



## VCU Clinical Research Quality Assurance Assessment

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

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?

☐ Yes

☐ No

**If Yes**, what group monitored? \_\_\_\_\_

When was your last monitoring visit? \_\_\_\_\_

If Yes, please skip to Overall Assessment and Signatures Section on page 7.

**If No**, please complete the following Quality Assurance Assessment for your study. The goal is to assure that your study is being conducted according to Federal Regulations, Policies, Guidance, VCU policies and conditions of IRB approval. Gather your regulatory documents, consents, and participant files. Review the approved protocol and consent/assent documents. Review how you are actually conducting the research. Are they the same? To help with this assessment, complete the following sections.

## Consent Process Worksheet

Unless there is a waiver of all consent (parental permission) and assent, complete this section by randomly selecting 10 enrolled subjects. After reviewing their consent documents, answer the following questions. If less than 10 subjects have enrolled since the last assessment, review all subjects.

	Participant Number	Was the most recent approved consent utilized?	Was the ICF completed as approved by the IRB?	Was the consent process documented in the case records including the Medical Record (as appropriate)?	Was the assent conducted as approved? (if applicable)	Was HIPAA completed as approved? (if applicable)	Notes and/or Explanation of any "No" Answers
1		<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	
2		<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	
3		<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	
4		<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	
5		<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	
6		<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	
7		<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	
8		<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	
9		<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	
10		<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Yes <input type="radio"/> No	

Other Notes:

Amendments		Notes
Since your last Assessment, have you made ANY changes to the approved RAMSIRB study protocol?	<input type="radio"/> Yes <input type="radio"/> No	
If you have made changes to your protocol, did you submit them to the IRB and receive approval before implementing?	<input type="radio"/> Yes <input type="radio"/> No	
If No, was this done for subject safety?	<input type="radio"/> Yes <input type="radio"/> No	
If you are currently not conducting the protocol as approved, or utilizing non approved documents or advertisements, please submit an amendment and report.	<input type="radio"/> Yes <input type="radio"/> No	Is an amendment required?
Personnel		Notes
Are all engaged personnel approved by the IRB? (ie. Are they all listed as personnel in RAMSIRB?)	<input type="radio"/> Yes <input type="radio"/> No	
Is an amendment required?	<input type="radio"/> Yes <input type="radio"/> No	
Is the delegation and signature log(s) up to date and include all personnel?	<input type="radio"/> Yes <input type="radio"/> No	
Have all personnel completed required CITI training?	<input type="radio"/> Yes <input type="radio"/> No	
Is your training log/documentation complete with all study-specific personnel training?	<input type="radio"/> Yes <input type="radio"/> No	
Clinicaltrials.gov (If applicable)		Notes
Is clinicaltrials.gov up to date?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A	Is a change to your clinicaltrials.gov required?
OnCore		Notes
Have all subjects been entered into OnCore?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> N/A	

## Subject Case History Review

Select 3 or more subject files to review. Review the source documents, consent/parental permission/assent documents. Review study procedures paying attention to deviations, missing data, and study windows. Review for AEs/SAEs including documentation and reporting. Are all forms complete with signatures and/or initials where required?

Subject 1: ID #		Notes
Is there an original copy of the ICF and HIPAA authorization on file?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Waived	
Is the person who obtained consent on the personnel list and delegated to this task?	<input type="radio"/> Yes <input type="radio"/> No	
Is the consent (assent/parental permission) form complete (all pages present, all options complete, all signatures complete)?	<input type="radio"/> Yes <input type="radio"/> No	
Was the correct version of the consent/assent/parental permission utilized?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Waived	
Did the subject meet eligibility criteria and is it documented in the case files?	<input type="radio"/> Yes <input type="radio"/> No	
Were the subject visits conducted within the protocol designated time frame?	<input type="radio"/> Yes <input type="radio"/> No	
Were all tests/procedures performed and documented according to the protocol?	<input type="radio"/> Yes <input type="radio"/> No	
Did the subject experience any AEs or SAEs?	<input type="radio"/> Yes <input type="radio"/> No	
If yes, were these recorded and reported as required?	<input type="radio"/> Yes <input type="radio"/> No	
Are any amendments or reporting required?	<input type="radio"/> Yes <input type="radio"/> No	

Subject 2: ID #		Notes
Is there an original copy of the ICF and HIPAA authorization on file?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Waived	
Is the person who obtained consent on the personnel list and delegated to this task?	<input type="radio"/> Yes <input type="radio"/> No	
Is the consent (assent/parental permission) form complete (all pages present, all options complete, all signatures complete)?	<input type="radio"/> Yes <input type="radio"/> No	
Was the correct version of the consent/assent/parental permission utilized?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Waived	
Did the subject meet eligibility criteria and is it documented in the case files?	<input type="radio"/> Yes <input type="radio"/> No	
Were the subject visits conducted within the protocol designated time frame?	<input type="radio"/> Yes <input type="radio"/> No	
Were all tests/procedures performed and documented according to the protocol?	<input type="radio"/> Yes <input type="radio"/> No	
Did the subject experience any AEs or SAEs?	<input type="radio"/> Yes <input type="radio"/> No	
If yes, were these recorded and reported as required?	<input type="radio"/> Yes <input type="radio"/> No	
Are any amendments or reporting required?	<input type="radio"/> Yes <input type="radio"/> No	

**Other Notes:**

Subject 3: ID #		Notes
Is there an original copy of the ICF and HIPAA authorization on file?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Waived	
Is the person who obtained consent on the personnel list and delegated to this task?	<input type="radio"/> Yes <input type="radio"/> No	
Is the consent (assent/parental permission) form complete (all pages present, all options complete, all signatures complete)?	<input type="radio"/> Yes <input type="radio"/> No	
Was the correct version of the consent/assent/parental permission utilized?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Waived	
Did the subject meet eligibility criteria and is it documented in the case files?	<input type="radio"/> Yes <input type="radio"/> No	
Were the subject visits conducted within the protocol designated time frame?	<input type="radio"/> Yes <input type="radio"/> No	
Were all tests/procedures performed and documented according to the protocol?	<input type="radio"/> Yes <input type="radio"/> No	
Did the subject experience any AEs or SAEs?	<input type="radio"/> Yes <input type="radio"/> No	
If yes, were these recorded and reported as required?	<input type="radio"/> Yes <input type="radio"/> No	
Are any amendments or reporting required?	<input type="radio"/> Yes <input type="radio"/> No	

**Other Notes:**

## Overall Assessment

		Notes
Have you identified any amendments that need to be submitted?	<input type="radio"/> Yes <input type="radio"/> No	
Have you identified any issues that need to be reported?	<input type="radio"/> Yes <input type="radio"/> No	
During the review have you identified any problems or concerns that you are addressing which did not need to be reported or submitted as an amendment?	<input type="radio"/> Yes <input type="radio"/> No	

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Signature and date of study staff member completing this form

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Signature and date of Investigator reviewing this form

Please upload this form with your continuing review submission as a document at  
***[go.vcu.edu/submit/monitor](http://go.vcu.edu/submit/monitor)***.

Amendments and reports should be submitted through RAMSIRB.

### Revision History:

Version1: April 13, 2017

Version2: May 9, 2017