Post-Approval Monitoring and Education

Self-Evaluation Tool

Biomedical Research

#### VCU is required to have procedures that *“include formal mechanisms for monitoring compliance with human subject protection requirements” under its Federal-wide Assurance (FWA).* IRB Continuing Review is the primary method for fulfilling this requirement. A site visit by the institution, any time following IRB approval, is another method.

**Purpose of the Post-Approval Monitoring Study Evaluation Tool (PAME SET):**

The Post-Approval Study Self-Evaluation tool (PAME SET) is designed as a tool for human research investigators and staff to aid in:

1. Preparing for a VCU (PAME, CRC, Massey Cancer Center, etc.), sponsor, or regulatory agency site visit
2. A routine quality improvement exercise
3. Training new research personnel

Due to the comprehensive nature of this tool, certain sections may not apply to your research. Please skip sections those sections and make a note of the reason it doesn’t apply in the comment section.

Please refer to IRB Written Policy and Procedure (WPP) for information about the Post Approval Monitoring program and use of the PAME SETs.

<http://www.research.vcu.edu/human_research/irb_wpp/X-3.htm>

For a description of the Post Approval Monitoring and Quality Improvement process, please go to the process document link at

<http://www.research.vcu.edu/human_research/post_approval.htm>

Here is a link for helpful forms.

PAMQuIP Toolkit

[**http://www.research.vcu.edu/human\_research/conduct\_toolkit.htm**](http://www.research.vcu.edu/human_research/conduct_toolkit.htm)

If you are preparing for a PAME visit, please send the completed form to [viragoea@vcu.edu](mailto:viragoea@vcu.edu) , at least a week before the scheduled visit. The form contains sample questions that may be asked during the site visit. There are also optional review exercises you may choose to complete.

If this form is being completed to prepare for a sponsor visit, or for self-evaluation, feel free to forward it to Dr. Enid Virago, for feedback.

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

***Questions:*** If you have questions or concerns while completing this PAME SET, please contact Enid A. Virago, PhD, QI/QA Administrator for Human Research Protection, Office of Research Subject Protections at [viragoea@vcu.edu](mailto:viragoea@vcu.edu) or (804) 828-7712

Post-Approval Monitoring and Education

Self-Evaluation Tool

(PAME SET)

***Section nAVIGATION:*** *click to go directly to the following sections:*

1. [**Regulatory Documentation**](#regdocs)
2. [**IRB Documentation**](#irbdocs)
3. [**Subject Selection Criteria**](#subjectselectioncriteria)
4. [**Subject Recruitment Procedures**](#subjectrecruitment)
5. [**Informed Consent Process**](#informedconsentprocess)
6. **Risk/Benefit**
7. [**Unanticipated Problem (a.k.a. AE/SAE) Reporting**](#upreporting)
8. [**Protocol Violations/Deviation Reporting**](#protocolviolationsdeviations)
9. **Registry/Repository**
10. **Genetic Data**
11. **Drug/Device**
12. [**Recordkeeping**](#recordkeeping)/ Data Security
13. Special Conditions

|  |  |  |
| --- | --- | --- |
| Post-Approval Study Evaluation Completed by: | | |
| PI or Coordinator (name of person completing this form) | |  |
| Role on the Research Team (i.e. PI, Coordinator, Project Manager, etc. | |  |
| Date Study received IRB approval: | |  |
| Date first subject was enrolled: | |  |
| Date Self-Study Completed: | |  |
| Date Self-Study sent to the QI/QA Administrator | | \*email: [viragoea@vcu.edu](mailto:viragoea@vcu.edu) |
| Study Information (please add other personnel and their contact information as needed) | | |
| Study Title: | |  |
| VCU IRB #: | |  |
| PI Name: | Contact information: | |
| Study Coordinator: | Contact information: | |
| Student Name (if Student project): | Contact information: | |
| IRB Used | 🗆 VCU IRB Panel **(A,B,C, or D) \_\_\_\_\_\_\_**  🗆 Western IRB  🗆 Central IRB  🗆 Other: **\_\_\_\_\_\_\_\_\_\_\_** | |
| Funding Sources: | 🗆 Industry  🗆 Federal  🗆 Foundation  🗆 Internal/Departmental (or not  funded)  🗆 Other: **\_\_\_\_\_\_\_\_\_\_\_\_** | |
| Monitoring Sources: | 🗆 Sponsor  🗆 Federal **\_\_\_\_\_\_\_\_\_\_\_\_\_**  🗆 Foundation  🗆 Internal/Departmental  🗆 CRC  🗆 CRO **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  🗆 Massey **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  🗆 Foundation  🗆 Other: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | |
| Date of last monitoring visit and by whom: |  | |
| # Enrolled\* to Date and/or when enrollment stopped: | |  |
| *“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).* | | |
| 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: \_\_\_\_\_\_\_\_is not listed. |

**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 <http://www.research.vcu.edu/human_research/wpp_guide.htm> to determine reporting requirements to the VCU IRB.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Protocol Version | | | ***YES*** | ***NO*** | ***N/A*** |
| 1.1 | Is the most recent version of the research plan/protocol on RAMS IRB? | |  |  |  |
| 1.2 | Are there previous versions of the research plan/protocol? ***(If no, go to 1.2.2)*** | |  |  |  |
| 1.2.1 | If yes, are they on RAMS IRB? | |  |  |  |
| 1.2.2 | Are you able to identify each version and date of the protocol? | |  |  |  |
| 1.2.3 | Are you tracking the version numbers and dates in a submission log? | |  |  |  |
| 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 | What is the expected closure date on the FDA Letter of Agreement? |  | | | |
| 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 | If yes, is there a signed FDA 1571 on file (IND only)? | |  |  |  |
| 1.5.2 | Have you submitted a copy to the IRB? | |  |  |  |
| 1.5.3 | If yes, are there 1571s on file for the following: | |  |  |  |
| 1.5.4 | Original application? | |  |  |  |
| 1.5.4.1 | All amendments? | |  |  |  |
| 1.5.4.2 | Annual Reports? | |  |  |  |
| 1.5.5 | Who (organization or individual) is listed as the monitor in Section 14 of the 1571? |  | | | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 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? <https://www.citiprogram.org/Default.asp>? | |  |  |  |
| 1.6.1 | If applicable, is the CITI Refresher up to date? | |  |  |  |
| 1.6.2 | Are all CITI Certificates on file? | |  |  |  |
| 1.6.2 | If applicable, has the IRB approved an alternative research ethics training program? Please explain below. | |  |  |  |
| 1.6.3 | Have all key personnel received appropriate training on execution of the protocol? Please explain below. | |  |  |  |
| 1.6.4 | Are there CVs of PI/CO-PI and all study staff on file? ***(If no, go to 1.6.5)*** | |  |  |  |
| 1.6.4.1 | Are filed CVs updated within the past two years and signed and dated? | |  |  |  |
| 1.6.5 | Is the study being conducted on a clinical in-patient or out-patient unit? | |  |  |  |
| 1.6.5.1 | If yes, has the unit staff been informed and trained on the protocol? | |  |  |  |
| Enrollment | | | ***YES*** | ***NO*** | ***N/A*** |
| 1.7 | Is there a subject 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? |  | | | |
| 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)*** | |  |  |  |
| 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? | |  |  |  |
| Laboratory Records (Cont.) | | | ***YES*** | ***NO*** | ***N/A*** |
| 1.11.4 | Is the lab director’s CV on file (signed and dated)?  This should be updated every 2 years. | |  |  |  |

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| 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? Put the number of DSMB reviews and dates below. |  |  |  |

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| 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)](http://bioethics.gov/node/3183) |  |  |  |
|  | | | | |
| **Please describe any areas of concern identified, action(s) to take or taken, and other notes:** | | | | |

**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 <http://www.research.vcu.edu/human_research/wpp_guide.htm> 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? | | #: | | | | | |  |
| 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:*** | | |  | | |  | | |
| ***Exercise below (or skip to 2.3.3)*** | | | | | | | | | |
| ***Cycle 1*** | | | | | | | | | |
| Continuing Review Date Submitted: | | ***Date:*** | | | | | | | |
| Date Approved by the IRB: | | ***Date:*** | | | | | | | |
| Is the IRB Approval Letter on File? | | 🗆 YES | | | | 🗆 NO | | | |
| Number of enrolled subjects reported | | ***#*** | | | | | | | |
| *Notes:* | | | | | | | | | |
| ***Cycle 2*** | | | | | | | | | |
| Continuing Review Date Submitted: | | ***Date:*** | | | | | | | |
| Date Approved by the IRB: | | ***Date:*** | | | | | | | |
| Is the IRB Approval Letter on File? | | 🗆 YES | | | | 🗆 NO | | | |
| Number of enrolled subjects reported | | ***#*** | | | | | | | |
| *Notes:* | | | | | | | | | |
| ***Cycle 3*** | | | | | | | | | |
| Continuing Review Date Submitted: | | ***Date:*** | | | | | | | |
| Date Approved by the IRB: | | ***Date:*** | | | | | | | |
| Is the IRB Approval Letter on File? | | 🗆 YES | | | | 🗆 NO | | | |
| Number of enrolled subjects reported | | ***#*** | | | | | | | |
| *Notes:* | | | | | | | | | |

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|  | ***Continuing Review (cont.)*** | | | | | | | | ***YES*** | | ***NO*** | ***NA*** |
| 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 subject 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)*** | | | | | | | |  | |  |  |
| 2.5 | 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)? | | | | | | | |  | |  |  |
| 2.5.1 | Were there are changes to the study that were not IRB-approved? **Describe below** | | | | | | | |  | |  |  |
| 2.6 | 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). | | | | | | | ***#:*** | | | | |
| 2.7 | 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: \_\_\_\_\_\_\_\_ | | |  | |  | |  | |  | |  |  |
|  | |  | |  | |  | |  |  |
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| **Please describe any areas of concern identified, action(s) to take or taken, and other notes:** | | | | | | | | | | | | |

**3. Subject Selection Criteria**

To complete the optional exercise 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 <http://www.research.vcu.edu/human_research/wpp_guide.htm> to determine reporting requirements to the VCU IRB.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 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** | ***#:*** | | | |
| **3.8** | **Number of Subjects who withdrew** | ***#:*** | | | |
| 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? | |  |  |  |
| 3.9.2 | If compensation provided, is it consistent with protocol & IRB approval? | |  |  |  |
|  | Is amount and type of compensation still appropriate? | |  |  |  |
|  | | | | | |
| **Please describe any areas of concern identified, action(s) to take or taken, and other notes:** | | | | | |

**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 <http://www.research.vcu.edu/human_research/wpp_guide.htm> to determine reporting requirements to the VCU IRB.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Recruitment Methods | | | | | | | | |
| 4.1 | How are potential subjects identified? *(check all recruitment methods that apply)* | | 🗆 Clinical practice  🗆 Investigators:  🗆 Database  🗆 Medical record review | | | | | |
| 🗆 Treating physician or PCP  🗆 Subject response to recruitment materials  🗆 Subject response to direct mail  🗆 Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | |
|  | | | | ***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, # | | |  |  | |  | |
| 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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | |
|  | | | | ***YES*** | ***NO*** | ***N/A*** | |
| 4.5.1 | Have all recruitment materials (identified above) been approved by the IRB? | | |  |  |  | |
| 4.6 | Are all approved recruitment materials (identified above) uploaded to RAMS IRB? | | |  |  |  | |
| 4.6.1 | 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)*** | | |  |  |  | |
| 4.6.2 | If yes, was an amendment submitted to the IRB? | | |  |  |  | |
| 4.7 | Is a pre-screening telephone interview conducted? ***(If no, go to 4.8)*** | | |  |  |  | |
| 4.7.1 | If yes, is the script stamped with an approval by the VCU IRB? | | |  |  |  | |
| 4.8 | Is recruitment/enrollment at the expected level for this study? | |  | | | | |
| 4.8.1 | What is the rate of recruitment? | | ***Per month*** | | | | |
| 4.8.2 | Estimated closure date for this study | | |  | | | |

**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 <http://www.research.vcu.edu/human_research/wpp_guide.htm> to determine reporting requirements to the VCU IRB.

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 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:*** | ***Date Subject Signed*** | ***Date PI Signed*** | | | |
| 5.2.1 | |  |  |  |  | | | |
| 5.2.2 | |  |  |  |  | | | |
| 5.2.3 | |  |  |  |  | | | |
| 5.2.4 | |  |  |  |  | | | |
| 5.2.5 | |  |  |  |  | | | |
|  | | | | | | ***YES*** | ***NO*** | ***N/A*** |
| 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 a file? | | | | |  |  |  |
| 5.5.3 | Is consent a continuous process? If yes, when does this begin after the initial consent and the frequency thereafter (**note below**)? | | | | |  |  |  |
| 5.6 | Do you provide educational materials to subject? If so, please attach a copy to this document. | | | | |  |  |  |
| 5.6 | 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:** | | | | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Informed Consent – File Review Exercise** | | | | | | | | | | |
| 5.9 | 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. They must also be stored separately from the data collected.*** | | | | | | | | |
| ***Subject***  ***Code*** | | ***Did the subject sign/date the consent/assent document?*** | | ***Indicate the VCU IRB approval stamp date for the consent form signed by the subject.*** | ***If a witness signed, indicate the date of the signature.*** | ***Did an LAR sign the consent document?*** | | ***Is it documented in the study files that each subject received a copy of the signed/dated consent document?*** | | |
| ***Code Only*** | | ***YES*** | ***NO*** | ***DATE*** | ***DATE*** | ***YES*** | ***NO*** | ***YES*** | ***NO*** | |
| (1) | |  |  |  |  |  |  |  |  | |
| (2) | |  |  |  |  |  |  |  |  | |
| (3) | |  |  |  |  |  |  |  |  | |
| (4) | |  |  |  |  |  |  |  |  | |
| (5) | |  |  |  |  |  |  |  |  | |
|  | | | | | | | | | | |

***6.* 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 send a copy to the QI/QA office. **Put in link from Toolkit** |  |  |  |
| 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:** | | | | |

## 7. UNANTICIPATED PROBLEM 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 <http://www.research.vcu.edu/human_research/wpp_guide.htm> to determine reporting requirements to the VCU IRB.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Refer to the VCU IRB Reporting guidelines, above as you answer the followingquestions: | | ***YES*** | | ***NO*** | ***N/A*** | |
| 7 | Does the study have a documented plan for reporting Unanticipated Problems? |  | |  |  | |
| 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. | | |  | | |
| 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)  identified that have not been reported to the VCU IRB? |  | |  |  | |
| 7.5 | Have all UPs (including unanticipated AEs) 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)? | | | ***#:*** | | |
| 7.7 | Is the UP/AE reporting requirement to the VCU IRB clear?  *Note question or concern below:* | |  |  | |  | |
| 7.8 | Is the UP/AE reporting requirement to the sponsor or regulatory agencies  clear? *Note question or concern below:* | |  |  | |  | |
|  | | | | | | |
| **Please describe any areas of concern identified, action(s) to take or taken, and other notes:** | | | | | | |

**8. Protocol violations/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 <http://www.research.vcu.edu/human_research/wpp_guide.htm> to determine reporting requirements to the VCU IRB.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Overview – Violations/Deviations | | ***YES*** | ***NO*** | ***N/A*** | |
| 8.1 | Does your study have a plan for documenting protocol deviations and/or violations? |  |  |  | |
| 8.1.1 | 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 | Have all protocol violations/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.* |  |  |  | |
| 8.2.1 | Have all violations/deviations been approved by or reported to the sponsor (as appropriate/required)? |  |  |  | |
| 8.3 | How many protocol violations/deviations have been reported to the VCU IRB in the past 12 months, if any? | | ***#:*** | | |
| 8.4 | Do you keep a log of Problem Reports? |  |  |  | |
| 8.4.1 | If yes, is it up to data? |  |  |  | |
|  | | | | |
| **Please describe any areas of concern identified, action(s) to take or taken, and other notes:** | | | | |

**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 <http://www.research.vcu.edu/human_research/wpp_guide.htm> to determine reporting requirements to the VCU IRB.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Registry/Repository Overview | | | | | | |
| 9.1 | Is this a: | | 🗆 Registry  🗆 Repository  🗆 Registry & Repository  🗆 Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |
| 9.2 | Who is responsible for | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | 🗆 Receiving and sending data/specimens  🗆 Storage and data maintenance  🗆 Website maintenance (if applicable)  🗆 Cleaning data and coordinating incoming  data/specimens  🗆 Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |
| 9.3 | If the data/specimens are coded who will maintain the key? | | 🗆 Investigator  🗆 Research Nurse  🗆 Coordinator  🗆 Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |
|  |  | | | YES | NO | N/A |
| 9.4 | Is this being created/used by only the PI who is creating or who created the registry/repository? If so, go to 9.13 | | |  |  |  |
| 9.5 | Are there written policies and procedures that explain how the registry/repository functions and the organizational structure? | | |  |  |  |
| 9.6 | Are other PIs able to apply to use data/specimens? | | |  |  |  |
| 9.7 | Are other PIs able to apply to donate data/specimens? | | |  |  |  |
| 9.8.1 | Are there forms for these PIs to fill out to make these requests? | | |  |  |  |
| 9.8.2 | Is there a committee of non-affiliated experts to vet these requests and PIs? | | |  |  |  |
| 9.9.3 | Do you require applicant PIs to provide IRB approval letters for their study? | | |  |  |  |
| 9.10 | Do you require applicant PIs to provide proof that their Informed Consent document allows for their data/specimens to be used in for the proposed area of research? | | |  |  |  |
| 9.10.1 | Does the consent allow the subject to agree to the data being used for future research? | | |  |  |  |
| 9.11 | Will shared data/specimens contain identifiers? | | |  |  |  |
| 9.12 | Are you charging for PIs for receipt of data/specimens? | | |  |  |  |
| 9.13 | Do you use a data use or data security for any data (with identifiers) that is going outside the VCU/VCUHS system? | | |  |  |  |
| 9.14 | Is the registry/repository housed at VCU/VCUHS?  If not, provide the name and contact information for the registry/repository below. | | |  |  |  |
| 9.15 | Has this registry/repository been approved with a waiver of consent or waiver of documentation of consent? | | |  |  |  |
| 9.16 | Is there any possibility you will need to recontact subjects? | | |  |  |  |
| 9.16.1 | If subjects cannot be reached with current contact information, what methods will you employ to reach subjects? | |  | | | |
|  | | | | | | |
| **Please describe any areas of concern identified, action(s) to take or taken, and other notes:** | | | | | | |

**10. Genetic Data collection**

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 <http://www.research.vcu.edu/human_research/wpp_guide.htm> to determine reporting requirements to the VCU IRB.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Genetic Research Overview | | | | | |
|  |  | | 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)](http://bioethics.gov/node/3183) | |  |  |  |
| 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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |
| 10.12 | Who is the person authorized to release genetic material/data? | 🗆 Investigator  🗆 Research Nurse  🗆 Coordinator  🗆 Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |
|  | | | | | |
| **Please describe any areas of concern identified, action(s) to take or taken, and other notes:** | | | | | |

**11.** **Drug/Device dispensing 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 <http://www.research.vcu.edu/human_research/wpp_guide.htm> to determine reporting requirements to the VCU IRB.

Another resource for monitoring/auditing is the VCU Clinical Research/Trial Quality Control (QC) Systems.

*VCU’s Clinical Research Quality System is composed of several quality control programs and is overseen by a quality assurance program that is an independent, top down, systematic evaluation of processes and quality control. For more information, go to [http://research.vcu.edu/compliance\_program/clinical\_trial\_research.htm](http://research.vcu.edu/compliance_program/clinical_trial_research.htm" \t "_blank).*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Drug/Device Accountability Overview | | | | | |
| 11.1 | Who is responsible for shipping/receiving? | 🗆 Investigator  🗆 Investigational Drug Pharmacy  🗆 Study Staff  🗆 Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |
| 11.2 | Who is the person authorized to dispense and/or administer the drug/device to the subject? | 🗆 Investigator  🗆 Research Nurse  🗆 Coordinator  🗆 Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |
|  |  | | 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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |
| 11.12.1 | How much time is spent on subject instruction (per subject)? |  | | | |
|  | | | | | |
| **Please describe any areas of concern identified, action(s) to take or taken, and other notes:** | | | | | |

**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 VCU Written Policies and Procedures search <http://www.research.vcu.edu/human_research/wpp_guide.htm> to determine reporting requirements to the VCU IRB.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| General | | | ***YES*** | ***NO*** | ***N/A*** | |
| 12.1 | Do you keep a binder/folder (paper or electronic) 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 | Have there been any breaches in privacy or confidentiality that met the definition of a UP? If so, please describe the resolution action taken below. | |  |  |  | |
| 12.6 | Are any Personal Health Information or Private Personal data kept in electronic files? | |  |  |  | |
| 12.6.1 | Are data in storage de-identified? | |  |  |  | |
| 12.7 | Are you storing study data on a University secure server? What kind of data capture or storage system are you using? | |  |  |  | |
| 12.7.1 | Please include your server administrator’s name and contact information, if known. |  | | | | |
| 12.7.2 | Are you using REDCap for data capture and/or storage | |  |  |  | |
| 12.7.3 | Are you using Drop Box? | |  |  |  | |
| 12.8 | If you are storing data on a computer and/or portable storage device, are these devices password protected and/or encrypted? | |  |  |  | |
| 12.8.1 | Are these devices stored in a secure location? | |  |  |  | |
| 12.8.2 | Are there firewalls? | |  |  |  | |
| 12.8.3 | If portable, how is security maintained during transportation? | |  |  |  | |
| 12.8.4 | If using a “flash drive”, is it an Iron Key? | |  |  |  | |
| 12.8.5 | Does each person who has access to the data have a unique password? | |  |  |  | |
| 12.9 | \*If you send data through email, is this encrypted? | |  |  |  | |
| 12.9.1 | Do you use an electronic survey or data gathering tool? If so, please describe below. | |  |  |  | |
|  | | | | | |
| **Please use this space to describe any areas of concern, action(s) to take or taken, and other notes:** | | | | | |

**13. Special Research Conditions**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Special Conditions | | **YES** | ***NO*** | ***N/A*** |
| 13.1 | If non-VCU institutions or individuals are involved in the research, but not actively [‘\*engaged,’](http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm) have appropriate letters of permission been issued? Note: search <http://www.research.vcu.edu/human_research/wpp_guide.htm> S  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)]](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm" \l "46.102" \t "_blank). |  |  |  |
| 13.2 | If non-VCU institutions or individuals are [‘engaged’](http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm) in this research activity, are all agreements in place? Note: search <http://www.research.vcu.edu/human_research/wpp_guide.htm> |  |  |  |
| 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? Note: search <http://www.research.vcu.edu/human_research/wpp_guide.htm> |  |  |  |
| 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? Note: search <http://www.research.vcu.edu/human_research/wpp_guide.htm> |  |  |  |
| 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? Note: search <http://www.research.vcu.edu/human_research/wpp_guide.htm> |  |  |  |
| 13.6 | Are there any issues that are unique to your research, such as genetic testing, emergency procedures, or research involving deception?  search <http://www.research.vcu.edu/human_research/wpp_guide.htm> If yes, please briefly describe: |  |  |  |
| 13.7 | Has this research been approved for the involvement of children (<18)? search <http://www.research.vcu.edu/human_research/wpp_guide.htm>  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?  search <http://www.research.vcu.edu/human_research/wpp_guide.htm> |  |  |  |
|  | **Please describe any areas of concern identified, action(s) to take or taken, and other notes:** | | | |