

Quality Assurance Monitoring Program

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The University of Vermont
LARNER COLLEGE OF MEDICINE

Overview

- Quality Assurance Monitoring Program
- Common QA Review Findings
- Quality Assurance Review Process
- What we are Looking for
- Quality Assurance Review Response
- Quality Assurance Resources



UVM Quality Assurance Monitoring Program

The Larner College of Medicine, in conjunction with the UVM Research Protections Office (RPO), has instituted a Quality Assurance Monitoring Program.



Purpose: to be proactive in ensuring our institution is compliant with local research requirements and federal regulations

Selection: currently selecting active research studies that are more than minimal risk (IRB Full Committee Review) that are not actively monitored

- OCTR/RPO – more than minimal risk
- RPO – minimal risk

ICH GCP Section 5.18.1

The purpose of trial monitoring is to verify:

- (a) The rights and well-being of human subjects are protected.
- (b) The reported trial data are accurate, complete, and verifiable from source documents.
- (c) The conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP*, and with the applicable regulatory requirement(s).



The Process for IRB and LCOM tandem visit

- One week prior to the QA review:
 - Notification Email: The PI and the primary study contact will receive an email indicating that the study has been selected for QA monitoring
 - The email will contain the date and time of the review, as well as instructions on what documents to provide to the QA team prior to and at the time of the meeting
- The day of the QA review:
 - Introductory Meeting: The QA team will meet with the PI and designee(s) before the QA review (hear about the study, answer questions)
 - QA Review: The QA team will review the study materials (regulatory binder, subject charts etc.)
 - Exit Interview: The QA team will meet with the PI and designee(s) to provide an overview of the review and briefly discuss findings and action items requiring follow-up, if applicable
- Within 10 business days of the review:
 - QA Report: The PI will receive a written report of the review from the QA team detailing specific action items that require follow-up from the study team
- Within 10 business days of receiving the QA report:
 - QA Response: The PI and study team will have 10 business days to review the report and respond to the action items identifying the issues that were found and the corrective action plan to resolve the issues



What we look for

- The QA Reviews focus on (but are not limited to):
 - Regulatory Binder and Essential Documents
 - IRB approved protocol and study procedures were followed
 - Informed Consent and Consent Process Documentation for each subject
 - Eligibility Criteria are met and documented for each subject
 - EPIC research subject registration SOP requirements are being followed
 - Research Data Management & Security Plan is being followed

Audit Trail: Documentation that allows reconstruction of the course of events - ICH E6 GCP 1.9

Common QA Review Findings

- Consent
 - Person obtaining consent not on IRB Key Personnel in UVMClick
 - Pre-signing and dating of consent forms by PI/designee
 - The wrong version of the consent form was used (or non-IRB stamped version)
 - The consent form was not signed or dated by the study participant and/or PI/designee
 - The consent form was obtained via a Non-IRB approved method (verbally over the phone)
 - The consent process was not documented

- Eligibility
 - Study participant was ineligible for the study
 - The inclusion/exclusion criteria were not documented (no corresponding source document)

- Missing Essential Documents
 - Incomplete Regulatory Binder
 - CITI Training expired/lapses, CVs (signed and dated q 2 yrs), and Licenses
 - Delegation of Duties Log
 - Deviation Log
 - Documentation of Protocol Specific Training
 - Screening/Enrollment Log
 - Minutes of safety meetings/DSMB/training meetings



Protocol Compliance

- Documentation that the IRB approved protocol and processes (consent process, recruitment plan, study visits, data security and management plan, etc.) were followed
- Remember that any deviation from the approved protocol is a protocol deviation and should be appropriately recorded

“If it isn’t documented, it didn’t happen”



Study Subject Files

- These should be maintained so that an independent person, with no knowledge of the study, can review each subject file and follow the subject's entire study participation course without any input from the study team.
- This starts with the consenting process and follows through each study visit and study communication.

The Consent Process and Documentation

- Consenting according to the IRB approved process
 - Correctly delegated and trained member of the study's IRB approved key personnel

- Consent Process Documentation:
 - Three different templates can be found in the [IRB Forms Library](#) under Consent Process Documentation
 - The form can be utilized at the beginning of the research and throughout the clinical study, when updates and revisions to the consent form(s) are required
 - Informed Consent Form + Source Documentation of Consent Process = No Audit Findings



Documentation of Informed Consent

IRB #	
PI	
Study Subject	
Version of consent used:	
Consent obtained by:	
Date of consent:	

Check all that apply (provide necessary *details* in the notes space below):

- The study was explained and the consent form was reviewed with the participant.
 - All of the participant's questions were answered and all the consent elements, such as purpose, procedures, and risks were reviewed.
 - The participant was given sufficient time to consider participation.
 - The participant agreed to participate in the study and personally signed and dated the consent form.
 - The consent form was signed and dated by the researcher.
 - The participant was given a copy of the signed informed consent form.
 - The consent process was completed *prior to the start of research procedures*.
- If Applicable:
- The consent process was witnessed by an impartial witness.
 - Verbal consent/assent was obtained (as approved by the IRB)
 - Participant agreed to audio or videotaping

Notes about the consent process (i.e. who was involved in consent process, what questions did the participant have, translator number, whether a teach-back process was used, was debriefing was completed, etc.):

PI/Designee Signature: _____ Date: _____

How Do Researcher's Document the Consent Process?

Example of a note to the research file or Smartphase in EHR documenting the informed consent process:

03/30/2019 @ 3:30pm: Mrs. Jones was seen in GI clinic today. After reviewing her labs she was found to meet all eligibility criteria. Reviewed the consent form; specifically explained the purpose of the study, risks and benefits, expected duration of participation, the number of visits per year, weekly diaries, confidentiality, right to withdraw at any time and emergency contact information. She was given time to review the consent form and asked questions prior to signing.

All questions were answered.

Mrs. Jones signed/dated the consent form and was given a copy for her records. She will begin research procedures on 04/05/2019. -Judith Smith, MD

Special Circumstances Require *More* Documentation

- ✓ Legally Authorized Representative
- ✓ Participant physically unable to sign consent (i.e., bandaged hands, tremor, stroke)
- ✓ Participant not able to read a consent form (i.e., illiteracy, vision-impairment)
- ✓ Signature illegible
- ✓ Screen failure
- ✓ Cognitively impaired
- ✓ Ward of the state
- ✓ Non-English speaking consent process

The Consent Error - Examples

Statement of Consent
You have been given and have read or have had read to you a summary of this research study. Should you have any further questions about the research, you may contact the person conducting the study at the address and telephone number given below. Your participation is voluntary and you may refuse to participate or withdraw at any time without penalty or prejudice to your present and/or future care.

You agree to participate in this study and you understand that you will receive a signed copy of this form.

Signature of Subject

5/21/19

Date

Name of Subject Printed

Melanie Locher

Signature of Principal Investigator or Study Designee

5/21/19

Date

Melanie Locher

Name of PI or Study Designee Printed

Sherrie Khadanga M.D.
UVMC Cardiology Division
62 Tilley Dr.
South Burlington, VT 05403
802-847-4545

May 13, 2019

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CHRMS (Medical) #18-0568 Approved: 5/20/2019



Statement of Consent
You have been given and have read or have had read to you a summary of this research study. Should you have any further questions about the research, you may contact the person conducting the study at the address and telephone number given below. Your participation is voluntary and you may refuse to participate or withdraw at any time without penalty or prejudice to your present and/or future care.

You agree to participate in this study and you understand that you will receive a signed copy of this form.

Signature of Subject

5/21/19

Date

Name of Subject Printed

Melanie Locher

Signature of Principal Investigator or Study Designee

5/21/19

Date

Melanie Locher

Name of PI or Study Designee Printed

Sherrie Khadanga M.D.
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802-847-4545

May 13, 2019

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The Consent – Case Study 1

You have submitted a protocol for a minimal risk study. The IRB approves your protocol. In your submission the informed consent process will involve documenting subjects' consent using the IRB approved consent form. You are in the field and are speaking to a subject eligible for enrollment into your study. You discover you do not have the consent documents with you. You have described all the study procedures to the subject and allowed ample time for the subject to consider whether to participate. The subject indicates he does not need anything in writing and agrees to participate.

Question: Is it OK to continue with the research activities with this subject?

NO. The IRB approved the protocol with the understanding that written informed consent would be obtained. Obtaining verbal consent does not satisfy this requirement. Changes in research procedures, the informed consent process, and/or the consent document cannot be initiated by the researcher without IRB review and approval. Any research procedures conducted that do not follow the IRB approved protocol are considered protocol deviations and should be reported to the IRB.



The Consent – Case Study 2

A researcher has approval from the IRB to conduct a drug study for which subjects must have a certain level of kidney function. As a screening procedure, the researcher draws blood to assess kidney function. After the researcher has determined which individuals are eligible for the study, she explains the study to these individuals and invites them to participate, using her IRB-approved consent process.

Question: Did the researcher obtain appropriate consent from her participant?

NO - The researcher should have obtained subject consent before any research procedures were done. The research protocol inclusion criteria required confirmation of adequate kidney function. The subject should have been consented as the blood draw procedure was necessitated by the research protocol.



Eligibility

- Eligibility needs to be documented and confirmed for each research subject
 - We recommend developing an eligibility checklist for an easy way to document that all eligibility criteria were met.
 - Make sure it has a place for the key personnel with a delegated responsibility for determining eligibility to sign and date
 - A template can be found on the [Commons](#) website

Research Subject Eligibility Form



Study Name:	
IRB Protocol #:	
Protocol Version # and/or Date:	
Principal Investigator:	

SUBJECT # _____				
INCLUSION CRITERIA <i>Must be "yes"</i>	Yes	No	Location of supporting source documentation	Notes
1.				
2.				
3.				
4.				
EXCLUSION CRITERIA <i>Must be "no"</i>	Yes	No	Location of supporting source documentation	Notes
1.				
2.				
3.				
4.				

This subject is:

Eligible for participation Ineligible for participation

Signature:	Date:
Printed Name:	

Registering Research Subjects in EPIC

- The PI or designated key personnel are responsible for registering patients as active research subjects by associating them to the research study in EPIC
- Our review based on UVM MC Research4 Policy:
 - Ensure subjects were registered with an active research flag within 24 hours after signing the informed consent form
 - Ensure subjects' research flag status has been updated within 24 hours after a research status change (study completion/withdrawal/long term follow-up)
- In-depth instructions for these actions can be found on the OCTR [Commons page](#)

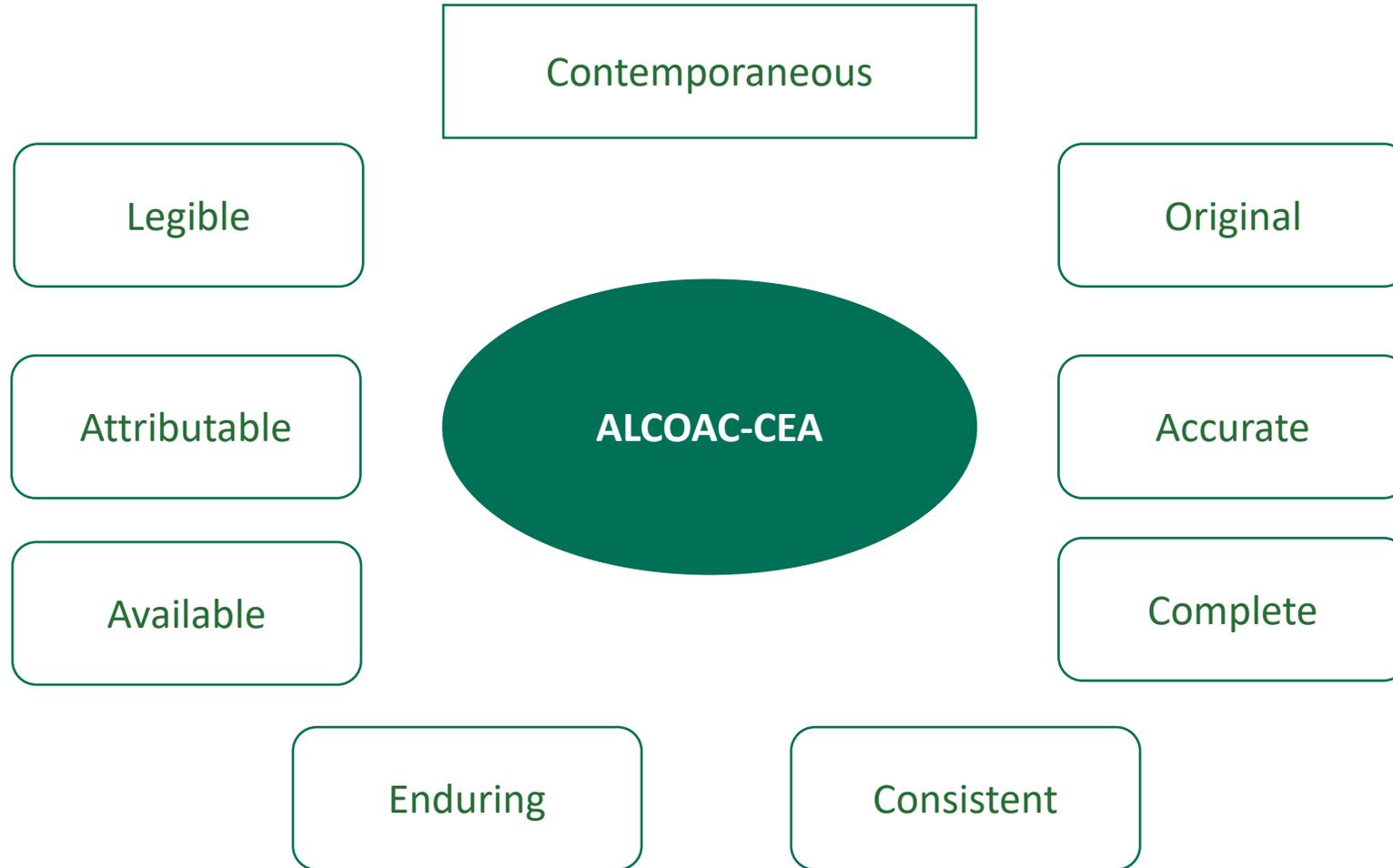


Data Collection, Management and Storage

- **Source Documents:** All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies). [Section 1.51 ICH E6 GCP](#)
 - Note: All source material must be signed and dated by the person who documented the information (this includes electronic signatures)
- **Case Report Forms (CRFs):** A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject. [Section 1.11 ICH E6 GCP](#)
 - CRFs can be paper or electronic, for example: REDCap, RAVE, InForm, Excel
 - Note: All data reported on a CRF requires a complementary source document



ALCOAC-CEA Principles



ALCOAC-CEA

Error	Do's	Don'ts
<ul style="list-style-type: none">• Correction needed on the original source document or a case report form	<ul style="list-style-type: none">• Cross out wrong information with a single line and initial and date the correction	<ul style="list-style-type: none">• Scribble over the mistake• Use white out• Write over the original data to correct it• Destroy the originals
<ul style="list-style-type: none">• Missing data located at a later date	<ul style="list-style-type: none">• Incorporate the data into the research record with the current date	<ul style="list-style-type: none">• Ignore the missing data• Backdate or predate the information



Activity 1 – ALCOA-C



IRB Protocol # Mind Study
 Study PI [Redacted]

Subject Demographics Form

Subject ID: 001-007 Date: 111112019

1.	First Name:	<u>John</u>
2.	Last Name:	<u>Snow</u>
3.	Date of Birth:	<u>12/26/1986</u> m m d d y y y y
4.	Age:	<u>32</u>
5.	Sex:	<u>Male</u>
6.	Height (in meters):	<u>5'8"</u>
7.	Weight (in kilograms):	<u>80</u>
8.	BMI (in kg/m ²):	<u>[Redacted]</u>
9.	Race (check one box only):	<input checked="" type="checkbox"/> White, not Hispanic origin <input type="checkbox"/> Black, not Hispanic origin <input type="checkbox"/> Hispanic <input type="checkbox"/> Asian <input type="checkbox"/> Native American <input type="checkbox"/> Native Hawaiian or Pacific Islander <input type="checkbox"/> Unknown or Declined to State <input type="checkbox"/> Other (please specify below)
10.	Ethnicity (check one box only):	<input type="checkbox"/> Hispanic or Latino <input checked="" type="checkbox"/> Not Hispanic or Latino <u>ARC</u> <input type="checkbox"/> Other (please specify below) <u>Northerner</u>

BP: 110/70
Temp: 97.8

Study Personnel Signature: [Signature]

Completion Date: [Redacted]

JOHN DOESN'T LIKE TO BE CALLED AT HOME AND PREFERS TO HIS RESIDENCE FOR ALL FUTURE STUDY CORRESPONDENCE



IRB Protocol #: 00-001
 Study PI: Samuel Tully

Subject Demographics Form

Subject ID: 001-007 Date: 111112019
ARC 11/11/19

1.	First Name:	<u>John Jon</u> <u>ARC 11/11/19</u>
2.	Last Name:	<u>Snow</u>
3.	Date of Birth:	<u>12/26/1986</u> m m d d y y y y <u>ARC 11/11/19</u>
4.	Age:	<u>32</u>
5.	Sex:	<u>Male</u>
6.	Height (in meters):	<u>1.73</u>
7.	Weight (in kilograms):	<u>80</u>
8.	BMI (in kg/m ²):	<u>26.6</u>
9.	Race (check one box only):	<input checked="" type="checkbox"/> White, not Hispanic origin <input type="checkbox"/> Black, not Hispanic origin <input type="checkbox"/> Hispanic <input type="checkbox"/> Asian <input type="checkbox"/> Native American <input type="checkbox"/> Native Hawaiian or Pacific Islander <input type="checkbox"/> Unknown or Declined to State <input type="checkbox"/> Other (please specify below)
10.	Ethnicity (check one box only):	<input type="checkbox"/> Hispanic or Latino <input checked="" type="checkbox"/> Not Hispanic or Latino <u>ARC 11/11/19</u> <input checked="" type="checkbox"/> Other (please specify below) <u>Northerner</u>

Study Personnel Signature: [Signature]

Completion Date: 11/11/19

Contact Preference: Raven sent to home address
50 Castle Black Road
The North, 00101

Version 11/01/2019

ARC 11/11/19

Essential Documents

- Federal and state regulations, institutional policy, and good clinical research practices require investigators to maintain essential documents related to human subjects research.
- These documents should be maintained so that an independent person, with no knowledge of the study, can review the regulatory binder (and subject files) and follow the life cycle of the study without input from the study team.
 - If there are any gaps or errors, a note to file should be generated to explain the inconsistency.
- The regulatory binder is the first thing reviewed during an audit.

Regulatory Binder

Table of Contents

- 1. Protocol**
- 2. IRB**
- 3. Consent and HIPAA Authorization Forms**
- 4. Key Personnel**
5. Other Reporting Agencies (FDA, NIH, DOD/OHRP, etc)
6. Sponsor
7. Monitoring/DSMB
8. Product Information
9. Laboratory Documentation
10. Drug/Device Accountability
- 11. Data Collection**
- 12. Study Logs (Delegation, Training, Deviation)**

<https://commons.med.uvm.edu/dean/comclntrl/SitePages/Regulatory%20Documents%20and%20Resources.aspx>



Regulatory Binder - Key Personnel Delegation and Training

5.1 Responsibilities of Principal Investigators

The PI has primary responsibility for protecting the rights and welfare of human subjects in research. The PI's primary responsibilities includes, but is not limited to, the following:

1. Delegation of Responsibilities

PIs must personally perform or delegate to qualified co-investigators or research staff all of the necessary tasks to carry out their studies. Even when specific tasks are delegated, the PI remains ultimately responsible for proper conduct of the study and fulfillment of all associated obligations.

2. Oversight of Research Team

The PI must provide members of the research team with sufficient oversight, training and information to facilitate appropriate safety procedures and protocol adherence.

“If it isn’t documented, it didn’t happen”

https://www.uvm.edu/rpo/irb-policies-and-procedures#responsibilities_II



Regulatory Binder - Key Personnel Delegation and Training

ICH GCP E6 4.1.5 - The investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties.

ICH GCP E6 4.2.4 - The investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions.

Regulatory Binder – Delegation

- Delegation of responsibility/duties/authority log
- A template can be found on [Commons](#)



Delegation of Authority Log

IRB Number:
Study Title:

Principal Investigator:

The purpose of this form is to serve as the 'Delegation of Authority Log' and assure that the individuals performing study related tasks/procedures are appropriately trained and authorized by the Investigator to perform the task/procedure. This form should be completed prior to the initiation of any study-related tasks/procedures. The original form should be maintained at your site in the study regulatory/study binder. This form should be updated during the course of the study as needed.

Printed Name	Title	Responsibilities*	Signature	Initials	Start Date	PI Initials/Date	Stop Date

*Use code numbers provided below.

Principal Investigator:

(Sign at study closure) Printed Name

Signature

Date

Responsibilities: (examples below, tailor to your specific protocol)

1 – Informed Consent Discussion	5 – Study Drug Accountability	
2 – Informed Consent Signature	6 – Study Drug Dispensing	
3 – Eligibility Confirmation	7 – Case Report Form Completion	
4 – Physical Exam	8 – Regulatory Documents	

Version 08/26/2019

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Regulatory Binder – Training



Staff Training Log for Groups

- Key Personnel Training Log
- A template can be found on [Commons](#)

IRB Number:
Study Title:

Principal Investigator:

This log documents training of groups of staff members. Complete one form for each group training topic (i.e. protocol training, amendment training, consent training, REDCap training). To record individual training for staff members (if easier) refer to "Staff Member Training Log."

Date Training	Name(s) of Trainer(s)	Description of Training (attach agenda and training materials as applicable)	Trainer Signature	Expiration date (if applicable)



Names of Trainees	
Printed Name	Signature

Names of Trainees	
Printed Name	Signature

UVM and UVM MC Research Trainings

Training	Link	Audience
CITI - IRB - Human Subjects	https://www.uvm.edu/rpo/citi-program-training	Required for all IRB Key Personnel
CITI - GCP - Good Clinical Practice*	https://www.uvm.edu/rpo/citi-program-training	Required for all IRB Key Personnel on a Clinical Trial involving Human Subjects or a UVM Larner College of Medicine Affiliate. *All those affiliated with the UVM Larner College of Medicine are required to complete GCP training regardless of whether the research project fits the NIH clinical trial definition.
Study Specific Training: Protocol, Electronic Data Capture (EDC), Lab Processing, IATA, Consenting, etc		Required for all IRB Key Personnel per the Delegation of Authority Log.
UVM Medical Center Credentialing	http://www.med.uvm.edu/clinicaltrials/credentialing	Required for all UVM IRB Key Personnel on studies involving the UVM Medical Center
Billing Compliance Training	802-847-2667 or Compliance@uvmhealth.org	Required for all IRB Key Personnel on studies involving the UVM Medical Center
UVM Lab Training	https://www.uvm.edu/sites/default/files/UVM-Risk-Management-and-Safety/NewEmployeeChecklist2019.pdf	Required depending on the specific type of laboratory you are working in. See your Lab Safety Officer for more details.
Epic Research Training	Cornerstone	Required for all IRB Key Personnel registering subjects in Epic.
Fundamentals in the Conduct of Clinical Research*		Required for all Key Personnel STAFF on a Clinical Trial involving Human Subjects or a UVM Larner College of Medicine Affiliate. *All those affiliated with the UVM Larner College of Medicine are required to complete GCP training regardless of whether the research project fits the NIH clinical trial definition.

Study Visits

	<u>Requirements</u>	<u>Subject ID#</u>
32		
33	<u>Visit 1</u>	
34	Height	
35	Weight	
36	BP	
37	CBC	
38	CMP	
39	Glucose (fasting)	
40	Documentation of Fasting	
41	QOL prior to CT Scan	
42	Documentation QOL prior to CT Scan Results	
43	CT Scan	
44	<u>Visit 2 (2 weeks post visit 1 +/- 3 days)</u>	
45	Visit within the correct timeframe?	
46	Height	
47	Weight	
48	BP	
49	CBC	
50	CMP	
51	Glucose (fasting)	
52	Documentation of Fasting	
53	QOL	
54	Documentation QOL prior to CT Scan Results	
55	CT Scan	
56		

QA Review Outcomes

- Within 10 business days of the QA review
 - QA Report: The PI will receive a written report via email from the QA team detailing the findings and specific action items, if any, and determine one of the following outcomes:
 - Acceptable; No further action required
 - Acceptable; Additional action required by Investigator
 - Additional action required by Investigator
 - Further Committee review required
- Within 10 business days of receiving the QA report
 - QA Response: The study team will be expected to respond to the report.



Response to the QA Report

Responses should include a Corrective and Preventative Action Plan (CAPA) for each action item in the QA report.

- Elements of your CAPA
 - Description of the problem
 - Narrative of events
 - Number of subjects affected/harmed
 - Number potentially affected/harmed
- The root and contributing causes for each finding
 - Include how this was determined
- Corrective actions and preventive actions taken or to be taken
 - Include description of new or changed processes and/or SOPs
 - Describe plan for training
 - Describe plan for evaluating the effectiveness
- Reporting
 - The IRB may have additional actions after their review of the RNI.

RPN Workshop “Developing Effective Corrective and Preventative Action Plans (CAPAs)”
<https://commons.med.uvm.edu/dean/comcntril/SiteAssets/SitePages/Research%20Professionals%20Network/June-2019-RPN-Workshop-CAPAs.pdf>



Example Response

Action Item:

Subject 03 signed and dated the consent form the day before the PI signed and dated the consent form. The day the subject signed the consent form they participated in study procedures. Per the protocol, consenting will be conducted in person by the PI prior to the start of any study events (Deviation).

Response:

It was discovered that the PI wrote the wrong date on the consent form. This was confirmed by the subject's electronic medical record documentation of their clinic visit (see attached) which was on the same date that the subject signed the consent form.

Corrective Action:

A Note to File was written describing this error and was signed by the PI and placed in the subject file with their consent form. In the future, all consent fields will be double checked by another member of the study team to ensure the consent form was properly executed. This RNI was submitted to the IRB.



Example Note to File

Date:
IRB #:
PI:
To: Participant Files
From:
RE: Consent

The PI misdated the informed consent form for subject 03. It was confirmed with the PI that the informed consent process was conducted in person per the protocol and on the date that the subject signed the consent form. Subject 03 had a clinic visit on the same date that they signed consent, confirming they were present in person the day they signed consent (see attached documentation of clinic visit). This deviation has been reported to the IRB as an RNI.

PI Signature

Dated by the PI



Note to File

GENERAL INSTRUCTIONS – delete this box from the completed form

A Note-to-File should:

- Explain clearly the reason for the error/omission/discrepancy or process/policy it aims to address.
- Be generated on a case-by-case basis, or used to describe multiple of the same error/omission/discrepancy or process/policy.
- Include the protocol number and participant ID number(s) it refers to, as applicable.
- Be signed and dated by the individual who prepared it.
- Include any corrective action and/or follow-up action taken.
- Be filed with the regulatory document, participant file, or in the study binder tab to which it applies.

Red text represents instructions to you – to be deleted from the final version.

Date: _____

IRB #: _____

PI: _____

To: **Select one:** Regulatory Files / Participant Files

From: **Person preparing note**

RE: _____

Description:

- Include information about an issue, cause of the issue, and corrective actions taken to prevent issue from occurring again
- Explain alternative location that files may be stored
- Clarify a policy or process

Signature _____ Date _____

Response to QA Report Action Items

1. Subjects 2, 4, and 6 were found to have completed their final study questionnaire outside of the study protocol's approved timeline of 2 weeks after the final study visit. Please review all other subject files to check for, and note, any other study timeline deviations. Please provide a plan to increase compliance around this questionnaire.
 - This deviation was noted on the study's deviation log.
 - A thorough review of all other subject files (1-20) revealed that subjects 10 and 15 had also completed the final study questionnaire outside of the approved 2-week window. These deviations were also noted on the deviation log.
 - Moving forward, subjects will be reminded to complete the final study questionnaire within the 2-week window and if they return the questionnaire outside of this window, the deviation will be noted on the deviation log in real time.
 - We have amended the protocol (MOD#) to increase the window since there was no scientific reason for the 2-week timeframe.
 - We have amended the protocol (MOD#) to allow for the questionnaire to be filled out electronically or verbally over the phone.



Response to the QA Report

- QA Response, and all supporting documentation, should be emailed to the QA team for review
- Once the response has been reviewed and approved by the QA team, it should be submitted to the IRB as a single RNI and include:
 - The QA report
 - Study Team Response (Corrective and Preventive Action Plan)
 - All protocol deviations outlined in the QA review, and any additional deviations discovered in your review of the remaining study participant charts (deviation log)
 - Supporting documents (e.g. Notes to File, updated logs)
 - May require a corresponding MOD
- The IRB may have additional action items following their review of the RNI.



Tips For Always Being Audit Ready



- Making sure you and your study team know the protocol and the IRB approved processes and documents
 - Know where to find information – Commons, IRB Policies and Procedures Manual
- Build QA into your study management from the beginning
 - Have someone double check your work
 - Use tracking logs for KP, IRB approved documents, etc.
 - Use checklists for both study visits and study maintenance
- Research Navigator Program: We are here to help!





Quality Assurance Monitoring Program

Commons Home

OCTR Home

Budgeting/Contracts

COVID-19 Information for Researchers

Education and Training Resources

Events Calendar

Funding Opportunities

Investigators

Nursing or Coordinator Support

LCOM & UVM Health Network Research Professionals Training

Quality Assurance Monitoring Program

Registering a Clinical Trial Clinicaltrials.gov

Regulatory Documents and Resources

Research Navigator

Research Professionals Network

Research Subject Registration EPIC

UVMHC Forms/Policies /Procedures

UVM Researcher Credentialing

Commons > Office of the Dean > Office of Clinical Trials Research

Quality Assurance Monitoring Program

In an effort to be proactive in assuring that our institution is compliant with local and federal research requirements, The Larner College of Medicine, in conjunction with the UVM Research Protections Office, has instituted a Clinical Trial Quality Assurance (QA) Monitoring Program. These targeted QA reviews will focus on regulatory compliance, consent process and documentation, and study participant eligibility. More in-depth reviews will be conducted as necessary.

Quality Assurance Review Process

1. Prior to the QA Review:

- Notification of the review will be sent to the Principal Investigator (PI), and primary study contact as appropriate, one week prior to the QA Review date. The email will contain the date, time, and location of the scheduled review, as well as instructions on what documents to provide to the QA team prior to and at the time of the review meeting.

2. Day of the QA Review:

- The QA team will meet with the PI and/or their designee to discuss the QA review process. (est. 30 minutes)
- The study team should bring the study's regulatory binder(s) and all study participant files.
- After the initial meeting, the QA team will thoroughly review the study's regulatory binder(s), and the study participant files for completeness and compliance.
 - All of the subject files will be reviewed for consent and eligibility
 - A subset of the subject files will be thoroughly reviewed for all study documentation
- At the end of the review, the QA team will again meet with the PI and/or designee to provide an overview of the review and discuss any findings that will be included in the QA report. (est. 30-60 minutes, dependent on the review findings)

3. Within 10 Business Days After the QA Review:

- The PI, and primary study contact as appropriate, will receive a written report of the review from the QA team. The report will include specific findings from the review and some best practices for how to address certain findings.
- The end of the report will detail any specific action items that the study team will need to address in their response to the QA report. The response should be written as a Corrective and Preventive Action Plan (CAPA) to each action item, and should include supporting documents (e.g. study logs, notes to file etc.) to support the study team's address of each action item.
- CAPA Plans for each action item should include:
 - Description of the problem
 - Narrative of events (what happened, why it happened)
 - Number of subjects affected/harmed



“If it isn’t documented, it didn’t happen”



Resources to Assist with Compliance

Kim Luebbers
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Research Navigator
Research.Navigator@med.uvm.edu

OCTR Commons Site
<https://commons.med.uvm.edu/dean/comcIntril/default.aspx>

Melanie Locher
Director of IRB
Melanie.locher@uvm.edu

UVM IRB Policies and Procedures Manual
<https://www.uvm.edu/rpo/irb-policies-and-procedures>

UVM MC Compliance and Privacy Department
<https://www.uvmhealth.org/medcenter/Pages/Departments-and-Programs/compliance-and-privacy.aspx>

