managed Microsoft OneDrive. | ☐ | ☐ | ☐ |
| 12.9.10 | Share data using School or Department file share (e.g. T: drive, S: drive). | ☐ | ☐ | ☐ |
| 12.9.11 | VCU or VCUHS managed telephone/cell phone (Voice or SMS). | ☐ | ☐ | ☐ |
| 12.9.13 | None, I am not transferring any project data. | ☐ | ☐ | ☐ |
| 12.9.14 | Other. If other, please describe the mechanisms below. | ☐ | ☐ | ☐ |
| ***Data Access:*** *(Complete this section if VCU Google Drive, VCUHS Microsoft OneDrive, or Department file share are selected in the previous data storage and/or data transmission sections.)* | | ***YES*** | ***NO*** | ***N/A*** |
| 12.10 | ***Access Scope:*** | ☐ | ☐ | ☐ |
| 12.10.1 | I have a dedicated project data folder that is only accessible by me. No one else has or will be granted access. | ☐ | ☐ | ☐ |
| 12.10.2 | I have a dedicated project data folder that is only accessible by individuals on my project team. | ☐ | ☐ | ☐ |
| 12.10.3 | I have a dedicated project data folder that is accessible by anyone in my department. | ☐ | ☐ | ☐ |
| 12.10.4 | I have a dedicated project folder that is accessible by anyone at VCU. | ☐ | ☐ | ☐ |
| 12.10.5 | I have a dedicated project folder that is accessible by anyone with a link to access it. | ☐ | ☐ | ☐ |
| 12.10.6 | I have a dedicated project folder that is accessible by anyone on the internet. | ☐ | ☐ | ☐ |
| 12.11 | ***Access Permission Control:*** | ***YES*** | ***NO*** | ***N/A*** |
| 12.11.1 | I am the only person who can or can authorize the addition or removal of individuals who can access my project data in the project data folder. | ☐ | ☐ | ☐ |
| 12.11.2 | I and one or two of my designated project team members can or can authorize the addition or removal of individuals who can access my project data in the project data folder. | ☐ | ☐ | ☐ |
| 12.11.3 | Anyone on my project team can or can authorize the addition or removal of individuals who can access my project data in the project data folder. | ☐ | ☐ | ☐ |
| 12.11.4 | Anyone in my department, school, or college can or can authorize the addition or removal of individuals who can access my project data in the project data folder. | ☐ | ☐ | ☐ |
| 12.11.5 | Anyone at VCU can or can authorize the addition or removal of individuals who can access my project data in the project data folder. | ☐ | ☐ | ☐ |
| 12.12 | ***Access Management:*** | ***YES*** | ***NO*** | ***N/A*** |
| 12.12.1 | I or designated members of my project team keep track of individuals who need access and record any change to access to my project data | ☐ | ☐ | ☐ |
| 12.12.2 | I or designated members of my project team keep track of individuals who no longer need access and promptly remove their access to my project data. | ☐ | ☐ | ☐ |
| 12.12.3 | I or designated members of my project team periodically review the current list of individuals who have access to my project data and ensure the list is accurate. | ☐ | ☐ | ☐ |
| 12.13 | ***Physical Security Protections:*** | ☐ | ☐ | ☐ |
| 12.13.1 | We do not print any paper documents containing project data. | ☐ | ☐ | ☐ |
| 12.13.2 | Our workspace is located in a secured area in a building where authenticated access (e.g. key and lock, active badge) is required. | ☐ | ☐ | ☐ |
| 12.13.3 | We lock documents containing sensitive data away when the physical space is not occupied. | ☐ | ☐ | ☐ |
| 12.13.4 | We have designated personnel who are responsible for escorting visitors to and from our space. | ☐ | ☐ | ☐ |
| 12.13.4 | We issue visitor badges to all visitors who come to the area containing our project data. | ☐ | ☐ | ☐ |
| 12.13.6 | All access to physical space containing our project data or devices with access to our project data are logged (e.g. paper log or electronic door access log). | ☐ | ☐ | ☐ |
| 12.13.7 | We have video surveillance that continuously monitors and records access to our physical space. | ☐ | ☐ | ☐ |
| 12.13.8 | Other: If other, please describe the security protections below. | ☐ | ☐ | ☐ |
| 12.14 | ***Personnel Access:*** | ***YES*** | ***NO*** | ***N/A*** |
| 12.14.1 | I have ensured that all project personnel with access to project data (e.g. employees, student workers, contractors, and external collaborators) have undergone and passed standard employment background checks. | ☐ | ☐ | ☐ |
| 12.14.2 | I have provided an acceptable use statement or a memorandum of understanding outlining the expectations of project information security and privacy to all project personnel with access to project data. | ☐ | ☐ | ☐ |
| 12.14.3 | I have taken steps to ensure that all project personnel have completed their required compliance and security training annually. | ☐ | ☐ | ☐ |
| 12.14.4 | I have documented procedures to handle issues related to an individual’s misuse of the project data. | ☐ | ☐ | ☐ |
| 12.14.5 | Other: If other, please describe the personnel access below. | ☐ | ☐ | ☐ |
|  | | | | |
| **Please describe any areas of concern identified, action(s) to take or taken, and other notes:**  Click or tap here to enter text. | | | | |

**13.** **SPECIAL CONDITIONS**

For additional information regarding the below items, please reference the VCU HRPP’s Written Policies and Procedures at <https://research.vcu.edu/human-research/hrppirb/hrpp-policies-and-guidance/>

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Special Conditions | | ***YES*** | ***NO*** | ***N/A*** |
| 13.1 | If non-VCU institutions or individuals are involved in the research, but not actively [‘engaged,’](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html) have appropriate letters of permission been issued?  A non-VCU institution becomes "engaged" in human subjects research when its employees or agents (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes [[45 CFR 46.102(d)-(f)]](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.102). | ☐ | ☐ | ☐ |
| 13.2 | If non-VCU institutions or individuals are [‘engaged’](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html) in this research activity, are all agreements in place? | ☐ | ☐ | ☐ |
| 13.3 | If the research has not been approved to allow for the involvement of prisoners, has any data collection or other interaction/intervention taken place that involves persons who are incarcerated, detained, or otherwise compromised in terms of freedom participate in confidential appointments and retain confidential personal records? | ☐ | ☐ | ☐ |
| 13.4 | If participants may have limited English proficiency, are consent materials provided in the languages other than English for those who may have limited English proficiency? | ☐ | ☐ | ☐ |
| 13.5 | Are appropriate procedures in place to evaluate the effectiveness of the consent process in order to ensure that each participant exhibits adequate decision-making abilities for providing consent to participate? | ☐ | ☐ | ☐ |
| 13.6 | Are there any issues that are unique to your research, such as genetic testing, emergency procedures, or research involving deception?  If yes, please briefly describe: | ☐ | ☐ | ☐ |
| 13.7 | Has this research been approved for the involvement of children (<18)?  If so, are any of these children wards of the state? | ☐ | ☐ | ☐ |
| 13.8 | Has this research been approved with a waiver of consent or waiver of documentation of consent? | ☐ | ☐ | ☐ |
|  | | | | |
| **Please describe any areas of concern identified, action(s) to take or taken, and other notes:**  Click or tap here to enter text. | | | | |