VCU Human Research Protection Program

Post-Approval Monitoring and Education

Self-Evaluation Tool

Social Behavioral 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

1. A routine quality improvement exercise
2. 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.

[WPP X-3 Post Approval Monitoring of IRB Approved Protocols](http://www.research.vcu.edu/irb/wpp/flash/X-3.htm)

For more information, please see: [Post approval monitoring and education (PAME) Process](http://www.research.vcu.edu/irb/PAME+process+draft+3-1-2011.docx)

If you are preparing for a PAME visit, completing this form will help focus the content of the 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. After you have filled out the PAME SET form, please send it to Dr. Enid Virago. Receipt of this completed form a week before the PAME meeting will help facilitate better use of the meetingtime.

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, Research Liaison Specialist, Office of Research Compliance and Education at [viragoea@vcu.edu](mailto:viragoea@vcu.edu) or (804) 828-7712.

VCU Human Research Protection Program

Post-Approval Monitoring and Education

Self-Evaluation Tool (PAME SET)

Social Behavioral Research

***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. [**Unanticipated Problem (a.k.a. AE/SAE) Reporting**](#upreporting)
7. [**Protocol Violations/Deviation Reporting**](#protocolviolationsdeviations)
8. [**Recordkeeping**](#recordkeeping)/ Data Security
9. 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 Began: |  |
| Date Self-Study Completed: |  |
| Date Self-Study sent to the Research Liaison Specialist: | \*RLS 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\_\_\_\_  🗆 Western IRB  🗆 Central IRB  🗆 Other: \_\_\_\_\_\_\_\_\_\_\_ |
| Funding Sources: | 🗆 Industry  🗆 Federal  🗆 Foundation  🗆 Internal/Departmental (also not funded)  🗆 Other: \_\_\_\_\_\_\_\_\_\_\_\_ |
| Monitoring Sources: | 🗆 Sponsor  🗆 Federal \_\_\_\_\_\_\_\_\_\_\_\_\_  🗆 Foundation  🗆 Internal/Departmental  🗆 CRC  🗆 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 * 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 the [VCU IRB Written Policies and Procedures](http://www.research.vcu.edu/irb/VCUIRBWPP.doc) ([http://www.research.vcu.edu/irb/VCUIRBWPP.doc](http://www.research.vcu.edu/irb/VCUIRBWPP)) to determine reporting requirements to the VCU IRB.

|  |  |  |  |
| --- | --- | --- | --- |
| Protocol Version (refer to study binder or file) | | ***YES*** | ***NO*** |
| 1.1 | Is the most recent version of the approved research plan/protocol and IRB Letter of Approval on file? |  |  |
| 1.1.2 | Are there previous versions of the research plan/protocol? ***(If no, go to 1.2)*** |  |  |
| 1.1.3 | If yes, are they on file? |  |  |
| 1.1.4 | Are you able to identify each version and date of the protocol? |  |  |
| 1.1.5 | Is the version# and version date on the bottom of each document? |  |  |
| Training and Experience | | ***YES*** | ***NO*** |
| 1.2 | 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 Social-Behavioral Research?  <https://www.citiprogram.org/Default.asp>?  If you are using an alternative IRB-approved training, please explain below. |  |  |
| 1.2.1 | If applicable, is the CITI Refresher up to date? |  |  |
| 1.2.2 | Have all key personnel received appropriate training on execution of the protocol? Please explain on the bottom of this section. |  |  |
| 1.2.3 | Are meetings of study staff conducted at regular intervals? How often? |  |  |
| 1.2.4 | Are CVs on file in the study office for each member of the study staff? (Should be less than 2 years old) |  |  |
| Laboratory Records (If you use a lab, if not go to 1.11) | | ***YES*** | ***NO*** |
| 1.3 | Are lab tests a part of this study? ***(If no, go to 1.12)*** |  |  |
| 1.3.1 | Is a copy of the normal lab values on file? |  |  |
| 1.3.2 | Is lab certification on file? |  |  |
| 1.3.3 | Is the lab director’s CV on file (signed and dated)? |  |  |
| Data Safety Monitoring | | ***YES*** | ***NO*** |
| 1.4 | If this study is more than minimal risk: Is there a DSMP or data oversight panel for this study? ***(If no, go to 2.1)*** |  |  |
| 1.4.1 | Have they met in accordance with the IRB approved protocol? |  |  |
| 1.4.2 | Are the appropriate reports and recommendations on file? |  |  |
| 1.4.3 | Have the Panel report(s) or review(s) been submitted to the VCU IRB? |  |  |
|  | | | |
| **Please use this area to describe any areas of concern , action(s) to take or taken, and other notes:** | | | |

**2.** **IRB Documentation:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| General IRB Correspondence | | | | ***YES*** | ***NO*** |
| 2.1 | Is all correspondence (signed/dated applications, responses, approvals) to the IRB on file? | | |  |  |
| 2.1.1 | Is other correspondence (e.g., emails) to and from the IRB on file? | | |  |  |
| Initial Review | | | | ***YES*** | ***NO*** |
| 2.2 | Is the initial IRB approval letter on file? | | |  |  |
| Continuing Review | | | | ***YES*** | ***NO*** |
| 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 | List number of subjects enrolled as noted on each continuing review - Optional | | |  |  |
|  | |  | | | |
|  | |  | | | |
|  |  | | | ***YES*** | ***NO*** |
| 2.3.2.1 | Are the IRB Approval Letters for continuing review on File? | | |  |  |
|  |  | | | ***YES*** | ***NO*** |
| 2.3.3 | Was each Continuing Review submitted by the due date (provided by the IRB)? | | |  |  |
| 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 | Was 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)*** | | |  |  |
| 2.3.8 | If yes, was there written justification and approval by the IRB? | | |  |  |
| Changes in Research (Amendments) | | | | YES | ***NO*** |
| 2.4 | Have there been **any** changes to the study? ***(If no, got to 3)*** | | |  |  |
| 2.5 | If there have been changes to the study, were amendments for each change approved by the IRB prior to implementation (unless necessary to ensure the safety of the research subjects & IRB approved)? | | |  |  |
| 2.4 | If changes were not approved, please explain 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). | | | ***#:*** | |
|  | | | | | |
| **Please use this area to describe any areas of concern, action(s) to take or taken, and other notes:** | | | | | |

**3. Subject Selection Criteria:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Subject Selection | | | ***YES*** | ***NO*** | |
| 3.1 | | Is there an eligibility checklist containing inclusion/exclusion criterion? ***(If no, skip to 3.4)*** |  |  | |
| 3.1.1 | | (**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). |  | |  |
| 3.2 | | If any subjects did not meet the eligibility criteria (and were enrolled), was this reported to the IRB (as a protocol deviation or violation)? |  | |  |
| 3.3 | Number of Subjects excluded | | ***#:*** | | |
| 3.4 | Number of Subjects who withdrew | | ***#:*** | | |
| 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 | | Are there any enrollment issues (such as slow enrollment)? |  | |  |
| 3.6.1 | | Are there any subjects enrolled that are outside the inclusion criteria? |  | |  |
| 3.6.2 | | Does the current distribution of subjects (by race, gender, etc.) meet expectations (outlined within the protocol or at the time of IRB submission)? |  | |  |
| 3.6.3 | | If enrollment is low relative to goal, is there a plan to meet the goal?  See WPP for Guidance <http://www.research.vcu.edu/irb/wpp/flash/XII-4.htm>. Please explain plan below. |  | |  |
| 3.6.4 | | Do you plan to continue recruitment/enrollment/interventions? |  | |  |
| 3.6.5 | | Is IRB-approved compensation being provided? Is it still appropriate? |  | |  |
|  | | | | | |
| **Please use this space to describe any areas of concern, action(s) to take or taken, and other notes:** | | | | | |

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Recruitment Methods | | | | |
| 4.1 | How are potential subjects identified? *(check all recruitment methods that apply)* | 🗆 Clinical practice  🗆 Investigators:  🗆 Database  🗆 Medical record review | | |
| 🗆 Subject response to hard copy recruitment materials   * Direct email   🗆 Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| 4.1.1 | Does anyone refer potential subjects or provide access to materials in order to identify potential subjects? If so, who? |  | | |
|  | | | ***YES*** | ***NO*** |
| 4.2 | Are recruitment ***methods*** (identified above) stated in the IRB approved protocol? http://www.research.vcu.edu/irb/wpp/flash/XII-4.htm | |  |  |
| 4.2.1 | Is this a community based study? | |  |  |
| 4.2.2 | Have there been community forums to explain the study? If so, # | |  |  |
| 4.2.3 | Are community members/leaders involved in your study? | |  |  |
| 4.3 | Is initial contact made in compliance with the IRB-approved protocol? | |  |  |
| 4.4 | If recruitment ***materials*** have been used, please check all that apply: | 🗆 None Used ***(Go to section 4.7)***  🗆 Print Advertisements (print or postings)  🗆 Televised or Radio Advertisements  🗆 Flyers  🗆 Web postings/email \_\_\_\_\_\_\_\_\_\_\_\_  🗆 Letters  🗆 Pre-screening forms  🗆 Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
|  | | | ***YES*** | ***NO*** |
| 4.4.1 | Have all recruitment materials (identified above) been approved by the IRB? | |  |  |
| 4.5 | Are all stamped, approved recruitment materials (identified above) on file? | |  |  |
| 4.6 | Were any changes made to recruitment materials since last continuing review? ***(If no, go to section 4.7)*** | |  |  |
| 4.6.1 | 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 as noted in the IRB submission materials? | |  |  |
| 4.8.1 | What is the rate of recruitment? (Per month or year) | |  |  |
| 4.9 | Estimated closure date for this study | |  |  |
|  | | | | |
| **Please use this space to describe any areas of concern, action(s) to take or taken, and other notes:** | | | | |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Informed Consent | | | | | | | | | | | | | | | | |
| 5.1 | | | | Please identify all consent 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. You may add more spaces. - Optional* | | | | | | | | | | | | |
|  | | | | ***Version ID (your code) & Date:*** | | | | | | ***Valid/IRB Approval Date:*** | | | | | | |
| 5.1.1 | | | |  | | | | | |  | | | | | | |
| 5.1.2 | | | |  | | | | | |  | | | | | | |
| 5.1.3 | | | |  | | | | | |  | | | | | | |
|  | | | | | | | | | | | | | | ***YES*** | | ***NO*** |
| 5.2 | | | | Are all-prior IRB-approved versions of the IRB approved consent being retained? | | | | | | | | | |  | |  |
| 5.3 | | | | Does the place where you consent the subject allow the participants to preserve their privacy? | | | | | | | | | |  | |  |
| 5.4 | | | | Is the consent form read to the subject and discussed / left with them?  Please note below how much time potential subject have to decide whether to participate. | | | | | | | | | |  | |  |
| 5.5 | | | | Are subjects given a copy to keep in case they have future questions? | | | | | | | | | |  | |  |
| 5.5.1 | | | | Do you make a note in your subject log that subjects that received a copy of the consent form? | | | | | | | | | |  | |  |
| 5.5.2 | | | | Do you provide educational materials to subject? If so, please attach a copy to this document. | | | | | | | | | |  | |  |
| 5.6 | | | | Is consent a continuous process? If yes, when after initial consent and how often thereafter do you discuss consent with the subject (note below)? | | | | | | | | | |  | |  |
| 5.7 | | | | Will there be re-contacting for any reason? | | | | | | | | | |  | |  |
| 5.8 | | | | Is information on re-contacting in the Consent form? | | | | | | | | | |  | |  |
| **Please use this space to describe any areas of concern, action(s) to take or taken, and other notes:** | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | Informed Consent – File Review Exercise (Optional) | | | | | | | | | | | |
| 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***  ***Only*** | | | ***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? If parent is LAR, did 1 or2 parents sign as approved by IRB?*** | | | ***Does each subject file indicate whether the subject was included/***  ***excluded appropriately?*** | ***Is it documented in the study files that each subject received a copy of the signed/dated consent document?*** | | | | |
| ***Code*** | | | ***YES*** | | | ***NO*** | | ***DATE*** | ***DATE*** | ***YES*** | | ***NO*** | ***YES NO*** | ***YES*** | | ***NO*** | | | |
| (1) | | |  | | |  | |  |  |  | |  |  |  | |  | | | |
| (2) | | |  | | |  | |  |  |  | |  |  |  | |  | | | |
| (3) | | |  | | |  | |  |  |  | |  |  |  | |  | | | |
| (4) | | |  | | |  | |  |  |  | |  |  |  | |  | | | |
| (5) | | |  | | |  | |  |  |  | |  |  |  | |  | | | |
|  | | | | | | |  | | | | | | | | | | | | |

**6. Risk/Benefit**

|  |  |  |  |
| --- | --- | --- | --- |
|  | | ***YES*** | ***NO*** |
| 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 information regarding risk related to this research? |  |  |
| 6.4 | Does Investigator/Research Coordinator have the time and resources available to do the work? If not, please indicate what is needed below. |  |  |
| 6.5 | Does Research Coordinator attend Office of Research or other educational events? |  |  |
| 6.5.1 | Please note areas of further training that would be helpful below. |  |  |
| **Please use this space to describe any areas of concern, action(s) to take or taken, and other notes:** | | | |

**7.** **Unanticipated Problem (including unexpected adverse event) reporting:**

If there have been no AE/SAE/UPs, ***go to section 8***.

|  |  |  |  |
| --- | --- | --- | --- |
| Refer to the VCU IRB Reporting guidelines, above as you answer the following questions: <http://www.research.vcu.edu/irb/wpp/flash/VIII-7.htm> | | ***YES*** | ***NO*** |
| 7.1 | Number of Unanticipated Problems (UPs)/Prompt Reports in history of study? Please describe the problem(s) and the actions taken to resolve the problems in the space below. |  |  |
| 7.1.1 | Any Non-Prompt Reporting in history of study? Describe theme(s) represented by the Non-Prompt reports. If unexpected high frequency of similar issues, consider filing a Prompt Report. |  |  |
| 7.2 | Have there been any complaints from subjects? If so, what? |  |  |
|  | | | |
| **Please use this space to describe any areas of concern, action(s) to take or taken, and other notes:** | | | |

**8.** **Protocol violations/deviation Reporting:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Refer to the VCU IRB Reporting guidelines, above as you answer the following questions:<http://www.research.vcu.edu/irb/wpp/flash/VIII-7.htm> | | ***YES*** | ***NO*** | |
| 8.1 | Does your site 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 |  | |  |
| 8.1.2 | Have all protocol violations/deviations been reported to the VCU IRB if they met the definition of an ‘unanticipated problem involving risk to subjects or others?’ |  | |  |
| 8.1.3 | If not addressed in 7.1.1 above: Any Non-Prompt Reporting in history of study? Describe theme or themes represented by the Non-Prompt report. |  | |  |
|  | | | | |
| **Please use this space to describe any areas of concern, action(s) to take or taken, and other notes:** | | | | |

**10.** **Record Keeping/ Data Security:**

Reminder: if a problem has been identified, be sure to review the terms of approval (in your IRB approval letter) and the [VCU IRB Written Policies and Procedures](http://www.research.vcu.edu/irb/VCUIRBWPP.doc) (http://www.research.vcu.edu/irb/wpp/flash/XII-1.htm) to determine reporting requirements to the VCU IRB. For further information see the VCU data security policy; <http://infosecurity.vcu.edu/> and <http://www.ts.vcu.edu/kb/2311.html>

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| General | | | ***YES*** | ***NO*** |
| 10.1 | Do you keep a binder/folder for all regulatory documents (IRB approved documents, etc.)? | |  |  |
| 10.2 | Do you keep a binder/folder/section for IRB correspondence? | |  |  |
| 10.3 | Do you keep a study file for each subject? | |  |  |
| 10.4 | Are the study files stored separately from consent documents? | |  |  |
| 10.4 | Are the subject study files coded (by a unique number/letter combination), with the code key stored in a secure location? | |  |  |
| 10.5 | 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. | |  |  |
| 10.6 | Are any Personal Health Information data kept in electronic files?  <http://www.research.vcu.edu/irb/wpp/flash/XII-3.htm> | |  |  |
| 10.6.1 | Are data in storage de-identified (see 10.4)? | |  |  |
| 10.7 | Are you storing study data on a University secure server? What kind of data capture or storage system are you using? | |  |  |
| 10.7.1 | Do you have an available server/database administrator? If yes, please include your server administrator’s name and contact information here. | |  |  |
| 10.8 | If you are storing data on a computer and/or portable storage device, are these devices password protected and/or encrypted?  <http://www.ts.vcu.edu/kb/mc-docs/VCUSecurityStandardforEncryption.pdf> | |  |  |
| 10.8.1 | Are these devices stored in a secure location? | |  |  |
| 10.8.2 | Are there firewalls? | |  |  |
| 10.8.3 | If portable, how is security maintained during transportation? | Please describe below. | | |
| 10.8.4 | Does each person who has access to the data have a unique password?  http://www.ts.vcu.edu/kb/mc-docs/standard-information-security-20091130.doc | |  |  |
| 10.9 | If you send data through email, is this encrypted? | |  |  |
| 10.9.1 | 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:** | | | | |

## Special Research Conditions

For information on special conditions, please refer to http://www.research.vcu.edu/irb/wpp\_guide.htm

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | | | ***N/A*** | ***YES*** | ***NO*** |
| 11.1 | 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: See* [*VCU IRB WPP XVII-6*](http://www.research.vcu.edu/irb/wpp/flash/wpp_guide.htm)*.*  *A non-VCU institution becomes "engaged" in human subjects research when its employees or agents (1) intervene or interact with living individuals for research purposes; or (2) obtain individually identifiable private information for research purposes* [*[45 CFR 46.102(d)-(f)]*](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.102)*.* | |  |  |  |
| 11.2 | 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: See* [*VCU IRB WPP XVII-6*](http://www.research.vcu.edu/irb/wpp/flash/wpp_guide.htm)*.* | |  |  |  |
| 11.3 | 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 to participate in confidential appointments and retain confidential personal records? *Note: See* [*VCU IRB WPP XIV-1*](http://www.research.vcu.edu/irb/wpp/flash/wpp_guide.htm)*.* | |  |  |  |
| 11.3.1 | If treatments are involved, are provisions made to provide timely and appropriate treatments? | |  |  |  |
| 11.4 | If participants may have limited English proficiency, are IRB approved consent materials provided in the languages other than English for those who may have limited English proficiency? *Note: See* [*VCU IRB WPP XVII-1*](http://www.research.vcu.edu/irb/wpp/flash/wpp_guide.htm)*.* | |  |  |  |
| 11.4.1 | Is research being conducted in a foreign (non-US) location? | |  |  |  |
| 11.4.2 | If so, has the risk changed since initial approval? | |  |  |  |
| 11.5 | Are appropriate procedures in place to evaluate the decisional capacity of prospective participants? *Note: See* [*VCU IRB WPP XVII-7*](http://www.research.vcu.edu/irb/wpp/flash/wpp_guide.htm)*.* | |  |  |  |
| 11.6 | Are there any issues unique to your research, such as:  If so, please describe below | 🗆 Genetic testing  🗆 Tissue Banking  🗆 Emergency Procedures  🗆 Research Involving Deception  🗆 Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |
| 11.7 | Has this research been approved for the involvement of children (<18)? | |  |  |  |
| 11.7.1 | If so, are any of these children wards of the state? | |  |  |  |
| 11.8 | Has this research been approved with a waiver of some or all elements of informed consent or waiver of documentation of consent? | |  |  |  |
| 11.8.1 | If so, did you provide a formal rationale for the waiver request? | |  |  |  |
|  | | | | | |
| **Please use this space to describe any areas of concern, action(s) to take or taken, and other notes:** | | | | | |