| Department: Post Approval Monitoring and Education | | | |
|---|---|---|---|
| **AG # 1-1 Revision #10:** | **TITLE: Protocol Selection** | | **Page: 1 of 2** |
| Approved By: Associate VP for Research Operations, Compliance & Policy | Kelly Hochstetler | Date 7/15/24 | Date First Effective: 6/15/06 |
| Approved By: Research Compliance Monitor | Jane Lehmbeck | Date 7/15/24 | |
| Approved By Research Compliance Monitor | Elaine Dube | Date 7/15/24 | Revision Date: 11/01/06 6/30/15 2/18/20 3/1/09 3/27/17 4/3/20 8/10/11 2/5/18 5/11/20 7/15/24 |

**OBJECTIVE**
To define the procedures utilized to select protocols for the purpose of post-approval monitoring review.

**RESPONSIBILITY**
The Research Compliance Monitors will be responsible for the implementation of Post Approval Monitoring review.

**PROCEDURES**
**The following categories will define and prioritize the protocols for review:**

1. **Directed review.**
    - When research approval expires due to failure by the investigator to submit continuation status report and PI requests the study to be re-opened;
    - When requested by study team or others as an educational tool or as preparation for a sponsor or FDA audit;
    - As identified by PAM Working Group, PAM Advisory Committee or the IRB as special or emerging areas of concern. Examples for areas of focus:
        - new PI or CRC assessment
        - non-UVA IRB of record
        - UVA IRB-HSR is IRB of record for multi-site study
        - Follow-up for problems identified in previous audit
        - PI change if needed (the determination will be made based on a variety of factors such as experience level of study team and CRCs, audit results of PI's other studies, level of risk for study, number of subjects enrolled, etc).

2. **For cause.**
    - When requested by study team members on an IRB-HSR (or non-UVA IRB of record) approved protocol, IRB-HSR staff, research subject or other sources where compliance concerns have been raised.

3. **Random selection.**
    - Protocols will be randomly chosen from all those active which have not previously been reviewed and: 1) are "open for enrollment" or "closed to enrollment/subjects being treated;" and, 2) full committee review, expedited, exempt or exempt with limited IRB review.
    - The randomization schedule will be adjusted in the following risk-based manner: 75% full committee; 20% expedited; 5% exempt and exempt with limited IRB review.

- Review will be waived if the PI has had at least one protocol reviewed and received no scores other than "Satisfactory" in the previous two years.
- If a protocol is selected randomly that is internally monitored for safety by the CC DSMC, PAM will contact the OCR Compliance Managers to find out if the protocol has been recently reviewed within the last year. If applicable, PAM will ask the OCR Compliance Managers to share results (e.g. audit report). If there are no significant issues noted in the report, PAM will not audit the protocol. If the report is not shared, PAM will audit the protocol.

**REFERENCES:**
IRB-HSR AG5-19

| Department: **Post Approval Monitoring and Education** | | | |
|---|---|---|---|
| **AG # 1-2 Revision #6:** | **TITLE: Notification of Review and Selection of Research Subject's Records** | | **Page: 1 of 2** |
| Approved By: Associate VP for Research | David J. Hudson | Date 4/17/20 | Date First Effective: 6/15/06 |
| Approved By: Research Compliance Monitor | Jane Lehmbeck | Date 4/17/20 | |
| Approved By Research Compliance Monitor | Elaine Dube | Date 4/17/20 | Revision Date: 11/1/06 4/3/20 11/16/07 3/1/09 8/10/2011 6/30/15 3/27/17 |

**OBJECTIVE**

To define the procedure utilized for post-approval monitoring notification and to select research participants' records for review during a post-approval monitoring review.

**RESPONSIBILITY**

The Research Compliance Monitors will be responsible for the execution of the Administrative Guidance.

**PROCEDURES**

1. Prepare and send a letter via email one to four weeks prior to the anticipated review date to the Principal Investigator (PI) and the study coordinator (if applicable), notifying him/her that the study has been selected for post-approval monitoring. Request in the letter a convenient date and time to meet with study personnel.
   Note: A response to initial contact must be received within approximately 2 weeks:
   - If not – a second email will be sent
   - If no response to second email within 2 weeks, a phone call or repeated email may be attempted. In the event that no contact is made after approximately 4 weeks from the initial notification, the Associate Vice President for Research may send a letter via messenger mail to the investigator asking that one of the post approval monitors be contacted. Failure to contact the monitors within approximately 2 weeks after the VP for Research letter is sent may result in notification to the IRB-HSR committee members.

2. Include in the letter the specific areas to be reviewed.

3. Request in the letter the necessary records and resources required for the review.
   Note: Post-approval monitoring will include as applicable:
   - review of all or a portion of subject consent forms
   - complete review (including all source data and CRFs, if applicable) of 10% (or approximately 3-10) of the subjects currently enrolled in the study
   - investigational drug/device/biologic accountability review if applicable
   - review of regulatory files (paper or electronic) as applicable
   - review of adherence to protocol approved Data Safety Monitoring Plan and Data Security Plan

4. If subject enrollment has not occurred at time of initial notification to PI, monitor may contact study team again approximately every 3-6 months until subjects have been enrolled (or study is closed).

**REFERENCES:**
Notification of Review Letter 1-2 A
Cancer Center DSMC Notification of Review Letter 1-2 B
No Response Letter 1-2 C
Notification of Review Letter waiver of consent 1-2 D

Dear Dr. XXXXXXX,

Your study, IRB-HSR #xxxxx entitled "xxxxxx," has been selected for a Post Approval Monitoring Review (PAM). The PAM program is under the direction of the Office of the Vice-President for Research. The purpose of this program is to contribute to the research culture by: facilitating the safety, rights and welfare of study participants; providing feedback and education to investigators and their study teams; and to identify strengths and areas for improvement in research policies and practice at the University of Virginia.

We would like to complete as much of this audit as possible by electronic review. Please provide access to electronic copies of study files and electronic drives as applicable. EPIC medical records, OnCore (and REDCap or other database, if applicable), will be reviewed for study documentation as much as possible. If there are records that cannot feasibly be provided electronically, please let me know, and we can set up a date for review of those documents to be completed in person.

Please prepare or supply in advance the following items, as applicable to your study:

- Original signed consent forms for all subjects, including any screen failures
- Regulatory files - Protocol versions and correspondence with the sponsor (if applicable) and IRB-HSR (IRB approval forms, approved informed consent forms, protocol status reports, etc.)
- Subject records including case report forms, source documentation, medical records or shadow charts

The following parameters (as applicable) will be reviewed for each subject selected for complete review. Please have available documentation (i.e. medical records, clinic notes, source documentation) to provide an outline of study conduct and adherence to approved protocol.

- Eligibility – subjects have met all inclusion/exclusion criteria
- Study procedures have been performed consistent with approved protocol; missing procedures are noted and explained
- Data and safety monitoring and Data Security plans followed as per protocol
- Study drug or device exposure and accountability records

I would like to conduct this review as soon as is convenient. Please contact me by email xxxxx@virginia.edu by xx/xx/xxxx to confirm availability of the study files for review.

If you would like to learn more about the PAM program, please view our online introduction to the program. It is a voice-over flash presentation, so please turn up your volume and listen in at: https://hrpp.irb.virginia.edu/learningshots/PAM-Program-Overview/presentation_html5.html

Thank you for your cooperation in this process – please contact me with any questions.

Warm regards,

Dear Dr. xxxx,

Your study, HSR #xxxxxx entitled "xxxxxxx," has been selected for a Post Approval Monitoring Review (PAM). The PAM program is under the direction of the Office of the Vice-President for Research. The purpose of this program is to contribute to the research culture by: facilitating the safety, rights and welfare of study participants; providing feedback and education to investigators and their study teams; and to identify strengths and areas for improvement in research policies and practice at the University of Virginia.

We would like to complete as much of this audit as possible by electronic review. Please provide access to electronic copies of study files and electronic drives as applicable. EPIC medical records, OnCore (and REDCap or other database, if applicable), will be reviewed for study documentation as much as possible. If there are records that cannot feasibly be provided electronically, please let me know, and we can set up a date for review of those documents to be completed in person.

Please prepare or supply in advance the following items, as applicable to your study:

- Original signed consent forms for all subjects, including any screen failures
- Regulatory files - Protocol versions and correspondence with the sponsor (if applicable), IRB-HSR and sIRB of record (IRB approval forms, approved informed consent forms, protocol status reports, IRB Reliance Agreement Request Form, etc)
- Subject records including case report forms, source documentation, medical records or shadow charts

The following parameters (as applicable) will be reviewed for each subject selected for complete review. Please have available documentation (i.e. medical records, clinic notes, source documentation) to provide an outline of study conduct and adherence to approved protocol.

- Eligibility – subjects have met all inclusion/exclusion criteria
- Study procedures have been performed consistent with approved protocol; missing procedures are noted and explained
- Data and safety monitoring and Data Security plans followed as per protocol
- Study drug or device exposure and accountability records

I would like to conduct this review as soon as is convenient. Please contact me by email xxxxx@virginia.edu by xx/xx/xxxx to confirm availability of the study files for review.

If you would like to learn more about the PAM program, please view our online introduction to the program. It is a voice-over flash presentation, so please turn up your volume and listen in at: https://hrpp.irb.virginia.edu/learningshots/PAM-Program-Overview/presentation_html5.html

Thank you for your cooperation in this process – please contact me with any questions.

Warm regards,

Dear Dr. XXXXXX,

This letter is in follow-up to a previous communications regarding your study, IRB-HSR #xxxxx, entitled "
." The following communications have been made to schedule a post approval monitoring review with you: xxxxxxxx.

As described in the initial notifications, this study was selected for review as part of the Post Approval Monitoring program (PAM). This program is part of UVA's commitment to assure human subject safety, provide education to research professionals, identify strengths and areas for improvement in policies and to enhance academic research practice at the University of Virginia. Unfortunately, the Research Compliance Monitor has not received any reply to emails or phone calls to you regarding this matter.

Please note that this review is required by the IRB as part of compliance with the University's Federal Wide Assurance Agreement and is not considered optional. Failure to comply may result in suspension of IRB approval for this study. Therefore, please contact the monitor at xxx-xxxx or by email at xxx@virginia.edu within the next 14 working days to schedule a meeting.

Sincerely,

Kelly Hochstetler, PhD
Associate Vice President for Research Operations, Compliance & Policy
Phone: 434-982-5725
Email: kjh@virginia.edu

Cc: Department Chair
Research Compliance Monitor
IRB-HSR Chair (if IRB-HSR is IRB of record)
SOM CTO Educator

Dear Dr. XXXXXXX,

Your study, IRB-HSR #xxxxx entitled "xxxxxx," has been selected for a Post Approval Monitoring Review (PAM). The PAM program is under the direction of the Office of the Vice-President for Research. The purpose of this program is to contribute to the research culture by: facilitating the safety, rights and welfare of study participants; providing feedback and education to investigators and their study teams; and to identify strengths and areas for improvement in research policies and practice at the University of Virginia.

We would like to complete as much of this audit as possible by electronic review. Please provide access to electronic copies of study files and electronic drives as applicable. EPIC medical records, OnCore (and REDCap or other database, if applicable), will be reviewed for study documentation as much as possible. If there are records that cannot feasibly be provided electronically, please let me know, and we can set up a date for review of those documents to be completed in person.

Please prepare or supply in advance the following items, as applicable to your study:

- Correspondence with the IRB-HSR or IRB of record (and sponsor, if applicable)
- Recorded/collected data

The following parameters (as applicable) will be reviewed for each subject selected. Please have available documentation that will support these parameters:

- Capture of identifiers and health information
- Privacy plan

I would like to conduct this review as soon as is convenient. Please contact me by email xxxxx@virginia.edu by xx/xx/xxxx to confirm availability of the study files for review.

If you would like to learn more about HIPAA and Waiver of Consent, please view our online learning shot. It is a voice-over flash presentation, so please turn up your volume and listen in at:

https://hrpp.irb.virginia.edu/learningshots/Data-Protections-Part-1/presentation_html5.html

Thank you for your cooperation in this process – please contact me with any questions.

Warm regards,

| Department: Post Approval Monitoring and Education | | | |
|---|---|---|---|
| **AG# 1-3 Revision #7:** | **TITLE: Monitoring of Regulatory Files** | | **Page: 1 of 2** |
| Approved By: Associate VP for Research Operations, Compliance & Policy | Kelly Hochstetler | Date 7/19/24 | Date First Effective: 6/15/06 |
| Approved By: Research Compliance Monitor | Jane Lehmbeck | Date 7/19/24 | |
| Approved By Research Compliance Monitor | Elaine Dube | Date 7/19/24 | Revision Date: 11/1/06 3/27/17 11/16/07 4/3/20 3/1/09 7/19/24 6/30/15 12/14/16 |

**OBJECTIVE**
To define the procedure utilized to review the IRB-HSR and the Principal Investigator's regulatory file in preparation for a post approval-monitoring visit for studies with IRB-HSR approval and oversight.

**RESPONSIBILITY**
The Research Compliance Monitors will be responsible for the execution of the SOP.

**PROCEDURES**

1. Obtain a print-out or electronic copy of events from the IRB database prior to conducting the post-approval monitoring visit.

2. For studies with UVA IRB-HSR as IRB of record: review the research protocol file (electronic file) maintained by the IRB-HSR office:
   - Dates of initial protocol review and approval by the IRB-HSR
   - Nature and dates of any modifications to the IRB-HSR approved protocol
   - Dates of approval granted by the IRB-HSR of any changes
   - A copy of the most recent IRB-HSR approved protocol and informed consent form, including the DSMP as appropriate
   - Review the regulatory files maintained by the investigator utilizing the event printout from the IRB database and notes from the IRB-HSR file review. Both the IRB-HSR and investigator files should reflect consistent information regarding approval and correspondence

3. For studies with a non-UVA IRB of record (NCI CIRB, WIRB, NeuroNext CIRB, Advarra, etc):
   - Obtain copies of protocol and informed consent forms from the study team and/or OnCore (Oncology database) prior to conducting Post Approval Monitoring audit
   - At time of audit, review regulatory files and IRB approval forms of IRB of record as applicable (including training records, DSMB reports or other documentation as required)

**REFERENCES:**

1-3A FORM Post Approval Monitoring Review
1-3B FORM Post Approval Monitoring –waiver of consent
1-3C FORM IRB-HSR Q

**University of Virginia**
**Vice President's Office for Research**
**Post Approval Monitoring Review Form**

IRB-HSR #_____

Principal Investigator_____

*Study Coordinator_____

Review Date_____

Approval: (UVA IRB-HSR) ☐ expedited ☐ full committee

☐ IRB of record (not UVA): _____

Funding: _____

Is this a multi-center trial? ☐ yes ☐ no

Total number of subjects consented?_____

Is the study conducted under an IND or IDE? ☐ Yes ☐ No (if applicable)

#_____

Is IND held by UVA MD (name if applicable)? ☐ Yes ☐ No

_____

Does the study enroll minors? ☐ Yes ☐ No

If yes, are 2 parent signatures required? ☐ Yes ☐ No

Is the study approved for surrogate consent? ☐ Yes ☐ No

Is the study approved to enroll non-English speaking subjects (i.e. English and Spanish informed consent short forms)? ☐ Yes ☐ No All should be YES: Comment on all NOs.

| Review Item | YES | NO | N/A | Comments |
|---|---|---|---|---|
| Is the consent form consistent with the protocol? | | | | |
| Are there systems in place to protect subject confidentiality? | | | | |
| Is the number of subjects signing consent less than the number approved by the IRB-HSR (or IRB of record)? | | | | |
| Are there consents present for all subjects enrolled? | | | | |
| Is there a subject log (all who have signed consent) available? | | | | |
| If applicable, have copies of signed informed consent forms been sent to EPIC medical records? | | | | |

| | | | | |
|---|---|---|---|---|
| Are all copies (most recent and any previous versions) of the protocol on file or electronically available? | | | | |
| Is all correspondence (investigator agreement/initial IRB approval letter, approvals, modifications, continuations and stamped consents) to and from the IRB-HSR (or IRB of record) on file? | | | | |
| Is there a delegation of duties form and training certificate if applicable? | | | | |
| If applicable, has study been entered in OnCore database? | | | | |
| Have subjects been entered in OnCore database? | | | | |
| Studies with non-UVA IRB of record (CIRB, NeuroNEXT, Partners, etc) | | | | |
| Were continuation approvals submitted to IRB-HSR within 14 days of study team receiving approval from IRB of record? | | | | |
| Was local language agreed upon in IRB Reliance Agreement inserted in ICF? | | | | |
| Is CITI Training Certification present following initial approval and each continuation approval? | | | | |
| Review Item | YES | NO | N/A | Comments |
| If specimens are processed in an investigator lab, has IBC approval been obtained? Is this question answered correctly in the HSR database? | | | | |
| Is Radiation Safety Committee approval required? If yes, are these approvals and correspondence on file? | | | | |
| If advertising, are approvals on file and does the advertising match the study? | | | | |
| Was there any lapsed periods between IRB approvals? If yes, were any subjects enrolled during this lapsed period? | | | | |
| Decoding procedure for blinded studies? | | | | |

**Drug (Device if applicable) Inventory-if applicable**
**Where is the drug maintained?**_____

| Review Item | YES | NO | N/A | Comments |
|---|---|---|---|---|
| Is the study drug stored separately from non study items and securely and with limited access?<br>• Locked space<br>• Limited access to keys, etc. | | | | |

| | | | | |
|---|---|---|---|---|
| DARF records reviewed and complete?<br>• Shipping receipts available/complete and documented<br>• Dispensings recorded and clear<br>• Patient Returns documented<br>• Disposition of returns and unused drug documented<br>• Balances are correct | | | | |
| Temp logs maintained and monitored?<br>• Excursions noted and acted upon in an acceptable manner | | | | |
| Completed IDS Waiver Form signed by IDS Pharmacist and followed? | | | | |
| Study drug is not expired? | | | | |
| Expired meds are sequestered/stored separately? | | | | |
| Is the drug dispensed for each patient per approved protocol?<br>Are the following details regarding drug dispensation and return documented?<br>• Subject name (to whom dispensed)<br>• Date drug dispensed<br>• Amount of drug dispensed<br>• Date remaining study drug returned<br>• Name of person giving drug and completing documentation (i.e. tracking via paper drug log, electronic IVRS system) | | | | |
| Take home labeling requirements met:<br>• Childproof container<br>• Emergency contact info on label<br>• Minimum labeling requirements met: Patient ID, Drug Name, Sponsor or Protocol #, Instructions for Use, cautionary statements | | | | |

**Study Monitoring:**

| Review Item | YES | NO | N/A | Comments |
|---|---|---|---|---|
| Is the DSMP appropriate for the study (r/t level of risk, duration and details of subject participation, etc)? | | | | |
| Was the plan followed as outlined per approved protocol? | | | | |

| | | | | |
|---|---|---|---|---|
| Has the safety monitoring taken place according to the frequency dictated in the DSMP? | | | | |
| Have SAEs been submitted to the IRB-HSR or IRB of record if required? | | | | |
| Have any unanticipated problems occurred? If yes, have they been submitted to the IRB-HSR or IRB of record as required? | | | | |
| Have SAEs and/or unanticipated problems been reported to the sponsor within required timeframes if applicable? | | | | |
| If applicable, have AEs and SAEs been entered in OnCore database as required? | | | | |
| If applicable, have DSMB reports been submitted to the IRB-HSR as required? | | | | |
| Were privacy and confidentiality standards and procedures implemented as approved by the IRB-HSR? | | | | |
| Are the computing devices used secured according to UVa requirements (e.g. no personal laptop computers, etc.)? | | | | |
| Are electronic data secured (password protected, etc.) as approved by the IRB-HSR? | | | | |
| Is all data collected stored securely as listed in the approved Data Security Plan (e.g. approved servers used)? | | | | |
| Has data been shared/transferred only per the approved protocol and Data Security Plan? | | | | |
| If applicable, are links to coded data or specimens stored separately and without HIPAA identifiers? | | | | |
| Are identifiers stored/disposed of as approved by the IRB-HSR? | | | | |

Comments: _____
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Reviewer: _____ Date:_____

**University of Virginia**
**Office of the Vice President for Research**
**Post-Approval Monitoring Review Form**
**For Studies with Waiver of Consent or Waiver of Documentation of Consent**
**Or Exempt**

IRB-HSR #_____

Principal Investigator_____

Review Date_____

Funding: _____

| Review Item | YES | NO | N/A | Comments |
|---|---|---|---|---|
| Have all individuals involved in the conduct of the study completed IRB-HSR training and are they listed with the IRB as personnel for this study? | | | | |
| Did the researchers follow the privacy plan as outlined in the protocol? | | | | |
| Did the researcher collect only the data and identifiers outlined in the protocol? | | | | |
| If data are being sent outside of UVA is the data being sent only with the identifiers as stipulated in the protocol? | | | | |
| Are all copies (most recent and any previous versions) of the protocol on file or electronically available? | | | | |
| Were there any lapsed periods between IRB approvals? If yes, were any subjects enrolled during this lapsed period? | | | | |
| Is there evidence that subjects met the eligibility criteria for enrollment? | | | | |
| Is there evidence that the protocol is being conducted as approved? | | | | |

**Study Monitoring:**

| | | | | |
|---|---|---|---|---|
| Is the safety and monitoring plan appropriate for the study? | | | | |
| Was the DSMP and privacy plan followed as outlined in approved protocol? | | | | |
| If there were unanticipated problems- were they reported to the IRB appropriately? | | | | |

Comments: _____
_____
_____

Reviewer: _____ Date:_____

| Department: Post Approval Monitoring and Education | | | |
|---|---|---|---|
| **AG # 1-4 Revision #4:** | **TITLE: Review of Study Signed Consent Forms** | | **Page: 1 of 1** |
| Approved By: Associate VP for Research | David J. Hudson | Date 4/17/20 | Date First Effective: 6/15/06 |
| Approved By: Research Compliance Monitor | Jane Lehmbeck | Date 4/17/20 | |
| Approved By Research Compliance Monitor | Elaine Dube | Date 4/17/20 | Revision Date: 11/1/06 4/6/20 3/1/09 6/30/15 3/27/17 |

**OBJECTIVE**

To define the procedures utilized to review the informed consent documents maintained in the investigator's research records. This procedure is to verify that documentation of informed consent is performed according to Federal Policy (45 part 46) and, where applicable FDA (21 CFR 50). The informed consent process must also meet the policies of the University of Virginia's IRB-HSR and, where applicable, the School of Medicine Clinical Research Standard Operating Procedures.

**RESPONSIBILITY**

Research Compliance Monitors are responsible for verifying the appropriate documentation of informed consent for research studies selected for Post Approval Monitoring review.

**PROCEDURES**

1. Review subject signed informed consent forms for the presence of the following documentation:
   - date the informed consent document was signed;
   - utilization of the correct version of the IRB approved consent forms denoted by the presence of the IRB approval stamp date (if applicable);
   - the signature and date of the subject or the signature of the subject's legal representative;
   - the signature and date of the person obtaining consent.

2. Additional items that may be assessed during the review of the informed consent documents include but are not limited to:
   - consistency between the type and frequency of side effects listed in the informed consent document to those that actually occurred;
   - approved consent is consistent with approved protocol;
   - presence of any extemporaneous modifications to the consent documentation;
   - subject signed prior to study-specific procedures being initiated;
   - non-English speaking subjects signed an approved version of consent form if applicable (i.e. English and Spanish short forms)

**REFERENCES:**

Form Informed Consent Checklist 1-4A

# University of Virginia Post Approval Monitoring Review Form
# Informed Consent Verification Checklist

**IRB-HSR#_____** **Date of Initial IRB-HSR (or IRB of record) Approval _____**

**Complete gray area if applicable for enrollment of minors:**

| Subject ID# or Initials | Date consent signed | Did subject or legal representative sign and date correct version of CF? | List version date of consent form:<br><br>Approval date stamp (if applicable): | If the correct version of consent form was not signed, what version should have been used? | Did person obtaining consent sign and date CF? | Was the POC listed with the IRB? | Was optional section (e.g. tissue banking) completed or initialed if applicable? | Were 2 parent signatures obtained if required?<br><br>Was assent form signed by minor and parent(s) if required? |
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**Comments?**_____

_____

**Date PAM Review Conducted _____Signature of Reviewer _____**

| Department: Post Approval Monitoring and Education | | | |
|---|---|---|---|
| **AG # 1-5 Revision #5:** | **TITLE: Review of Research Participant Records and Source Documentation For Research Approved by Full IRB-HSR Committee or other IRB of Record** | | **Page: 1 of 1** |
| Approved By: Associate VP for Research | David J. Hudson | Date 4/17/20 | Date First Effective: 6/15/06 |
| Approved By: Research Compliance Monitor | Jane Lehmbeck | Date 4/17/20 | |
| Approved By Research Compliance Monitor | Elaine Dube | Date 4/17/20 | Revision Date: 11/1/06 4/6/20 11/16/07 3/1/09 6/30/15 3/27/17 |

**OBJECTIVE**
To define the procedures utilized to review research records maintained by the investigator for research study participants.

**RESPONSIBILITY**
The Research Compliance Monitors are responsible for conducting reviews of research participants' research records.

**PROCEDURES**

1. Review the source documentation and the data collected for each study participant included in the post-approval monitoring review.

2. Determine whether there is adequate documentation to assure that all subjects reviewed were consented prior to any study-specific procedures being performed.

3. Determine whether there is adequate documentation to assure that all subjects reviewed were eligible for enrollment.

4. Verify study procedures were carried out as written in the IRB-approval protocol.

5. Review adverse event documentation and assure reporting is as required per Data Safety Monitoring Plan and IRB approval.

6. Determine whether there are records of exposure of the subject to the test article, if applicable.

**REFERENCES:**

FDA/ORA Compliance Program Guidance 7348.811 Clinical investigators
1-5A FORM Review of Individual Subject Records

# University of Virginia
# Office of the Vice President for Research
# Individual Subject Review Form

Protocol IRB-HSR #_____ Subject _____

Date consent signed: _____

Randomization, if applicable_____

| **Review Item** | YES | NO | N/A | Comments |
|---|---|---|---|---|
| Informed consent: | | | | |
| Was consent obtained prior to any study procedures? | | | | |
| Is there an informed consent process note present? | | | | |
| If applicable: were subjects entered in OnCore database as required? | | | | |
| Subject selection criteria: | | | | |
| Did the subject meet the inclusion/exclusion criteria of the current approved protocol at time of enrollment? | | | | |
| Is eligibility checklist present? | | | | |
| If applicable, has the checklist been signed/dated by CRC and/or Investigator? | | | | |
| Documentation and verification of protocol compliance | | | | |
| Were all study intervention/procedures administered according to the IRB-HSR approved protocol and consent in the timeline specified?<br><br>If NO, did missed procedures have reasons documented?<br><br>If considered violations, were they reported to the IRB? | ☐<br><br>☐<br><br>☐ | ☐<br><br>☐<br><br>☐ | | |
| Was any research related activity (e.g. specimen or data collection, procedure or intervention, etc.) conducted for a research purpose that was not specified in the IRB-HSR approved consent and protocol? | | | | |

| Review Item | YES | NO | N/A | Comments |
|---|---|---|---|---|
| Study drug/device accountability: | | | | |
| Was the correct study drug/treatment and dose given per protocol? | | | | |
| Is there documentation of exposure of each subject to the test article (including time, date, amount, by whom) and of returns & missed doses? | | | | |
| Compliance with DSMP: | | | | |
| Did the subject experience any serious adverse events?<br><br>If yes, were they reported to the IRB or other required sponsors within the required time frame? | ☐<br><br>☐ | ☐<br><br>☐ | | |
| Were all expected and unexpected adverse events recorded according to DSMP? | | | | |
| Oncology studies: were AEs and SAEs entered in OnCore database as required? | | | | |

General Comments:

_____

_____

_____

_____

_____

Reviewer: _____Date_____

| Department: Post Approval Monitoring and Education | | | |
|---|---|---|---|
| **AG # 1-6 Revision #4:** | **TITLE: Documentation of Post Approval Monitoring Review Findings** | | **Page: 1 of 2** |
| Approved By: Associate VP for Research | David J. Hudson | Date 4/17/20 | Date First Effective: 6/15/06 |
| Approved By: Research Compliance Monitor | Jane Lehmbeck | Date 4/17/20 | |
| Approved By: Research Compliance Monitor | Elaine Dube | Date 4/17/20 | Revision Date: 11/1/06 4/6/20 3/1/09 6/30/15 3/27/17 |

**OBJECTIVE**
To define the procedures utilized to prepare a report of findings for each review performed.

**RESPONSIBILITY**
The Research Compliance Monitors are responsible for preparing PAM reports for each review performed.

**PROCEDURES**

1. Prepare the final report utilizing information gathered during the review.

2. Structure of the PAM reports.

   The heading of the PAM report should include the following information:
   - The IRB-HSR number and the title of the research study;
   - IRB of record;
   - The name of the principal investigator;
   - The name of the research coordinator;
   - The date(s) on which the audit was conducted. Level of review/approval (Full Committee, Expedited, Exempt)
   - Funding source

   The introduction of the PAM report should include but not be limited to the following:
   - A brief summary of the research study;
   - The number of subjects approved and currently enrolled in the study;
   - The number of research records reviewed.
   - Dates of initial and most recent IRB approvals.

The body of the PAM report should include the following summaries:
- IRB approvals and correspondence;
- Informed consent documentation;
- Subject selection criteria;
- Documentation of study procedures and verification of protocol compliance;
- Recording/reporting of adverse events and data safety monitoring and data security plans compliance ;
- Study drug documentation and accountability, if applicable.

Recommendations shall be made for findings, as indicated.

- Regulations will be cited to support recommendations, as applicable.

The general comment section reflects the Research Compliance Monitor's overall assessment of the findings and the study team's response. An initial education and follow-up recommendation is made by the Research Compliance Monitor based on the number and severity of deviations found.

**REFERENCES:**

FORM Post Approval Monitoring Form 1-6A

**University of Virginia**
**Office of the Vice President for Research**
**Post-Approval Monitoring Report**

**Protocol:** IRB-HSR# **IRB of record:** **Principal Investigator:**

**Title**:

**Study Coordinator:** **Date of Review:**

**IRB Review type:** **Sponsor:**

**Introduction of what was reviewed:** *(Formatting suggestion: use two columns for text in this section, like in a textbook)*

| **Findings:** | **Regulations:** | **Recommendations:** | **Resolution (to be completed by investigator/study team)** |
|---|---|---|---|
| *Regulatory documentation:* | UVA IRB-HSR Responsibilities of Principal investigators (PI) https://research.virginia.edu/irb-hsr/responsibilities-principal-investigators<br>PIs are required to maintain a research file.<br>A research file may consist of paper, electronic and/or other media.<br>The requirements for a research file include, but are not limited to:<br>• all correspondence with the IRB and the sponsor (if applicable),<br>• documentation of subject eligibility, and<br>• a copy of the signed informed consent form (if applicable) obtained from all subjects participating in and/or who have participated in the protocol regardless of whether or not the subjects completed the study.<br>The file will act as the investigator's documentation regarding proper performance of the study.<br>This information may be reviewed by | | |

| | | | |
|---|---|---|---|
| | the IRB, Federal or local authorities, sponsors, and other authorized individuals to ensure proper performance of the study.<br>Faculty advisors are required to maintain research files for student research completed under their direction. | | |
| *Documentation of informed consent*: | 4.8.8 Prior to a subject's participation in the trial, the written informed consent form should be signed and personally dated by the subject or by the subject's legally acceptable representative, and by the person who conducted the informed consent discussion.<br><br>UVA Investigator Agreement: That all subjects will sign a current copy of the approved consent form.<br><br>UVA IRB Investigator Agreement: That no personnel will be allowed to work on this protocol until they have completed the IRB-HSR On-line training and the IRB-HSR has been notified.<br><br>Link to Informed consent discussion<br>To view, press the "control key" on your keyboard and right click your mouse on this link:<br>https://hrpp.irb.virginia.edu/learningshots/IC_Process_6-13/player.html | | |
| *Subject Selection Criteria:* | 4.5.1 The investigator/institution should conduct the trial in compliance with the protocol agreed to by the sponsor and, if required, by the regulatory authority(ies) and which was given approval/favorable opinion by the IRB/IEC. The investigator/institution and the sponsor should sign the protocol, or | | |

| | | | |
|---|---|---|---|
| | an alternative contract, to confirm agreement. | | |
| *Documentation that approved protocol was implemented as outlined:* | 4 4.5.2 The investigator should not implement any deviation from, or changes of the protocol without agreement by the sponsor and prior review and documented approval/favorable opinion from the IRB/IEC of an amendment, except where necessary to eliminate an immediate hazard(s) to trial subjects, or when the change(s) involves only logistical or administrative aspects of the trial (e.g., change in monitor(s), change of telephone number(s)). | | |
| *Study Drug or Device Accountability and Documentation:* | ICH GCP 4.6.3 The investigator and/or a pharmacist or other appropriate individual, who is designated by the investigator, should maintain records of the product's delivery to the research site, the inventory at the site, the use by each subject, and the return to the sponsor or alternative disposition of unused product. These records should include dates, quantities, bath/serial numbers, expiration dates, and the unique code numbers assigned to the drug and trail subjects. Investigators should maintain records that document adequately that the subjects were provided the doses specified by the protocol and reconcile. | | |
| *Documentation of Data Safety Monitoring and protection of confidentiality:* | NIH Guidance on DSMP: All clinical research required monitoring -- Data and safety monitoring is required for all types of research, including physiologic, toxicity, and dose-finding studies (phase I); efficacy studies (phase II); efficacy, effectiveness and comparative research (phase III); etc. | | |

| | | | |
|---|---|---|---|
| | Monitoring should be commensurate with risks -- The method and degree of monitoring needed is related to the degree of risk involved. | | |

**General Comments**: This report will be copied to the Post Approval Monitoring Working Group and the IRB PAM Advisory Committee *(and the Cancer Center DSMC or UVA Investigational Drug Services if applicable)*. They will contact you if any further actions need to be taken. *(Please provide PAM report to IRB of record if required – insert if applicable).*

XXXXXX
Research Compliance Monitor
Office of the Vice President for Research

**University of Virginia**
**Office of the Vice President for Research**
**Post-Approval Monitoring Report**

**HSR-IRB#** **IRB of Record:** **Principal Investigator:**

**Review Type:** ***( PICK ONE)*** Exempt OR Exempt with Limited IRB Review **Regulated by:** **(*PICK ONE)*** Pre 2018 Common Rule OR 2018 Common Rule

**Title:**

**Study Coordinator:** **Date of Review:**

**Introduction of what was reviewed:**

*Electronic study files (Excel spreadsheets and copies of protocol, Exempt application, etc.) were reviewed.*

| **Findings:** | **Regulations/Guidance:** | **Recommendations:** | **Resolution (to be completed by investigator/study team)** |
|---|---|---|---|
| *Regulatory documentation:* | UVA IRB-HSR Exempt Determination Process:<br>Investigator Responsibilities:<br>• If the investigator feels the project meets the criteria for exempt determination, he/she should submit an Exempt application to the IRB-HSR office. The application is obtained via Protocol Builder. In order to fulfill requirements for the proper review of research, investigators cannot "self-exempt" from IRB review. | | |
| *Documentation of informed consent*:<br><br>N/A – Exempt Determination. | *COPY AND PASTE THE EXEMPT CATEGORY THAT STUDY WAS EXEMPTED UNDER FROM IRB ONLINE*<br>*(May be found on Determination Documentation from the IRB-HSR)*<br><br>Investigator Responsibilities:<br>• The exemption is granted only for the study as written at the time of the initial review when the decision to exempt was determined.<br>• Investigators who conduct research exempt from IRB oversight must report any changes that will alter the study in | | |

| | | | |
|---|---|---|---|
| | such a way that it is no longer exempt from federal regulations. | | |
| *Subject Selection Criteria:* | Investigator Responsibilities:<br>• The exemption is granted only for the study as written at the time of the initial review when the decision to exempt was determined.<br>• Investigators who conduct research exempt from IRB oversight must report any changes that will alter the study in such a way that it is no longer exempt from federal regulations. | | |
| *Documentation that approved protocol was implemented as outlined:* | *COPY AND PASTE THE EXEMPT CATEGORY THAT STUDY WAS EXEMPTED UNDER FROM IRB ONLINE*<br>*(May be found on Determination Documentation from the IRB-HSR)* | | |
| *Data Security Plan:* | IF STUDY REGULATED UNDER<br>**PRE 2018 COMMON RULE** INSERT:<br><br>University of Virginia Data Security Policies<br><br>IF STUDY REGULATED UNDER<br>**2018 COMMON RULE:**<br>Add the following here if the study is approved under exempt criteria requiring Limited IRB Review per any of the following criteria:<br>• *45CFR46.104(d)(2)(iii)*<br>• *45CFR46.104(d)(3)(i)(c)*<br>• 45CFR46.104(d)(4)(iii) :<br><br>There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data per 45CFR46.111(a)7).<br><br>University of Virginia Data Security Policies | | |

**General Comments**:

| Department: Post Approval Monitoring and Education | | | |
|---|---|---|---|
| **AG # 1-7 Revision #7:** | **TITLE: Dissemination of Post Approval Monitoring Findings** | | **Page: 1 of 4** |
| Approved By: Associate VP for Research | Kelly Hochstetler | Date 1/1/24 | Date First Effective: 6/15/06 |
| Approved By: Research Compliance Monitor | Jane Lehmbeck | Date 1/1/24 | |
| Approved By Research Compliance Monitor | Elaine Dube | Date 1/1/24 | Revision Date: 11/1/06 3/27/17 11/16/07 4/8/20 3/1/09 10/18/23 7/7/09 9/21/09 6/30/15 |

**OBJECTIVE**
To define the possible outcomes of Post Approval Monitoring findings and the dissemination of the PAM report.

**RESPONSIBILITY**
Research Compliance Monitors will be responsible for creating the reports that are submitted to the IRB-HSR for review.

**PROCEDURE:**

1. Individual PAM reports will be categorized and disseminated per the following:

   **Category 1:** Regulatory documents and source documentation are complete and protocol compliance is consistent with good clinical practice; or some deviations noted, education and/or follow-up may be suggested or required:

   - Submit the post-approval monitoring report, along with a level 1 transmittal letter via electronic mail to the study team (study team consists of Principal Investigator, Study Coordinator and IRB Coordinator as appropriate), the IRB-HSR for their files, and the School of Medicine Clinical Trials Office Educator. The report will also be sent to the Cancer Center Data & Safety Monitoring Committee (CC DSMC) as appropriate.
   - PI's response is optional.
   - Enter the findings of the post approval monitoring review into the audit database (except for rating).
   - Submit the preliminary PAM report and the PI response (if any), to the PAM working group one week prior to their monthly meeting.
   - Ratings (Satisfactory) will be assigned by the PAM working group.

   **Category 2:** One or more major deviations or multiple minor deviations noted, education and/or follow-up may be suggested or required, continued non-compliance may be observed:

   - Submit a preliminary post-approval monitoring report, along with a level 2 transmittal letter via electronic mail to the study team (study team consists of Principal Investigator, Study Coordinator and IRB Coordinator as appropriate), the IRB-HSR for their files, and

the School of Medicine Clinical Trials Office Educator. The report will also be sent to the Cancer Center Data Safety Monitoring Committee (CC DSMC) as appropriate.

- PI response (if requested) will be required within 10 working days. The response should be made on the PAM report in the "Resolution Column". If investigators have not responded to the PAM report within 10 days of receipt or re-negotiated a response time with a Research Compliance Monitor, contact may be made by the latter via email or telephone call. The PI may be asked if they have received the letter/PAM report and had a chance to review it. The PI may also be told that if no response is made within 5 working days, another letter will be sent and copied to the department chair. Finally, if appropriate, this letter to the PI and copy to the department chair will be sent via email. If the Research Compliance Monitor still does not receive a response, the issue will be referred to the IRB-HSR PAM Advisory Committee.
- Enter the findings of the post approval monitoring review into the audit database (except for rating).
- Submit the preliminary PAM report and the PI response to the PAM working group one week prior to their monthly meeting. The PI response will also be sent to the IRB-HSR for their files, and the Cancer Center DSMC as appropriate.
- Ratings (Marginal) will be assigned by the PAM working group. The PAM working group may also select category 3 if there are concerns regarding subject safety.

**Category 3:** Serious concerns regarding safety of subjects and/or possible serious non-compliance:

- Prior to or while formulating a written PAM report, Monitors may take their concerns to the Senior Associate VP for Research. In addition, the IRB Chair and/or a consultant may be contacted for assistance with the review of the study. This consultant may be a specialist in the area of the research or a regulatory specialist. The Senior Associate VP for Research or IRB Chair may change the status of the study at any time for concerns of subject safety. If the status is changed, the IRB-HSR director or designee will be notified.
- Monitors will submit a PAM report, along with a level 3 transmittal letter via electronic mail to the study team (study team consists of Principal Investigator, Study Coordinator and IRB Coordinator as appropriate), the Senior Associate VP for Research, IRB-HSR Director and Chair or designee and consultant (if applicable).
- A written response from the PI will be required within 3 working days. If investigators have not responded within 3 days of receipt, contact will be made by the Research Compliance Monitor or Senior Associate VP for Research via telephone call or email. The PI will be asked if they have received the report and had a chance to review it, and will be asked to respond within 24 hours. If the Research Compliance Monitor does not receive a response, findings will be considered by the Senior Associate VP without PI input. This step will already have been completed if the study was first considered a category 2 and then changed to 3 by the PAM Working Group.
- The Senior Associate VP for Research will call a meeting to be held within 3-7 working days after the preliminary report is sent to the PI. The following individuals may be invited (as determined by the VP for Research) to the meeting: the Research Compliance Monitors, consultant(s) as appropriate, the SOM Associate Dean for Clinical Research or appropriate Dean or their designee, the Chair, Vice Chair, Director and Associate Director of the IRB-HSR, the PI, other applicable parties. The preliminary report will be shared with all in attendance. The purpose of this meeting is to examine the concerns of

subject safety. Possible outcomes of this meeting may include determining if: the study should be closed, interventions stopped, additional information is needed, or the PAM audit process should continue as per category level 1 or 2. Minutes will be taken by the PAM Compliance Monitors, or another meeting attendee if they are absent. When issues related to the PI's lack of compliance indicate possible research misconduct, the Senior Associate VP for Research will coordinate efforts to address these issues.

- If it is determined at the initial meeting, that concerns of subject safety or serious non-compliance remain and if the PI did not attend the initial meeting, the Senior Associate VP for Research may contact the investigator and schedule a second meeting with the PI, if the PI did not attend the initial meeting. The Senior Associate VP for Research will determine additional attendees at this meeting as necessary. The purpose is to allow the PI the opportunity to discuss the concerns in person and for the Senior Associate VP for Research to obtain additional information/ clarifications. The Senior Associate VP for Research or designee will document the outcome of this meeting and share this report with those in attendance at the previous meetings.
- All relevant information along with the written response from the investigator will be presented to the IRB-HSR PAM Advisory Committee. Documents must be given to the IRB-HSR PAM Advisory Committee prior to their meeting to allow them time to review the reports. The IRB-HSR PAM Advisory Committee will use a primary reviewer to present the information to the full IRB of record.
- Following the PAM Advisory Committee meeting, the IRB-HSR Chair will present the information to the full IRB-HSR (if IRB-HSR is the IRB of record) at the next scheduled full IRB meeting.
- The IRB of record (as per IRB-HSR AG 2-8 if IRB-HSR is IRB of record) will make further recommendations for action.
- The Research Compliance Monitor will enter the findings of the post-approval monitoring review into the audit database (including rating Unacceptable).

2. Aggregate PAM reports will be disseminated as follows:

    - Monthly to the PAM Working Group and the IRB-HSR PAM Advisory Committee - all reviews completed the previous month (See SOP 1-8). These reports will be grouped in a packet and will include the Post Approval Monitoring Reports and educational reports completed in the previous month. In addition, the IRB-HSR PAM Advisory Committee will receive a copy of the minutes from the PAM working group meeting.

3. Recommendations made by the PAM working group and the PAM IRB-HSR Advisory Committee will be disseminated as follows:

    - Recommendations generated from one or both committees will be communicated via a letter to the study team from the Senior Associate VP for Research (VPR), unless the IRB-HSR Advisory Committee determines that the letter should come from both the VPR and the IRB-HSR. If the letter is to come from both, the Senior Associate VP for Research and the Chair of IRB-HSR will sign the letter. The letter will be sent within 5 working days after the PAM IRB-HSR Advisory Committee meets (the fourth Tuesday of each month) via messenger mail or email and will be copied to the applicable department chair. The letter will also be sent to the School of Medicine Clinical Trials

Office Educator, the IRB-HSR chair, and the Cancer Center Data & Safety Monitoring Committee (CC DSMC) as appropriate.

4. The findings and the rating of the post approval monitoring review will be entered into the audit database.
5. An aggregate summary of all reviews shall be sent to the full IRB every year.

**REFERENCES:**

IRB SOP 2-8- Post Approval Monitoring
IRB SOP 2-7 Notification of Federal Regulatory Agencies
Transmittal letter –category 1 1-7 A
VPR letter –exceptional 1-7 A.2
Transmittal letter-category 2 1-7 B
VPR letter-satisfactory 1-7 B.2.a
VPR letter-marginal 1-7 B.2.b
Transmittal letter –category 3 1-7 C
PAM SOP-8-PAM Working Group

**AG 1-7A transmittal letter –category 1**

September 19, 2024

Dear Dr. XXXXXX,

As you may know, a Post Approval Monitoring review was completed for your study on xxx/xx/xxxx. Many thanks to you and your study team for the time spent preparing the study files and meeting with me to discuss your study.

The main objective of the post approval monitoring review is to enhance the quality of clinical research and provide the investigator and study team with recommendations for corrections, improvements and education.

Attached, please find the report of the review of the above-named study. Once you have read the report, please contact me for any explanations or clarifications of the findings noted.

Thank you once again for your cooperation in facilitating this review. Best wishes with your research.

Regards,

**AG 1-7B transmittal letter –category 2**

Dear Dr. Xxxx,

As you may know, a Post Approval Monitoring (PAM) review was conducted for your study on xx/x/xx. Many thanks to you and your study team for the time spent with me during the monitoring visit. The main objective of the PAM review is to enhance the quality of clinical research and provide the investigator and study team with recommendations for corrections, improvements and education.

Attached, please find the report of the review of the above-named study. Once you have read the report, please contact me for any explanations or clarifications of the findings noted. Please also provide a response in the column titled "Resolution" within 10 working days to jff7c@virginia.edu. Once your response has been received, a copy of the report will be sent to the PAM working group and the IRB PAM Advisory Committee for additional review and recommendations.

Thank you once again for your cooperation in facilitating this review.

Best regards,

Dear Dr. XXXXXX,

I write to thank you for your cooperation in the recent post approval monitoring (PAM) review of your clinical research protocol entitled, IRB-HSR # xxxxx – "_____" completed on xx-xx-xx.

Members of the PAM Working Group and the IRB PAM Advisory Committee have had an opportunity to review the PAM report and have no additional recommendations. We commend you and your study team for your efforts and commitment to good research practices.

If you have any questions about the findings and recommendations of your post-approval monitoring, please contact our office.

Sincerely,

Kelly Hochstetler, PhD
Associate Vice President for Research Operations, Compliance & Policy
Phone: 434-982-5725
Email: kjh@virginia.edu

Cc: Post Approval Monitors
Department Chair
Study Coordinator
IRB-HSR Administrator
Chair, IRB-HSR
SOM CTO Educator
Cancer Center DSMC (if needed)

September 19, 2024

Dear Dr. XXXXXX,

I write to thank you for your cooperation in the recent post approval monitoring (PAM) review of your clinical research protocol entitled, HSR # xxxxx – "_____" completed on xx-xx-xx.

Members of the PAM Working Group and the IRB PAM Advisory Committee have had an opportunity to review the PAM report (and your response if applicable) and agree with the recommendations made in the report. Please make any corrective actions requested in a timely manner. Additionally, the Committee requests the following:

- xxxxxxx

If you have any questions about the findings and recommendations of your post-approval monitoring, please contact our office.

Sincerely,

Kelly Hochstetler, PhD
Associate Vice President for Research Operations, Compliance & Policy
Phone: 434-982-5725
Email: kjh@virginia.edu

Cc: Post Approval Monitors
Department Chair
Study Coordinator
IRB-HSR Administrator
Chair, IRB-HSR
SOM CTO Educator
IRB-HSR Director
Cancer Center DSMC (if needed)

**AG 1-7C Transmittal letter –category 3**

September 19, 2024

Dear Dr. XXXXXX,

As you know, a Post Approval Monitoring (PAM) review was conducted for your study on _____. Thank you for the time you and your staff spent with me during the monitoring visit. The main objective of the post approval monitoring review is to enhance the quality of clinical research and provide the investigator and study team with recommendations for corrections, improvements and education.

Attached, please find the report of the review of the above-named study. Please note that the Senior Associate VP for Research has been consulted for help in determining recommendations and further actions regarding the study findings. Once you have read the report, please provide a written response in the column titled “Resolution” within 3 working days to xxx@virginia.edu. Please include in your response any explanations or clarifications of the findings noted and a plan of action to correct and prevent future occurrences. A copy of the report and your response will be sent to the Senior Associate VP for Research, PAM working group and the IRB PAM Advisory Committee for additional review.

Sincerely,

| Department: Post Approval Monitoring and Education | | | |
|---|---|---|---|
| **AG # 1-8 Revision #6:** | **TITLE: Function of the PAM working group** | | **Page: 1 of 2** |
| Approved By: Associate VP for Research Operations, Compliance & Policy | Kelly Hochstetler | Date 7/18/24 | Date First Effective: 6/15/06 |
| Approved By: Research Compliance Monitor | Jane Lehmbeck | Date 7/18/24 | |
| Approved By Research Compliance Monitor | Elaine Dube | Date 7/18/24 | Revision Date: 11/1/06 3/27/17 7/18/24 3/1/09 4/8/20 6/30/15 4/18/22 |

**OBJECTIVE**

To define the purpose and function of the PAM working group.

**RESPONSIBILITY**

The PAM working group membership may consist of:

- Research Compliance Monitors
- School of Medicine Clinical Trials Office Educators, Director and Assistant Director
- Associate VP for Research Operations, Compliance & Policy
- Compliance Training Specialist, IRB
- Director, IRB-HSR

The Research Compliance Monitors will be responsible for creating the reports that are submitted to the group for review.

**PROCEDURE:**

1. The PAM working group will meet on the second Wednesday of each month to review all PAM and education reports conducted the previous month. The PAM reports will be submitted to the group by the Research Compliance Monitors.
2. The group will review each report considering the following:

    - Additional recommendations and/or educational needs.
    - Findings that the full IRB committee should address.
    - Trends or findings with service centers or departments (CRU, Cancer Center, Pharmacy, etc.)
    - Suggestions for policy and or procedural changes as needed.

3. Any IRB-HSR questions or concerns that are identified or any protocols with serious compliance issues will be submitted by the PAM working group to the IRB-HSR PAM Advisory Committee.

4. The PAM working group will assign a criticality score to the findings utilizing the following rating scale:

- Satisfactory (Category 1): Regulatory documentation complete, evidence of consistent protocol compliance and source documentation or few minor deviations noted. If a major deviation has occurred, there must be corrective actions in place and overall assessment of study conduct is good.
- Marginal (Category 2): At least one major deviation noted or many minor. Education and/or follow-up audit may be recommended. Follow-up audit may occur in approximately 3-6 months, or as determined by the PAM Working Group and IRB PAM Advisory Committee.
- Unacceptable (Category 3): Extremely deficient review, or after education and re-review, non-compliance is still evident, or the degree of subject risk is uncertain.

The ratings will be used for internal reporting to the IRB-HSR and for statistical reporting only.

Any studies deemed unacceptable by the PAM working group will fall back into category 3.

**REFERENCES:** none

| Department: **Post Approval Monitoring and Education** | | | |
|---|---|---|---|
| **AG # 1-9 Version #1:** | **TITLE: Consent Monitoring** | | **Page: 1 of 2** |
| Approved By: Associate VP for Research | David J. Hudson | Date 4/17/20 | Date First Effective: 3/27/17 |
| Approved By: Research Compliance Monitor | Jane Lehmbeck | Date 4/17/20 | |
| Approved By Research Compliance Monitor | Elaine Dube | Date 4/17/20 | Revision Date: 4/8/20 |

**OBJECTIVE**
To define the purpose and procedures used for informed consent monitoring.

**RESPONSIBILITY**
The Research Compliance Monitors and the SOM CTO Educator will be responsible for informed consent monitoring.

**PROCEDURE:**

1. In reviewing the adequacy of informed consent procedures for proposed research, the IRB may on occasion determine that special monitoring of the consent process by an impartial observer is required in order to reduce the possibility of coercion and undue influence, ensure that the approved consent process is being followed, or ensure that subjects are truly giving informed consent. Examples for which observation of the informed consent process may be needed:
    - High risk studies
    - Research involving particularly complicated procedures or interventions
    - Studies enrolling highly vulnerable populations (e.g. ICU patients, children who are wards)
    - Research conducted by study team members with minimal experience in administering consent to potential study participants
    - Other situations when the IRB has concerns that consent process may not be/is not being conducted appropriately

2. Consent monitoring may also be appropriate as a corrective action where the IRB has identified problems associated with a particular investigator or research project.

3. IRB members will determine requirements for consent monitoring. The investigator will be notified by the IRB of the determination for consent monitoring.

4. Consent monitoring may be conducted by the UVA Post Approval Monitoring & Education staff.

5. The following will be monitored during the observation of informed consent process:
    - Whether the informed consent process was appropriately conducted and documented
    - Whether the participant had sufficient time to consider study participation
    - Whether the consent process involved coercion or undue influence
    - Whether the information was accurate and conveyed in understandable language
    - Whether the subject appeared to understand the information and gave their voluntary consent

6. A report of the observation of informed consent process will be submitted to the IRB, which will determine next appropriate action in regard to the research.

**REFERENCES:** IRB-HSR AG 7.5.5 Consent Monitoring

| Department: Post Approval Monitoring and Education | | | |
|---|---|---|---|
| **AG # 1-10 Revision #1** | **TITLE: Function of the IRB PAM Advisory Committee** | | **Page: 1 of 2** |
| Approved By: Associate VP for Research Operations, Compliance & Policy | Kelly Hochstetler | Date 7/18/24 | Date First Effective: 4/18/22 |
| Approved By: Research Compliance Monitor | Jane Lehmbeck | Date 7/18/24 | |
| Approved By Research Compliance Monitor | Elaine Dube | Date 7/18/24 | Revision Date: 7/18/24 |

**OBJECTIVE**
To define the purpose and function of the IRB PAM Advisory Committee.

**RESPONSIBILITY**
The IRB PAM Advisory Committee membership may consist of:

- Research Compliance Monitors (2)
- IRB Chair
- IRB Vice-Chair
- IRB Director and IRB Associate Director
- IRB member(s) non-scientist or unaffiliated member
- IRB member Study Coordinator (if applicable)

Note: the composition of the committee and required members for attendance at the meetings may vary. If possible, the meeting attendance will consist of (at least): 1 Research Compliance Monitor, IRB Chair or Vice-Chair, IRB Director or IRB Compliance Coordinator.

**PROCEDURE:**

1. The IRB PAM Advisory Committee will meet on the 4th Mondayof every month. Alternate meeting times for the committee may be scheduled when needed. The committee will review all PAM and education reports conducted the previous month, as well as the minutes from the applicable PAM Working Group meeting.

   The Research Compliance Monitors will be responsible for creating the reports and meeting agenda submitted to the committee for review.

2. The committee will review each report considering the following:

   - Additional recommendations and/or educational needs.
   - Findings that the full IRB-HSR board may need to review.

3. The committee will consider the rating assigned for each study PAM report at the PAM Working Group meeting (criteria used for ratings below):

- Satisfactory: Regulatory documentation complete, evidence of consistent protocol compliance and source documentation or few minor deviations noted. If a major deviation has occurred, there must be corrective actions in place and overall assessment of study conduct is good.
- Marginal: At least one major deviation noted or many minor. Education and/or follow-up audit may be recommended. A follow-up audit may occur in approximately 3-6 months, or as determined by the PAM Working Group and IRB PAM Advisory Committee.

Unacceptable: Extremely deficient review, or after education and re-review, non-compliance is still evident, or the degree of subject risk is uncertain.

The committee will confirm the ratings assigned by the PAM Working Group if they agree, or may change the rating if needed. The IRB PAM Advisory Committee will make the final determination of a study PAM report rating.

**REFERENCES: 1-8 Function of the PAM Working Group**