

# Lessons Learned and Common Findings from QA Reviews of Research Studies

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## CLINICAL RESEARCH SEMINAR

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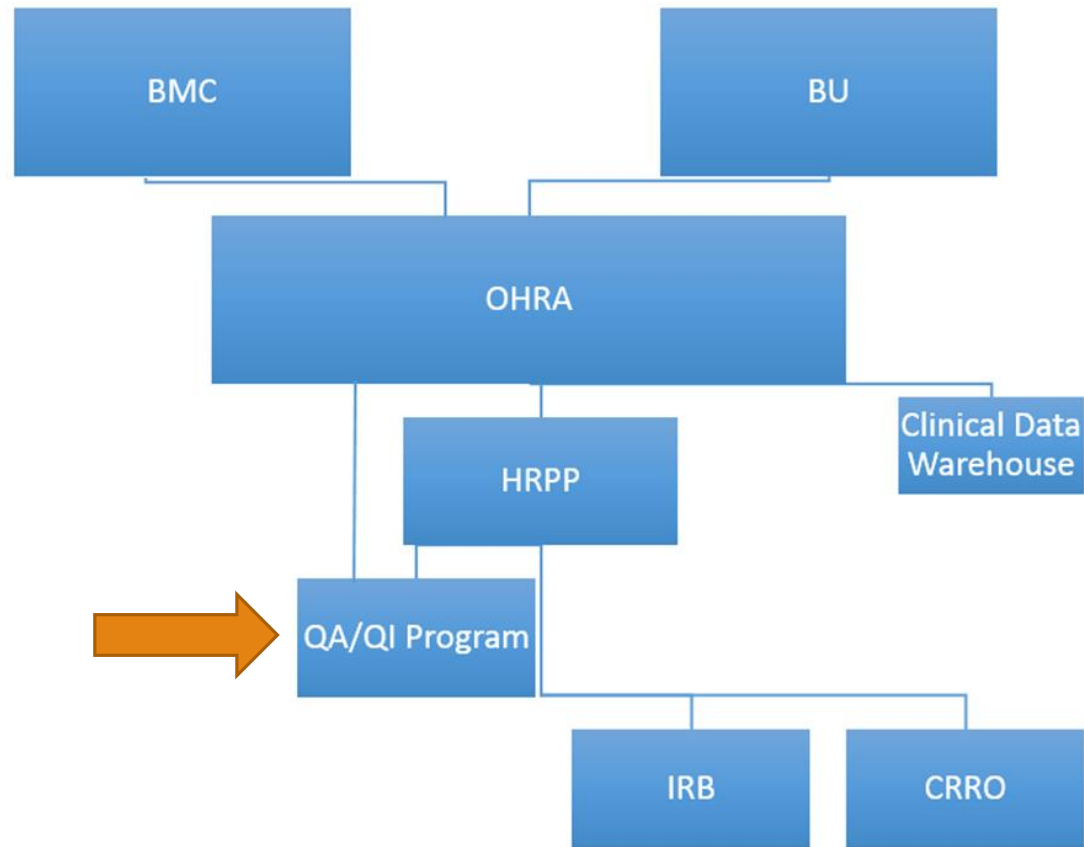
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# Objectives of Presentation

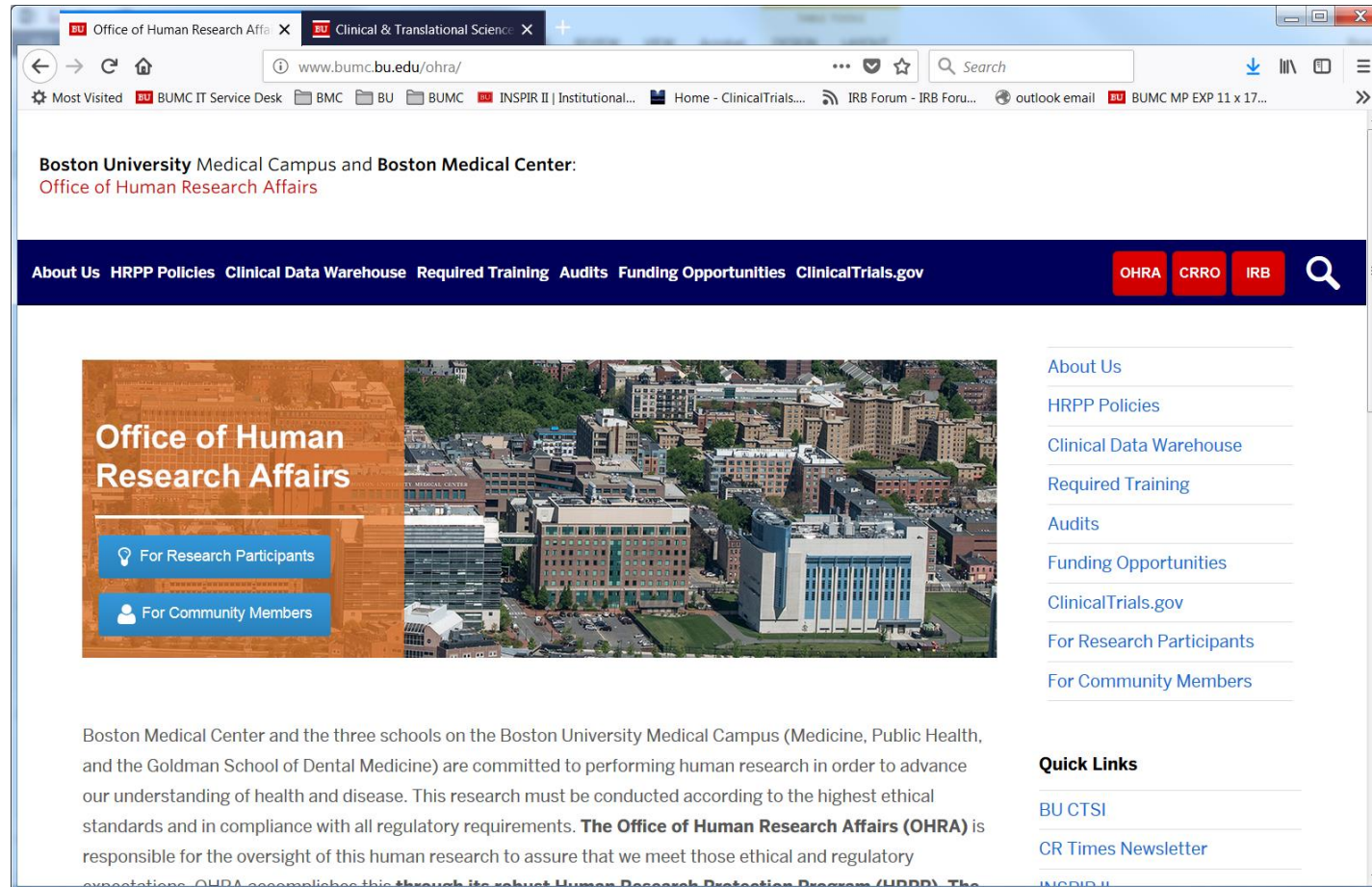
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1. Explain BMC/BU Medical Campus Office of Human Research Affairs (OHRA) Quality Program
2. Identify areas of focus of routine QA reviews
3. Give examples of common findings in routine QA reviews
4. Discuss QA take-away lessons for study teams

# BMC/BU Med Campus – OHRA



# http://www.bumc.bu.edu/ohra/



Quality Assurance Review	For-Cause Audit
Educational and consultative in nature	Investigative, but still educational in nature
Study is routinely selected based on QA criteria	Requested by HRPP
Scheduled when enrollment has begun (as early as possible)	Scheduled as soon as possible upon request
Scope: Broad review of IRB application, study documentation, and study processes	Scope: Targeted review of specific area of concern, or in-depth review to assess overall compliance
If deviations found, follow up meeting with study team to review report	Follow up meeting with study team to review report AND PI responds to audit report within 14 days
PIs submit deviations, Quality Manager confirms reporting	PIs submit deviations, Quality Manager confirms reporting

# Routine QA Review – Areas of Focus

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- Regulatory Binder(s)
- Informed Consent Procedures
- General Protocol Adherence
  - Participant Eligibility
  - Adverse Event Monitoring
- Confidentiality

# Routine QA Review Standards

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Standards that are assessed, as applicable:

- Federal Regulations (45 CFR 46, FDA regulated 21 CFR)
- BMC/BU HRPP Policies and Procedures
- Reviewing IRB Policies and Procedures
- International Conference on Harmonization (ICH) Good Clinical Practice (GCP)

# QA Reviews – Findings

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**Minor Deviations**: Any unapproved changes in the research study design and/or procedures that do not have a major impact on the participant's rights, safety or well-being, or on the reliability of the overall study data.

**Major Deviations**: Deviations that may:

- harm the participant's rights, safety or well-being,
- significantly damage the overall reliability of the study data, or
- represent noncompliance with IRB requirements that may be serious or continuing.



# Important Findings

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Findings that are not minor/major deviations but may require PI action and/or follow-up.

- Amendment needed
- Sponsor clarification required

# Best Practice Recommendations

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Best Practice Recommendations rooted in ICH GCP to supplement FDA/HHS regulations for the conduct of human subjects research:

- *“Good clinical practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects.”*
- *“assurance that the rights, safety, and well-being of trial subjects are protected”*
- *“and that the clinical trial data are credible.”*

# Common QA Review Findings

**Boston University** Medical Campus and **Boston Medical Center:**  
Clinical Research Resources Office

**About Us**

**Consultations**

**Training & Education**

**RPN**

**Resources**

## Study Documentation Tools

As per the International Conference on Harmonization Good Clinical Practice (ICH GCP), the responsibility of an investigator is to maintain trial-related documents and ensure the integrity of the trial and the quality of the data produced. These “Essential Documents” include the protocol, study documents and regulatory and protocol-related documents.

The customizable tools provided here are optional, but these (or similar) tools are highly recommended.

**Study Documentation Tools**

**Clinical Research Reference Guide**

**Recruitment Tools and Resources**

**Regulatory & Ethics Links and Guidance**

# Regulatory – Training Log

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HRPP policy, PI Responsibility #6: Ensure that prior to beginning work on the study, all members of the study team are **trained on study procedures** (sec 6.6.1).

Information is best maintained using a Study Staff Training Log.

## Common Findings:

- Training has occurred, log never created
- No training has occurred



# Regulatory – Delegation Log

HRPP policy, PI Responsibility #6: All members of the study team are **appropriately delegated responsibility for study procedures** (sec 6.6.1).

Information is best maintained using Study Staff Signature and Task Delegation Log.

## Common Findings:

- Staff delegated tasks that they are not qualified to perform
- Staff doing tasks they are not delegated to perform
- Tasks have been added to an entry at a later date, once staff receive a new training
- Staff missing from delegation log
- Delegation log is missing

## Signature/Task Delegation Log

CRRO Template Version 1.0, 5/24/2017

**GENERAL INSTRUCTIONS** – delete this box from the completed form

This log has two purposes. First, it documents signatures and initials of all staff that collect and record study data so that study documentation attributed to specific staff members may be verified. Second, it lists the study activities that the staff member may do, per delegation by the PI. Update this log in a timely manner when study personnel are added, removed, and/or when study roles change.

You should add/remove tasks from the list to reflect the study activities that apply to your study.

The PI should sign each entry to acknowledge the delegated tasks and sign at study closeout to attest that the list is complete and accurate.

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

Please ensure that all staff listed on this log are IRB-approved to do the task to which they are assigned (i.e. such as consenting participants) and that they are qualified by training, education, and license to do so (such as administering medications, performing physical exams and assessments, assessing AE seriousness, grade, attribution, etc.)

Print Name	Degree(s) <sup>1</sup>	Role on study	Signature	Initials	Delegated study tasks (see below)	Start date	End date	PI Initials/date



# Regulatory - Miscellaneous

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## Other Common Findings:

- Expired clinical licenses
- Very old CVs
- CVs not dated/signed
- Missing essential documents (1572, financial disclosure forms, etc.)

# Informed Consent-Procedures

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HRPP policy, PI Responsibility #10: Follow the IRB-approved research plan...by employing the approved process for obtaining and documenting informed consent...

## Common Findings:

- Consent not obtained by study staff as detailed in protocol and/or INSPIR application
- Consent obtained by Study Staff *not delegated* by PI

# Informed Consent-Procedures

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## Common Findings Continued:

- Consent obtained using an outdated version of stamped ICF
- ICF used does not have an IRB approval stamp (validation)
- Re-consent not obtained as required by IRB

# Scenario

In the Consent Procedures section of the IRB approved INSPIR application, the PI stated the following regarding which members of the study team would obtain informed consent

*“the PI or site investigator will be responsible for consenting participants”.*

Upon review of study ICFs, it was observed that the Study Coordinator had been obtaining informed consent and signing the ICF (note: PI had delegated coordinator task of obtaining consent)

**What is the problem here?**

**Is this a deviation?**

# Scenario

The IRB approved the following protocol amendment:

New study questionnaires to be sent via an email link to participants and can be completed by participants without an in-person study visit.

The IRB approval letter for amendment stated the following: *“The new/revised consent form(s) must be used for all newly enrolled subjects. Already enrolled subjects do not have to be re-consented.”*

Study team did not use the new/revised consent form when consenting new participants.

**What is the problem here?**

**Is this a deviation?**

# Documentation of Informed Consent

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## Common Findings:

- Check boxes on ICFs are incomplete
- Cross-outs or handwritten corrections made on IRB-approved ICF
- Staff dating ICF where participant/LAR should date.
- No documentation that participant was provided with copy of ICF

# Scenario

Study team providing copy of ICF to participants but there is no written documentation to support that this occurred.

**Is this a deviation?**

**How could this be avoided in the future?**

# Documentation of Informed Consent Template

## Documentation of Informed Consent

Participant:	
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.
  - ☐ Verbal consent/assent was obtained (as approved by the IRB).
  - ☐ Obtained consent from Legally Authorized Representative (as approved by the IRB).
- ☐ The consent form was signed and dated by the researcher.
- ☐ The consent process was witnessed by an impartial witness (if applicable).
- ☐ The participant was given a copy of the signed informed consent form.
- ☐ The consent process was completed *prior to the start of research procedures*.

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, etc.):

\_\_\_\_\_

Signature or initials of person completing this form: \_\_\_\_\_

Date form completed: \_\_\_\_\_



# Eligibility Criteria Adherence

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HRPP policy, PI Responsibility #10: Follow the IRB-approved research plan...by adhering to the approved inclusion and exclusion criteria and maintaining appropriate source documentation that demonstrates adherence

## Common Findings:

- Protocol change to eligibility criteria, but study still using old criteria.
- Sponsor provides eligibility form to site which differs from protocol.
- Approval from sponsor for eligibility exception, but exception not reviewed and approved by the IRB.

# Scenario

Eligibility Criteria #2: Age 18-64

Participant turns 65 today. Meets all other eligibility criteria. PI believes participant will be excellent candidate for study.

PI contacts the sponsor to request that this participant be allowed to enroll in the study. The sponsor approves the request.

**What are the next steps?**

# Eligibility Documentation

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HRPP policy, PI Responsibility #10: Follow the IRB-approved research plan...by adhering to the approved inclusion and exclusion criteria and maintaining appropriate source documentation that demonstrates adherence

## Common Findings:

- No source documentation for each inclusion/exclusion criterion.
- No source documentation (note) for eligibility criterion for which PI used judgment or queried a participant.
- No source for calculations (i.e. ANC, GFR, BMI)

RESEARCH SUBJECT ELIGIBILITY ASSESSMENT FORM

SUBJECT # <u>040</u>	
<b>INCLUSION CRITERIA</b> <i>Must be "yes"</i>	<b>Yes</b>
1. Age >18 and <65	<input checked="" type="checkbox"/>
2. Documentation of HIV diagnosis in the medical record by a licensed health care provider;	<input checked="" type="checkbox"/>
3. HIV-1 RNA assay demonstrating >1000 RNA copies/mL;	<input checked="" type="checkbox"/>
<b>EXCLUSION CRITERIA</b> <i>Must be "no"</i>	<b>No</b>
1. Active infection with hepatitis B or hepatitis C by serology	<input checked="" type="checkbox"/>
2. BMI less than 18 mg/m <sup>2</sup> or greater than 35 mg/m <sup>2</sup>	<input checked="" type="checkbox"/>
3. Known allergies to any of the study drug's components.	<input checked="" type="checkbox"/>
4. Life expectancy of less than 2 years	<input checked="" type="checkbox"/>

This subject is: ☒ Eligible for participation ☐ Ineligible for participation

PI Name: Bill White Signature: Bill White Date: 3/1/18

## Types of source data/documentation:

- Medical record data
- Lab report
- Questionnaire
- EKG
- Pharmacy dispensing records
- Radiology images
- Calculation
- Investigator note
- .....

## RESEARCH SUBJECT ELIGIBILITY ASSESSMENT FORM

CRRO Template Version 1.0, 4/25/2017

**GENERAL INSTRUCTIONS** – delete this box from the completed form

**NOTE:** This form is designed to be a starting point on eligibility assessment. Update it as necessary for your specific study.

All participants enrolled in the study must meet all inclusion criteria and not meet any of the exclusion criteria. All changes to inclusion/exclusion criteria must be approved by the IRB prior to implementation. Remember to modify this template any time the inclusion/exclusion criteria is changed.

Participant records should include source documentation (lab results, medical records, questionnaires, data collection tools, etc.) to support that the participant meets eligibility criteria.

All staff responsible for reviewing and/or determining subject eligibility should be listed on the IRB application, appropriately trained by study PI, and listed on the study delegation log.

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

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

[Complete this table with all inclusion/exclusion criteria listed in the IRB-approved protocol. Modify the number of rows as needed depending on the number of inclusion/exclusion criteria in your protocol.]

SUBJECT # _____				
INCLUSION CRITERIA <i>Must be "yes"</i>	Yes	No	Location of supporting source documentation	Notes
1.	<input type="checkbox"/>	<input type="checkbox"/>		
2.	<input type="checkbox"/>	<input type="checkbox"/>		
3.	<input type="checkbox"/>	<input type="checkbox"/>		
4.	<input type="checkbox"/>	<input type="checkbox"/>		
5.	<input type="checkbox"/>	<input type="checkbox"/>		

EXCLUSION CRITERIA <i>Must be "no"</i>	Yes	No	Location of supporting source documentation	Notes
1.	<input type="checkbox"/>	<input type="checkbox"/>		
2.	<input type="checkbox"/>	<input type="checkbox"/>		
3.	<input type="checkbox"/>	<input type="checkbox"/>		
4.	<input type="checkbox"/>	<input type="checkbox"/>		
5.	<input type="checkbox"/>	<input type="checkbox"/>		

This subject is:

☐ Eligible for participation      ☐ Ineligible for participation

[Signed by study team member who is (1) qualified to assess eligibility and (2) delegated this study task by the PI]

Signature:	Date:
Printed Name:	

# Adherence to Study Procedures

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HRPP policy, PI Responsibility #10 and #13: Follow the IRB-approved research plan and ensure IRB approval is obtained prior to making any changes to the approved plan.

## Common Findings:

- Study procedures described in Protocol or INSPIR application not being completed, or dropped from study (without prior IRB approval)
- Study procedures being completed outside of time window specified in protocol
- Study procedures completed by staff not qualified, trained, or delegated by PI

# Scenario

The INSPIR application indicates that a “*time-out*” procedure will be performed at the participant’s bedside prior to the administration of study drug. This “*time-out*” procedure will be performed by 2 people who will confirm participant’s identity, ID#, and study drug documentation.

Review of participant research record did not include any documentation indicating the “*time-out*” procedure occurred. PI confirmed that only he confirmed participant identify, ID#, and reviewed study drug documentation.

**What is the problem here?**

**Is this a deviation?**

# Scenario

Study is PI-initiated

The protocol indicates that a DSMB will be formed to review all AEs, and the DSMB will meet every 6 months once enrollment begins.

PI has had difficulty assembling a DSMB.

Enrollment in the study started 10 months ago, 2 participants have been enrolled and received study drug. To date, the DSMB has not been established and there has been no independent review of all study AEs.

**What is the problem here?**

**Is this a deviation?**



Study name:    
Study ID #:  

Study PI: 

### Protocol Deviation/Exception Log

This log tracks submissions of protocol deviations and exceptions to the IRB and the sponsor (as applicable). Maintaining such a log helps the site to view the current status and history of deviations and exceptions to assess overall compliance to the protocol. See IRB Policies & Procedures Manual: Protocol Deviations. Major deviations should be reported to the IRB within 5 days of being aware of the deviation. A list of minor deviations should be submitted to the IRB at the time of continuing review.

[illegible]

# Adverse Event Tracking and Reporting

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HRPP policy, PI Responsibility #12: Comply with all requirements for identifying and reporting Unanticipated Problems, Adverse Events, deviations, and safety monitors' reports, and any other new or significant information that might impact a subject's safety or willingness to continue in the study; and

## Common Findings:

- No AE procedures in place
- AEs documented but not assessed (...by qualified staff, in a timely manner, etc.)
- AEs not reported according to protocol
- There were no AEs, but no source documentation to confirm they were assessed

# Example

- 6.2.1 Adverse Event: Any unfavorable and unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with the use of a medical treatment or procedure regardless of whether it is considered related to the medical treatment or procedure (attribution of unrelated, unlikely, possible, probable, or definite).

MD

**Acute conjunctivitis of right eye, unspecified acute conjunctivitis type**  
Dx

Conversation

(Oldest Message First)

Note

Patient traveling with red eye; requests med for "pink eye." Given his distance from care, will provide ofloxacin eye drops.

Patient is a 53 y.o. male presenting with diarrhea. The history is provided by the patient.  
Diarrhea  
Quality: **Watery**  
Onset quality: **Sudden**  
Timing: **Constant**  
Progression: **Unchanged**  
Previous treatments: **Medications**  
Worsened by: **Nothing**  
Associated symptoms: **no abdominal pain and no fever**  
Risk factors: **suspect food intake**

? Sleep apnea (snoring, sleep interruption): referral Sleep Studies and Sleep specialist for evaluation

# Scenario

Participant 100 experienced a Serious Adverse Event in February 2016 involving hospitalization. The event occurred on February 13, 2016 and the study team became aware of the event on February 23, 2016. The event was reported to the sponsor on February 26, 2016.

The protocol states: The investigator should inform Sponsor of any SAE within 24 hours of being aware of the event. This must be documented on a FDA form XX.

**Is this a deviation?**

Explanation in CAPA: The deviation occurred because the event was discovered by patient report and the event occurred outside of the institution. It took a couple of days to obtain information from the outside institution.

**How could you avoid this?**

**Internal AE/UP Report Tracking Log**

This log tracks assessment and reporting of internal AEs. AEs should be assessed for seriousness, severity, expectedness, and relatedness. From this information, a determination of reporting can be made. Events that are serious OR pose a greater risk of harm than was previously known or recognized, at least possibly related to the research, and unexpected are Unanticipated Problems (UPs) and must be reported within two days to the BMC/BU Medical Campus IRB. Your sponsor may have different reporting requirements. Other AEs should be reported to the IRB at the time of the progress report. If the study is monitored by an outside independent monitoring committee then their report(s) will suffice instead of an AE summary at the time of the progress report. Investigators monitoring their own studies may use this log to submit to the IRB at the time of progress report.

Subj ID #	Date AE occurred	Date AE identified	AE description	SAE? <sup>1</sup>	Relatedness <sup>2</sup>	Expected?	Severity Grade <sup>3</sup>	UP? <sup>4</sup>	Date reported to sponsor (if applicable)	Dated reported to IRB
				<input type="checkbox"/> yes <input type="checkbox"/> no		<input type="checkbox"/> expected <input type="checkbox"/> unexpected		<input type="checkbox"/> yes <input type="checkbox"/> no		
				<input type="checkbox"/> yes <input type="checkbox"/> no		<input type="checkbox"/> expected <input type="checkbox"/> unexpected		<input type="checkbox"/> yes <input type="checkbox"/> no		
				<input type="checkbox"/> yes <input type="checkbox"/> no		<input type="checkbox"/> expected <input type="checkbox"/> unexpected		<input type="checkbox"/> yes <input type="checkbox"/> no		
				<input type="checkbox"/> yes <input type="checkbox"/> no		<input type="checkbox"/> expected <input type="checkbox"/> unexpected		<input type="checkbox"/> yes <input type="checkbox"/> no		
				<input type="checkbox"/> yes <input type="checkbox"/> no		<input type="checkbox"/> expected <input type="checkbox"/> unexpected		<input type="checkbox"/> yes <input type="checkbox"/> no		
				<input type="checkbox"/> yes <input type="checkbox"/> no		<input type="checkbox"/> expected <input type="checkbox"/> unexpected		<input type="checkbox"/> yes <input type="checkbox"/> no		
				<input type="checkbox"/> yes <input type="checkbox"/> no		<input type="checkbox"/> expected <input type="checkbox"/> unexpected		<input type="checkbox"/> yes <input type="checkbox"/> no		
				<input type="checkbox"/> yes <input type="checkbox"/> no		<input type="checkbox"/> expected <input type="checkbox"/> unexpected		<input type="checkbox"/> yes <input type="checkbox"/> no		
				<input type="checkbox"/> yes <input type="checkbox"/> no		<input type="checkbox"/> expected <input type="checkbox"/> unexpected		<input type="checkbox"/> yes <input type="checkbox"/> no		
				<input type="checkbox"/> yes <input type="checkbox"/> no		<input type="checkbox"/> expected <input type="checkbox"/> unexpected		<input type="checkbox"/> yes <input type="checkbox"/> no		
				<input type="checkbox"/> yes <input type="checkbox"/> no		<input type="checkbox"/> expected <input type="checkbox"/> unexpected		<input type="checkbox"/> yes <input type="checkbox"/> no		
				<input type="checkbox"/> yes <input type="checkbox"/> no		<input type="checkbox"/> expected <input type="checkbox"/> unexpected		<input type="checkbox"/> yes <input type="checkbox"/> no		
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				<input type="checkbox"/> yes <input type="checkbox"/> no		<input type="checkbox"/> expected <input type="checkbox"/> unexpected		<input type="checkbox"/> yes <input type="checkbox"/> no		
				<input type="checkbox"/> yes <input type="checkbox"/> no		<input type="checkbox"/> expected <input type="checkbox"/> unexpected		<input type="checkbox"/> yes <input type="checkbox"/> no		

<sup>1</sup> SAE Classification: AE is an SAE if it meets any of the criteria below.	<sup>2</sup> Relationship with study intervention, per MD	<sup>3</sup> Severity Grade	<sup>4</sup> Unanticipated problem: If AE meets all three criteria below report to IRB within 2 days.
<ul style="list-style-type: none"><li>- Results in death</li><li>- Life threatening</li><li>- Requires/prolongs hospitalization</li><li>- Results in disability or incapacity</li><li>- Congenital Anomaly/birth defect</li><li>- Medically Important event</li></ul>	<ul style="list-style-type: none"><li>1 - Definite</li><li>2 - Probable</li><li>3 - Possible</li><li>4 - Unlikely</li><li>5 - Unrelated</li></ul>	<ul style="list-style-type: none"><li>1 - Mild AE (not requiring treatment)</li><li>2 - Moderate AE (resolved with treatment)</li><li>3 - Severe (Inability to carry on normal activities/required professional medical attention)</li><li>4 - Severe: life threatening or disabling AE</li><li>5 - Death</li></ul>	<ul style="list-style-type: none"><li>- Unexpected</li><li>- Related/possibly related to the research</li><li>- Suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized.</li></ul>

# Privacy/Confidentiality

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HRPP policy, PI Responsibility #10: Follow the IRB-approved research plan...by maintaining the privacy of subjects and protection the confidentiality of data....

Common Finding: Not adhering to the Confidentiality section of INSPIR application, regarding PHI maintained in participant files.

## Other Findings:

Staff using personal laptops, that do not have required security settings, to access study databases.

Study documents not being stored as described in INSPIR application.

# Scenario

Section 14.2 of the INSPIR application indicates that all study documents will be coded and identified by a unique study ID #. However, source documentation maintained in participant study files contains identifiers such as participant's name, date of birth, address, and medical record number.

**Is this a deviation?**

# Study Documentation

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## Common Findings:

- Study not adequately documenting minor deviations.
  - Study Visit Checklists can help with this!
- Study documentation not adhering to ALCOAC documentation standards



# ALCOAC Documentation Standards

<b>Attributable</b>	Be clear who has documented the data
<b>Legible</b>	Capable of being read Changes don't obscure original entry Signatures should be legible
<b>Contemporaneous</b>	The documentation, signature, and date need to be completed at the same time and as close to the event as possible
<b>Original</b>	First recording of the information (paper, electronic)
<b>Accurate</b>	Consistent, real representation of facts Errors have been identified and corrected with notes to explain if needed
<b>Complete</b>	Study documentation must be complete

# Legible?

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Date 2/26/18

Date 2/24/18

# Original?

Study RA forgot to bring Vital Sign Source Data Collection Form to GCRU for study participant #001 study visit on 5/1/18. RA noted vitals on a sticky note. Once back at the office the RA transferred the vital data to the collection form. **Can the RA throw away the sticky note?**

**ABC Study**  
**Visit 1 Source Data Collection Form/CRF**

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Participant ID#: 001

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**Vitals/Urine Pregnancy Testing**

BP: 120/80 Height: 156 cm Weight: 68 Kgs Heart Rate: 80

Urine Pregnancy Test Completed: ☐ YES ☐ NO ☒ N/A Results: ☐ Positive ☐ Negative

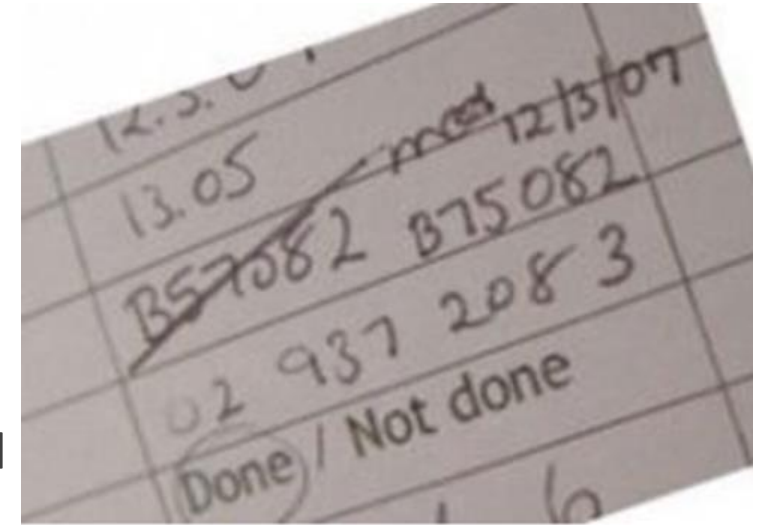
#001 5/1/18  
BP 120/80  
Height 156 cm  
wt 68 Kgs  
HTZ 80  
Joan Smith

# Corrections to Study Documentation

Corrections are expected!

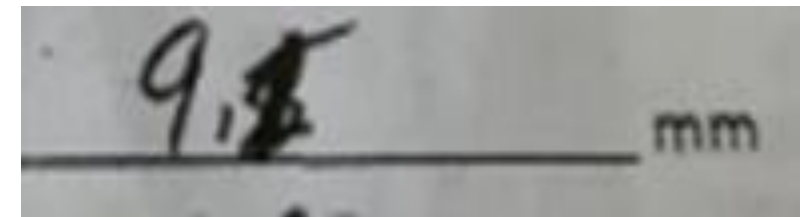
## Proper Corrections:

- One line through error, write new data, initial, date and explain (if necessary)
- Entries on study documents and changes to those entries should be made by study team members with the authority to do so as delegated by the PI.



## Unacceptable Corrections:

- Complete cross-out, correction fluid, write overs
- New information must not obliterate previous information
- Erasing/Recording in pencil
- Editing subject's personal writings or responses on forms



# Takeaways

# Takeaways

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- When a protocol changes, other document changes might be necessary
- Always read your IRB approval letters
- Request help!
  - Consultations with CRRO
  - Consultations with a QA reviewers
  - Request a QA review 😊
- Use CRRO documentation tools
- Conduct a study self assessment – review your protocol and forms

# Common Questions

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I have a study monitor. Do you still need to come review my study?

Who needs to be available for the review?

What files do you need access to?

Does anyone else get my report?

Will the IRB see my report?

# Examples of Information Contained in IRB Approval Letters

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This approval corresponds with the versions of the application and attachments in the electronic system most recently approved as of the date of this letter. The approved version of the attached protocol is Version 4, dated 25 August 2018.

The new/revised consent form(s) must be used for all newly enrolled subjects. Already enrolled subjects do not have to be re-consented.



The expiration or status check-in due date has not changed as a result of this amendment.

This approval corresponds with the versions of the application and attachments in the electronic system most recently approved as of the date of this letter. The approved version of the attached protocol is version 1.4.

Already enrolled subjects must be notified of the changes as follows: Already enrolled subjects should be informed of the changes at their next study visit, and a new signature for consent should be obtained.

The IRB of Record for this study will be: **HIRB**

The review, approval, and continuing oversight performed by HIRB will meet the human subjects protection requirements of the OHRP-approved FWAs for Boston Medical Center and for Boston University Medical Campus.

HIRB will follow written procedures for reporting its findings and actions to appropriate officials at Boston Medical Center and Boston University Medical Campus.

You must submit further communications regarding this study including amendments, progress reports, deviation reports, and notification regarding unanticipated problems involving risks to subjects or others to HIRB.

In addition, you must submit any study personnel changes to the BMC/BU Medical Campus IRB, then to HIRB with the approval letter from the BMC/BU Medical Campus IRB. You must also submit reports of internal unanticipated problems to the BMC/BU Medical Campus IRB in addition to the HIRB.

Questions?

# For More Information

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<p>Abdalla Abdussamad, MD, MA Human Research Quality Manager 617-358-7555 <a href="mailto:abdallaa@bu.edu">abdallaa@bu.edu</a></p>	<p>Gina Daniels Human Research Quality Manager 617-358-7385 <a href="mailto:gdaniels@bu.edu">gdaniels@bu.edu</a></p>
<p>Fiona Rice, MPH Human Research Quality Manager 617-358-7554 <a href="mailto:fionar@bu.edu">fionar@bu.edu</a></p>	