VCU Office of Research and Innovation

Worksheet: VCU Human Subject Research Quality Assessment

Principal Investigator	
Protocol Title	
Protocol IRB Number	
Name of Person Completing Assessment	
Date Assessment was Completed	

The goal of this assessment is to assure that the rights and well-being of human subjects are protected, the reported study data are accurate, complete, and verifiable, and the study is being conducted according to Federal Regulations, Policies, Guidance, VCU policies and conditions of IRB approval.

This form should be retained in your study files and may be used at the time of your continuing review submission for your "Summary Report: VCU Human Subject Research Quality Assessment" at ***go.vcu.edu/submit/quality***. Amendments and reports should be submitted through RAMS-IRB. This form, when complete, is part of the quality improvement process program and is not available to outside organizations without formal approvals.

Document Revision History:
DRAFTv6: February 12, 2018
Version1: February 19, 2018

Monitoring by Other Groups

In the last year, has your study been monitored by a Clinical Research Organization (CRO), Massey Cancer Center, VCU Johnson Center, or other internal/external monitoring group?

O Yes
O No

If "No," please go to the next page and complete the "Worksheet: VCU Human Subject Research Quality Assessment" for your study

If "Yes," please complete the next two questions and proceed to the Overall Assessment section on the last page.

1. What group monitored? _____

2. When was your last monitoring visit? _____

_____ _____
Signature of study staff member completing this form Date

_____ _____
Signature of Investigator reviewing this form Date

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Consent Process Worksheet

If your study obtains signed consent/parental permission/assent, complete this section by randomly selecting ten (10) enrolled subjects. After reviewing their consent/parental permission/assent documents (referred to as "the ICF" below), then answer the following questions. If less than ten (10) subjects have enrolled since the last assessment, review all subjects.

	1	2	3	4	5	Notes and/or Explanation of any "No" Answers:
Participant ID Number:						
Was the most recently approved version of the consent document utilized?	O Yes O No	O Yes O No	O Yes O No	O Yes O No	O Yes O No	
Is the IRB's approval stamp present and legible on the ICF?	O Yes O No	O Yes O No	O Yes O No	O Yes O No	O Yes O No	
Is there an original copy of the ICF on file?	O Yes O No	O Yes O No	O Yes O No	O Yes O No	O Yes O No	
Are all pages of the ICF present?	O Yes O No	O Yes O No	O Yes O No	O Yes O No	O Yes O No	
Are all options in the ICF completed?	O Yes O No	O Yes O No	O Yes O No	O Yes O No	O Yes O No	
Are all required signatures present?	O Yes O No	O Yes O No	O Yes O No	O Yes O No	O Yes O No	
Is the person who obtained consent on the personnel list and delegated to this task?	O Yes O No	O Yes O No	O Yes O No	O Yes O No	O Yes O No	
Was the ICF signed prior to any study related procedures being performed?	O Yes O No	O Yes O No	O Yes O No	O Yes O No	O Yes O No	
Was a copy of the ICF given to the participant?	O Yes O No	O Yes O No	O Yes O No	O Yes O No	O Yes O No	
Was the consent process documented in the case records including the Medical Record (as appropriate)?	O Yes O No	O Yes O No	O Yes O No	O Yes O No	O Yes O No	
Was the assent process conducted as approved?	O Yes O No O N/A	O Yes O No O N/A	O Yes O No O N/A	O Yes O No O N/A	O Yes O No O N/A	
For short form consents, were the required individuals present and required signatures obtained?	O Yes O No O N/A	O Yes O No O N/A	O Yes O No O N/A	O Yes O No O N/A	O Yes O No O N/A	
Is there an original copy of the HIPAA authorization on file?	O Yes O No O N/A	O Yes O No O N/A	O Yes O No O N/A	O Yes O No O N/A	O Yes O No O N/A	
Are all required signatures present on the HIPAA authorization?	O Yes O No O N/A	O Yes O No O N/A	O Yes O No O N/A	O Yes O No O N/A	O Yes O No O N/A	

Consent Process Worksheet continued…

	6	7	8	9	10	Notes and/or Explanation of any "No" Answers:
Participant ID Number:						
Was the most recently approved consent document utilized?	O Yes O No	O Yes O No	O Yes O No	O Yes O No	O Yes O No	
Is the IRB's approval stamp present and legible on the ICF?	O Yes O No	O Yes O No	O Yes O No	O Yes O No	O Yes O No	
Is there an original copy of the ICF on file?	O Yes O No	O Yes O No	O Yes O No	O Yes O No	O Yes O No	
Are all pages of the ICF present?	O Yes O No	O Yes O No	O Yes O No	O Yes O No	O Yes O No	
Are all options in the ICF completed?	O Yes O No	O Yes O No	O Yes O No	O Yes O No	O Yes O No	
Are all required signatures present?	O Yes O No	O Yes O No	O Yes O No	O Yes O No	O Yes O No	
Is the person who obtained consent on the personnel list and delegated to this task?	O Yes O No	O Yes O No	O Yes O No	O Yes O No	O Yes O No	
Was the ICF signed prior to any study related procedures being performed?	O Yes O No	O Yes O No	O Yes O No	O Yes O No	O Yes O No	
Was a copy of the ICF given to the participant?	O Yes O No	O Yes O No	O Yes O No	O Yes O No	O Yes O No	
Was the assent process conducted as approved?	O Yes O No O N/A	O Yes O No O N/A	O Yes O No O N/A	O Yes O No O N/A	O Yes O No O N/A	
For short form consents, were the required individuals present and required signatures obtained?	O Yes O No O N/A	O Yes O No O N/A	O Yes O No O N/A	O Yes O No O N/A	O Yes O No O N/A	
Is there an original copy of the HIPAA authorization on file if separate from the ICF?	O Yes O No O N/A	O Yes O No O N/A	O Yes O No O N/A	O Yes O No O N/A	O Yes O No O N/A	
Are all required signatures present on the HIPAA authorization if separate from the ICF?	O Yes O No O N/A	O Yes O No O N/A	O Yes O No O N/A	O Yes O No O N/A	O Yes O No O N/A	

Study Documentation Worksheet

Personnel		Notes and/or Explanation of any "No" Answers:
Are all engaged personnel approved by the IRB? (i.e. Are they listed as personnel in RAMS-IRB?)	O Yes O No	
Are the delegation and signature log(s) up to date and include all personnel?	O Yes O No	
Have all personnel completed required CITI training (HSR & GCP as applicable)?	O Yes O No	
Have all personnel completed protocol specific training and is documentation present (i.e. training logs)?	O Yes O No	
Are the credentials of all personnel current and documented (i.e. CV, license)?	O Yes O No	
Notes:		
Safety Reporting		**Notes and/or Explanation of any "No" Answers:**
Have all deviations from the protocol, SOPs, GCP, and/or any other regulatory requirements been communicated as necessary?	O Yes O No	
Were all adverse events (AEs) documented and reported appropriately within the required time periods?	O Yes O No O N/A	
Are your compiled AEs, SAEs, UPs, deviations on file or readily available in OnCore?	O Yes O No	
Notes:		
Research Facilities		**Notes and/or Explanation of any "No" Answers:**
Are all facilities (including laboratories and equipment) adequate to safely and properly conduct the study?	O Yes O No	
Have all research sites been approved by the IRB?	O Yes O No	
Notes:		
Drug/Device Accountability		**Notes and/or Explanation of any "No" Answers:**
Is the Investigational Pharmacy Plan or Device Storage & Dispensing Plan being followed?	O Yes O No O N/A	
Are your Drug/Device Accountability Records on file or readily available?	O Yes O No O N/A	
Notes:		

IRB Approval		Notes and/or Explanation of any "No" Answers:
Are all protocols, measures, ICFs, recruitment materials, and other items given to subjects the most recent, IRB approved versions?	O Yes O No	
Were all protocol changes/ amendments only implemented after being approved by the IRB?	O Yes O No O N/A	
Notes:		
Study Data		**Notes and/or Explanation of any "No" Answers:**
Have all subjects been entered into OnCore?	O Yes O No O N/A	
Have all screen failures' data been destroyed per IRB protocol?	O Yes O No O N/A	
Are data being stored securely per your approved protocol?	O Yes O No	
Notes:		
ClinicalTrials.gov		**Notes and/or Explanation of any "No" Answers:**
Is clinicaltrials.gov up to date for your study?	O Yes O No O N/A	
Notes:		
Billing		**Notes and/or Explanation of any "No" Answers:**
If there have been any changes to the protocol that require the Cost Coverage Analysis, has it been updated?	O Yes O No O N/A	
Notes:		
Study Documentation		**Notes and/or Explanation of any "No" Answers:**
Have you identified any issues with study documentation in your files?	O Yes O No O N/A	
Notes:		

Subject Case History Review

Select three (3) or more subject files to review. Review study procedures paying attention to deviations, missing data, and study windows. Review for AEs/SAEs, including the required documentation and reporting of these events. Review whether all forms are complete with signatures and/or initials where required.

Subject 1: ID #		**Notes and/or Explanation of any "No" Answers:**
Did the subject meet eligibility criteria and is it documented in the case files?	O Yes O No	
Were the subject visits conducted within the protocol-designated time frame?	O Yes O No	
Were all tests/procedures performed according to the protocol and in the protocol-designated time frames?	O Yes O No O N/A	
Was the correct treatment/intervention used and documented?	O Yes O No	
Are all missed visits, visits not conducted, and examinations not performed clearly reported on the CRFs?	O Yes O No	
Are any dose and/or therapy modifications well documented?	O Yes O No	
Did the subject experience any AEs or SAEs?	O Yes O No	
If yes, were these recorded and reported as required?	O Yes O No	
Are all source documents…?		
Accurate	O Yes O No	
Complete	O Yes O No	
Up to date	O Yes O No	
Properly Maintained	O Yes O No	
Are the CRF's consistent with the source documents?	O Yes O No	
Are any AEs, concomitant medications, and intercurrent illnesses reported in accordance with the protocol on the CRFs?	O Yes O No	
Are there any CRF entry errors, omissions, or eligibility concerns?	O Yes O No	
If yes, are any corrections, additions, or deletions in the CRF dated, explained (if necessary), and initialed?	O Yes O No	

Subject 2: ID #		Notes and/or Explanation of any "No" Answers:
Did the subject meet eligibility criteria and is it documented in the case files?	O Yes O No	
Were the subject visits conducted within the protocol-designated time frame?	O Yes O No	
Were all tests/procedures performed according to the protocol and in the protocol-designated time frames?	O Yes O No O N/A	
Was the correct treatment/intervention used and documented?	O Yes O No	
Are all missed visits, visits not conducted, and examinations not performed clearly reported on the CRFs?	O Yes O No	
Are any dose and/or therapy modifications well documented?	O Yes O No	
Did the subject experience any AEs or SAEs?	O Yes O No	
If yes, were these recorded and reported as required?	O Yes O No	
Are all source documents…?		
Accurate	O Yes O No	
Complete	O Yes O No	
Up to date	O Yes O No	
Properly Maintained	O Yes O No	
Are the CRFs consistent with the source documents?	O Yes O No	
Are any AEs, concomitant medications, and intercurrent illnesses reported in accordance with the protocol on the CRFs?	O Yes O No	
Are there any CRF entry errors, omissions, or eligibility concerns?	O Yes O No	
If yes, are any corrections, additions, or deletions in the CRF dated, explained (if necessary), and initialed?	O Yes O No	

Subject 3: ID #		Notes and/or Explanation of any "No" Answers:
Did the subject meet eligibility criteria and is it documented in the case files?	O Yes O No	
Were the subject visits conducted within the protocol-designated time frame?	O Yes O No	
Were all tests/procedures performed according to the protocol and in the protocol-designated time frames?	O Yes O No O N/A	
Was the correct treatment/intervention used and documented?	O Yes O No	
Are all missed visits, visits not conducted, and examinations not performed clearly reported on the CRFs?	O Yes O No	
Are any dose and/or therapy modifications well documented?	O Yes O No	
Did the subject experience any AEs or SAEs?	O Yes O No	
If yes, were these recorded and reported as required?	O Yes O No	
Are all source documents…?		
Accurate	O Yes O No	
Complete	O Yes O No	
Up to date	O Yes O No	
Properly Maintained	O Yes O No	
Are the CRFs consistent with the source documents?	O Yes O No	
Are any AEs, concomitant medications, and intercurrent illnesses reported in accordance with the protocol on the CRFs?	O Yes O No	
Are there any CRF entry errors, omissions, or eligibility concerns?	O Yes O No	
If yes, are any corrections, additions, or deletions in the CRF dated, explained (if necessary), and initialed?	O Yes O No	

Overall Assessment- go.vcu.edu/submit/quality	
Overall Assessment Question #1- Consent	Have you identified any issues with consenting? If so, what? Do you need to do any of the following regarding your consenting process? o Re-education of Staff o File an IRB or FDA report o File an Amendment to the Protocol o None of the above
Overall Assessment Question #2- Personnel	Have any personnel issues been identified? If so, what? Do you need to do any of the following regarding personnel? o Re-education of Staff o File an IRB or FDA report o File an Amendment to the Protocol o None of the above
Overall Assessment Question #3- Safety Reporting	Have any safety reporting issues been identified? If so, what? Do you need to do any of the following regarding safety reporting? o Re-education of Staff o File an IRB or FDA report o File an Amendment to the Protocol o None of the above
Overall Assessment Question #4- Research Facilities	Have any facility issues been identified? If so, what? Do you need to do any of the following regarding your research facilities? o Re-education of Staff o File an IRB or FDA report o File an Amendment to the Protocol o None of the above
Overall Assessment Question #5- Drug/Device Accountabilities	Have you identified any issues with the investigational product dispensing or your storage plan? If so, what? Do you need to do any of the following regarding your investigational product storage or dispensing? o Re-education of Staff o File an IRB or FDA report o File an Amendment to the Protocol o None of the above

Overall Assessment Question #6- IRB Approval	Have you identified any issues with the version of documents approved by the IRB? If so, what? Do you need to do any of the following regarding your IRB documents? o Re-education of Staff o File an IRB or FDA report o File an Amendment to the Protocol o None of the above
Overall Assessment Question #7- Study Data	Have you identified any issues with study data? If so, what? Do you need to do any of the following regarding study data? o Re-education of Staff o File an IRB or FDA report o File an Amendment to the Protocol o Other, define o None of the above
Overall Assessment Question #8- ClinicalTrials.gov	Have any issues with clinicaltrials.gov been identified? If so, what? Do you need to do any of the following regarding clinicaltrials.gov? o Re-education of Staff o Submit changes o Other, define o None of the above
Overall Assessment Question #9- Billing	If there have been any changes to the protocol that require changes to the cost coverage analysis have these been submitted? If so, what?
Overall Assessment Question #10- Study Documentation	Have any study documentation issues been identified? If so, what? Do you need to do any of the following regarding personnel? o Re-education of Staff o File an IRB or FDA report o File an Amendment to the Protocol o Other, define o None of the above
Overall Assessment Question #10- Subject Case History Review.	After review of at least 3 participants did you note any issues which require any of the following (choose all that apply). o Re-education of staff o Reporting to the IRB or FDA o Protocol amendment o No action required

After reviewing your study, did you or will you do any of the following? **Choose all that apply.**	1. Re-educate your Study Staff 2. Make an Amendment to your Protocol 3. Update your Study Documents 4. Submit a Report to the IRB 5. Develop a Corrective Action / Preventative Action (CAPA) Plan 6. Redesign your Case Report Forms (CRFs) 7. Develop Tools, Logs, and/or Templates 8. Seek Internal VCU Support or Education 9. Other, specify.
Would you like an educational visit to discuss any issues, questions, or procedures?	If Yes, please provide name and contact information for who we should contact regarding an educational visit.
Please provide any other comments or feedback.	
How helpful was this review in increasing the quality of your study?	