Self-Assessments

Check Yourself Before You Wreck Yourself

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Objectives

Attendees will design, develop, and apply provided best practice methods to daily activities associated with clinical research studies in evaluating clinical research conduct and improve study documentation.

Attendees will be able to design checklists or format survey type reviews of clinical studies to engage research team members and decrease the incidence of errors or missing information for clinical trials.

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Overview

1. **Self-assessment best practices**
2. **What we get out of self-assessments**
3. **Example of a self-assessment program at University of Florida**

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Thank You

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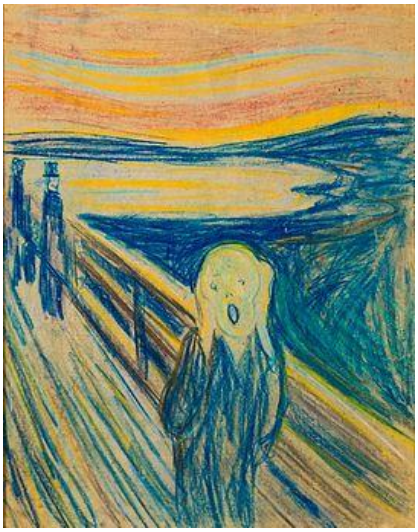

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Build Quality Assurance (QA) into your Study

Self-Assessment	Study Level	Office Department Level	Institution Level (IRB)	Sponsor	Federal Level (FDA, NCI, JC, CMS)

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Tools for Self-Assessment

- Computer Applications
- Communication Teamwork
- Standardization
- Checklists

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Computer Applications

Maximize features that Minimize errors

- Alerts
- Audit Trail
- Automation
- Calculation
- eConsent
- Field Validation
- Logic
- Permissions
- Queries
- Remote Data Capture
- Reports
- Scheduling

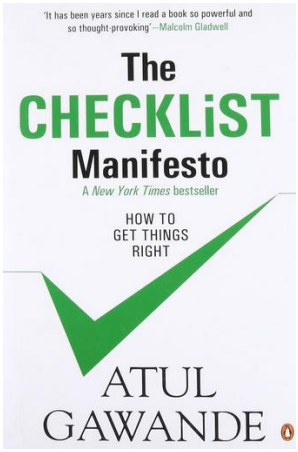
Communication Teamwork

- Regular Study Team Meetings

Standardization

- Follow SOPs, MOPS, Workflows
- Be Relentlessly Organized and Consistent

Checklists



How do we heal medicine

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Checklists

- Study Initiation Checklist
- Initial IRB Submission Checklist
- IRB Approval Checklist
- New Study Team Member Checklist
- New PI Checklist
- PI Leaving Checklist
- New Subject Enrolled Checklist
- Study Team Meeting Agenda Checklist
- Study Closure Checklist

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Checklists

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LARNER COLLEGE OF MEDICINE

New Subject Enrolled Checklist		
√	Task	Date Completed
Informed Consent Form (ICF) and HIPAA Authorization		
	Current IRB approved version of the ICF/HIPAA was used	
	ICF/HIPAA was signed and dated by research participant	
	ICF/HIPAA was signed and dated by delegated key personnel (KP)	
	Embedded questions in ICF/HIPAA were completed, if applicable	
	Track what the subject agreed to and declined (embedded questions)	
	Consent process was documented, signed, and dated by delegated KP	
	Identifiers were placed on each page of the ICF/HIPAA	
	Copy of the signed ICF/HIPAA form given to the research participant per Research3 Policy	
	ICF/HIPAA scanned and uploaded to UVM MC HIM SharePoint for uploading into EPIC per Research3 Policy	
EPIC		
	Activate research flag in EPIC with start date (consent date) per Research4 Policy	
	Add subject to patient lists in EPIC, if applicable	
	Associate subject encounters and link orders to research study in EPIC	
	Confirmed that the ICF/HIPAA was properly uploaded to EPIC per Research3 Policy	
Office		
	Add to screening and enrollment log	

Best Practices for Self-Assessments

- ✓ **Use your tools**
- ✓ **Have a self-assessment (QA) plan in writing and stick to it**
- ✓ **Use deviations and queries as opportunities to tighten up processes**

High Risk Areas

Consent Process

Embedded Questions, Signatures, Dates
Documentation of the Consent Process

Eligibility

Source Document for each Eligibility Criterion

Investigational Product Administration

Adverse Event Tracking, Serious Adverse Events, Dosing

Everyday Self-Assessment Ideas

Consent Process

Flag each page that requires an action (signature, initials, checkbox)

Eligibility

Use a computer-based eligibility checklist.

IP Administration

Always refer to the protocol.

Everyday Self-Assessment Ideas

QUESTION – Chat Storm

- Does anyone have any everyday self-assessment checks they can share with the group?

Goal of Self Assessment Exercises

A review plan is as important as passion towards Research:

- Evaluate knowledge and understanding.
- Identifying areas of improvement.
- Improving communications and collaborations.
- Setting professional goals.
- Promoting accountability and quality.

Chat Storm Questions

QUESTION – Chat Storm

- Do you have a ready to go planned system for a self-assessment?
  - If not, how soon can you get started with the review?
- Did a self-assessment on a project ever trigger more internal review?
- Daunting aspect of self assessment?

Review Plan

1. Department/Institutional Structure: Understand the departmental workflow to assess available resources, strengths, and weaknesses.

Resource allocation and support:

- Financial, human, and technological resources

Policies and standard operating procedures (SOPs):

- Reviewing existing policies, assessing comprehensiveness, evaluating processes for policy adherence.

Team communication:

- Communication channels between team members, departments, and stakeholders.

Review Plan

2. Construct the review plan: to review complete regulatory and clinical documentation

Establish purpose and scope:

- **Regulatory compliance, ethical considerations, study design**

Evaluation criteria:

- **Existing assessment tools (Paper/electronic checklists)**

Implementation plan and discussions:

- **Develop the plan and internally discuss with the team for any feedback or convey the scope and criteria.**

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Review Plan

3. Documenting Findings: Ensures insights, observations, and recommendations are captured systematically.

Develop structured report:

- **Sections pertaining to regulatory compliance, department structure, data management.**

Summarize key findings:

- **Highlighting any patterns on mistakes committed, notable successes.**

Grade or categorize findings:

- **Based on level of importance or urgency (requires PI, IRB, and sponsor notification?)**

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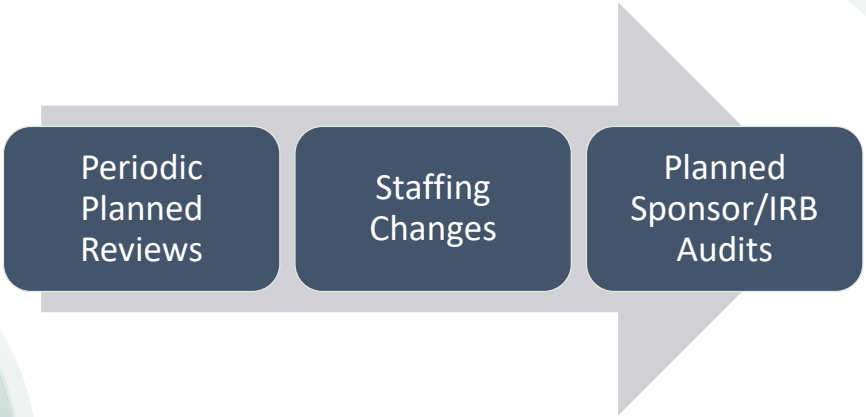
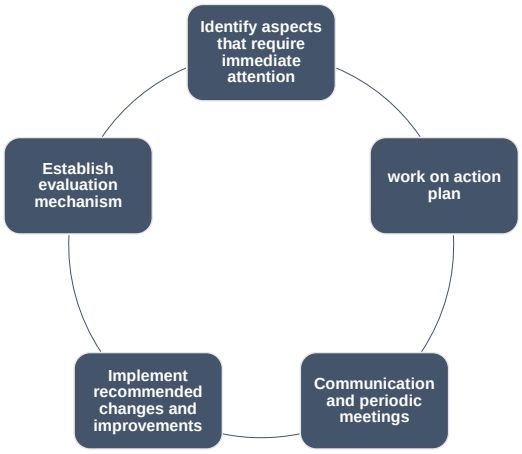
Review Frequency



Now what to do with the Findings?



Be proactive rather than reactive.

QUESTION – Chat Storm

- What method(s) do you use to prepare
  - For a continuing review?
  - For a visit from an external monitor?

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Introduction

- Internal assessment or internal audit
  - In the beginning
    - **Who** – faculty, fellows, residents, clinical research coordinators
    - **What** – we need to 'fix' things
    - **Why** – Repetitive issues with clinical research study errors
    - **When** – ASAP
    - **How –** More attention to detail prior to submission – ok

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Introduction

- Internal assessment or internal audit
  - **How**
    - An internal audit system
      - Good buy-in from the research staff
      - Development of REDCap internal audit system by staff
      - Numerous research division meetings
        - What needs included in the audit
        - Logistics

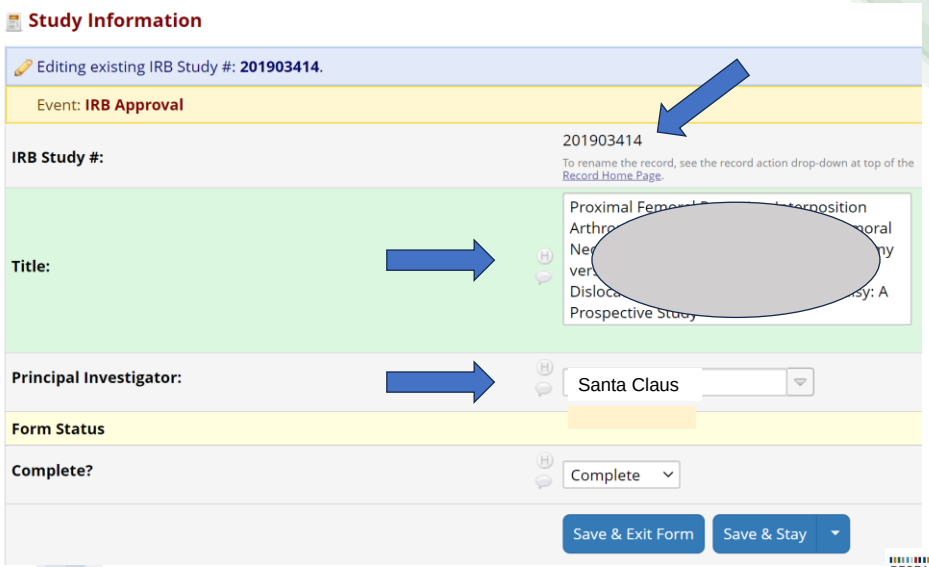
Where to Begin

- What format should we use for our internal audit system
  - REDCap
    - NCATS grant UL1TR001427
  - Other systems are available

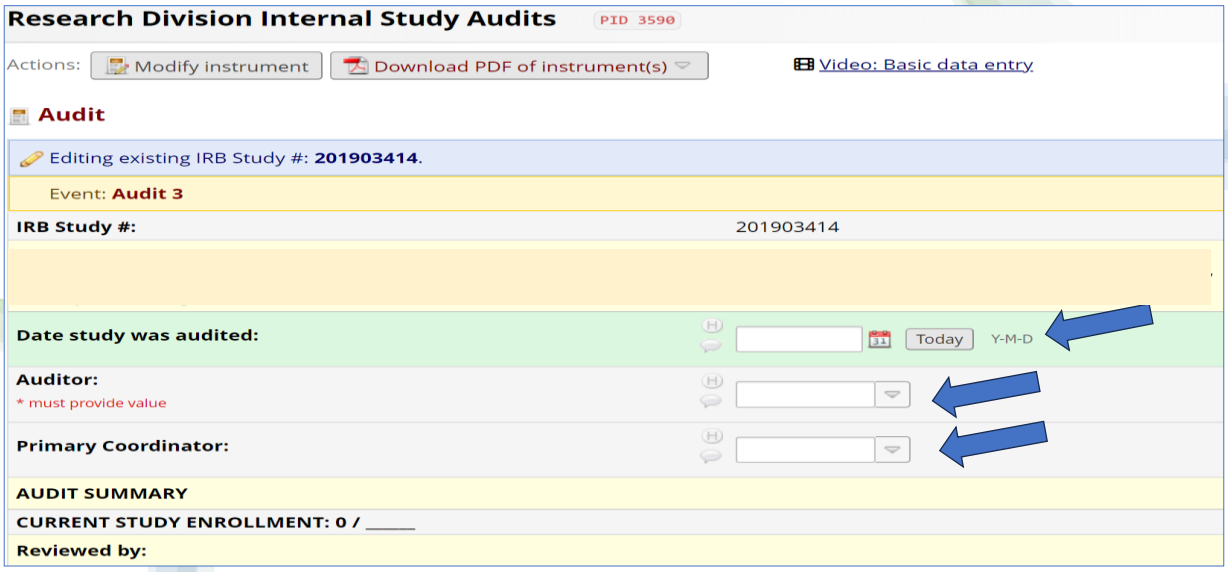
Where to Begin

- Internal audit
  - Clinical research coordinators **helping each other**
  - Completed at least **3 months in advance** of a continuing review
  - Recommend
    - Complete an internal audit after the first 2-5 patients have been enrolled in a new study

What and Who



What and Who



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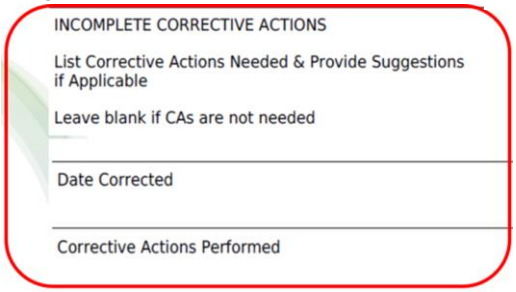
Basic Study Information

- IRB review type
  - Full board, expedited, exempt, data bank, non-human, HDE, ceded, other
- Study activity in the past year
  - Publications and/or abstracts for presentations
  - Did the previous audit identify and items requiring corrective actions
    - If yes, were the corrective actions completed

Corrective Actions

- Following each section of the internal audit
  - List corrective actions needed and provide suggestions (if applicable)
  - Completed the corrective action
    - Corrective action performed
    - Date corrected


INCOMPLETE CORRECTIVE ACTIONS

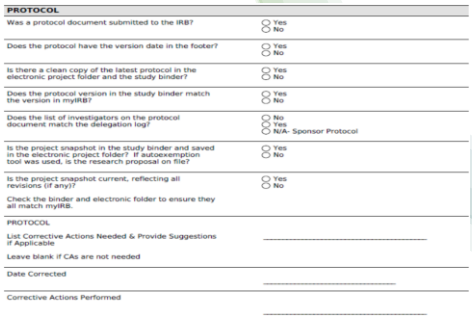
List Corrective Actions Needed & Provide Suggestions if Applicable

Leave blank if CAs are not needed

Date Corrected

Corrective Actions Performed

Protocol

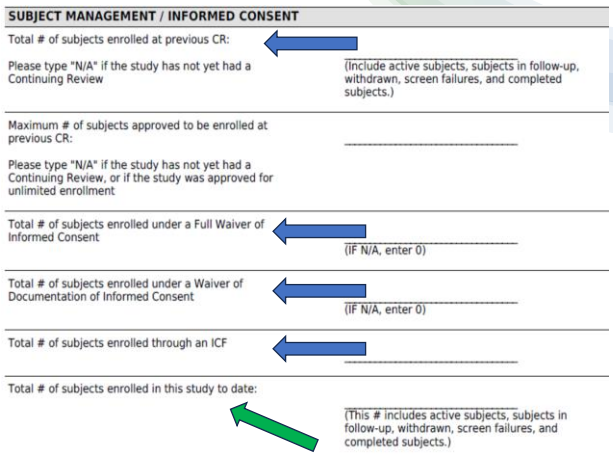


PROTOCOL	
Was a protocol document submitted to the IRB?	○ Yes ○ No
Does the protocol have the version date in the footer?	○ Yes ○ No
Is there a clean copy of the latest protocol in the electronic project folder and the study binder?	○ Yes ○ No
Does the protocol version in the study binder match the version in myIRB?	○ Yes ○ No
Does the list of investigators on the protocol document match the delegation log?	○ No ○ Yes ○ N/A- Sponsor Protocol
Is the project snapshot in the study binder and saved in the electronic project folder? If autoexemption tool was used, is the research proposal on file?	○ Yes ○ No
Is the project snapshot current, reflecting all revisions (if any)? Check the binder and electronic folder to ensure they all match myIRB.	○ Yes ○ No
PROTOCOL	
List Corrective Actions Needed & Provide Suggestions if Applicable Leave blank if CAs are not needed	_____
Date Corrected	_____
Corrective Actions Performed	_____

- Submitted to the IRB
- Protocol versions
- Investigators on protocol match the delegation log
- Study activity in the past year
  - Publications and/or abstracts for presentations
  - Did the previous audit identify and items requiring corrective actions
    - If yes, were the corrective actions completed

Subject Management

- Number of subjects
  - # enrolled since previous CR
  - How enrolled
    - # enrolled through ICF
    - # full waiver of consent
    - # waiver of documentation of ICF
  - Total # subjects to date



SUBJECT MANAGEMENT / INFORMED CONSENT

Total # of subjects enrolled at previous CR:

Please type "N/A" if the study has not yet had a Continuing Review

_____ (Include active subjects, subjects in follow-up, withdrawn, screen failures, and completed subjects.)

Maximum # of subjects approved to be enrolled at previous CR:

Please type "N/A" if the study has not yet had a Continuing Review, or if the study was approved for unlimited enrollment

_____

Total # of subjects enrolled under a Full Waiver of Informed Consent

_____ (IF N/A, enter 0)

Total # of subjects enrolled under a Waiver of Documentation of Informed Consent

_____ (IF N/A, enter 0)

Total # of subjects enrolled through an ICF

_____

Total # of subjects enrolled in this study to date:

_____ (This # includes active subjects, subjects in follow-up, withdrawn, screen failures, and completed subjects.)

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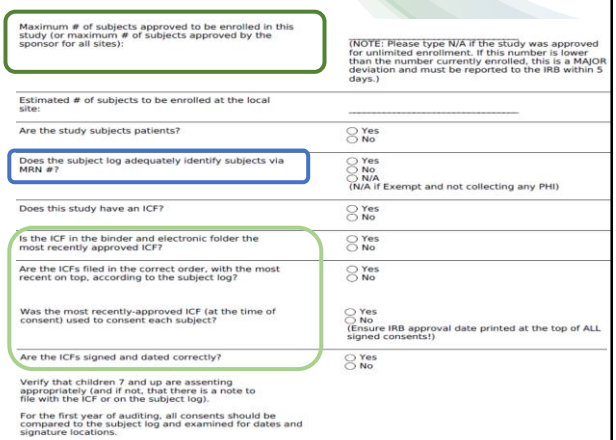
Subject Management

- Maximum # subjects
- Subject log
  - Correctly completed
    - MRN #
    - Withdrawals and screen failures
    - stipends
  - Up-to-date
- Most recently approved ICF used
  - ICF correctly completed
  - Proper signatures
    - Assent for minors



Maximum # of subjects approved to be enrolled in this study (or maximum # of subjects approved by the sponsor for all sites):

_____ (NOTE: Please type N/A if the study was approved for unlimited enrollment. If this number is lower than the number currently enrolled, this is a MAJOR deviation and must be reported to the IRB within 5 days.)

Estimated # of subjects to be enrolled at the local site:

_____

Are the study subjects patients?

○ Yes ○ No

Does the subject log adequately identify subjects via MRN #?

○ Yes ○ No ○ N/A (N/A if Exempt and not collecting any PHI)

Does this study have an ICF?

○ Yes ○ No

Is the ICF in the binder and electronic folder the most recently approved ICF?

○ Yes ○ No

Are the ICFs filed in the correct order, with the most recent on top, according to the subject log?

○ Yes ○ No

Was the most recently-approved ICF (at the time of consent) used to consent each subject?

○ Yes ○ No (Ensure IRB approval date printed at the top of ALL signed consents!)

Are the ICFs signed and dated correctly?

○ Yes ○ No

Verify that children 7 and up are assenting appropriately (and if not, that there is a note to file with the ICF or on the subject log).

For the first year of auditing, all consents should be compared to the subject log and examined for dates and signature locations.

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IRB Approvals

- Notifications of IRB approval
- Revisions
- Adverse events
- Deviations
- Continuing review

OCR & OnCore

- Clinical services
- Calendar
- Billing
  - Standard of care
  - Study only data
- Subject status
  - Must match subject log

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Data Management

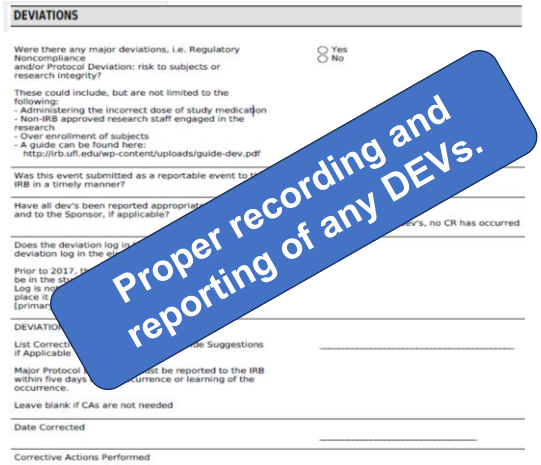
DATA MANAGEMENT

Data is collected on the following format(s):	☐ Paper forms ☐ Excel spreadsheet ☐ REDCap or Qualtrics ☐ Sponsor-specific Electronic Data Capture system ☐ Video or Photographs ☐ Other ☐ IDR or FPDS Report
Other data collection format:	_____
Has data been collected for this study?	○ Yes ○ No
Is the initial report request on file? (REDCap pdf for IDR, full report copy and pasted into a word document for FPDS)	○ Yes ○ No

1. **Format of data collection**
2. **CRFs**
3. **Inclusion/Exclusion criteria followed**
4. **Original data set properly stored and data releases appropriately logged**

Is the data report on file?	○ Yes ○ No
Is the study using data or identifying subjects from a databank (Ortho DB, Tissue Bank, etc)?	○ Yes ○ No
Has the data pull from the data bank been logged appropriately on the bank's electronic data distribution log?	○ Yes ○ No ○ N/A - non-
Are the CRFs complete?	○ Yes ○ No
Are any errors on CRF's marked appropriately? (Single strikeout, dated and initialed)	○ No ○ Yes ○ N/A- No e
Has inclusion/exclusion criteria been met per the protocol? If subjects are patients, confirm via medical chart review. If more than 50 subjects were enrolled in the last year, 10% (up to a maximum of 50 subjects) will be randomly selected for medical chart review; or if less than 50 subjects, 5 will be randomly selected for medical chart review. If less than 5 subjects are enrolled, then a medical chart review will occur on all 5.	○ Yes ○ No
Is the CRF management organized and well-maintained?	○ Yes
Are releases of data from the bank being appropriately logged on a data distribution log found in the electronic folder?	○ No ○ Yes ○ N/A- No d
DATA MANAGEMENT	
List Corrective Actions Needed & Provide Suggestions if Applicable Leave blank if CAs are not needed	_____
Date Corrected	_____
Corrective Actions Performed	

Deviations



DEVIATIONS

Were there any major deviations, i.e. Regulatory Noncompliance and/or Protocol Deviation: risk to subjects or research integrity? ○ Yes ○ No

These could include, but are not limited to the following:
- Administering the incorrect dose of study medication
- Non-IRB approved research staff engaged in the research
- Over enrollment of subjects
- A guide can be found here: http://irb.ufl.edu/wp-content/uploads/guide-dev.pdf

Was this event submitted as a reportable event to the IRB in a timely manner?

Have all dev's been reported appropriately and to the Sponsor, if applicable?

...ev's, no CR has occurred

Does the deviation log in the el...

Prior to 2017, th... be in the st... Log is not... place if ... [primar...

DEVIATIO...

List Correcti... if Applicable ...de Suggestions _____

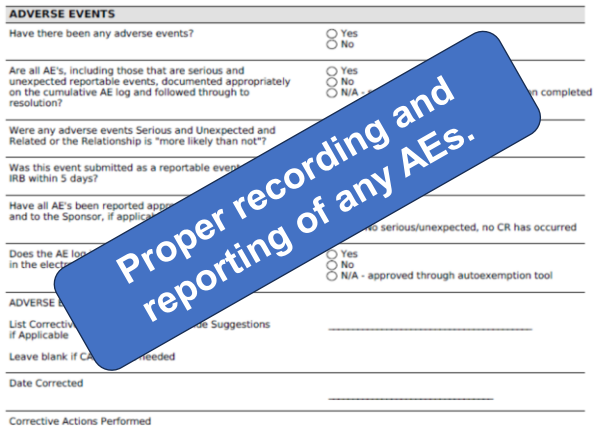
Major Protocol ... ...st be reported to the IRB within five days ...currence or learning of the occurrence.

Leave blank if CAs are not needed

Date Corrected _____

Corrective Actions Performed

Adverse Events



ADVERSE EVENTS

Have there been any adverse events? ○ Yes ○ No

Are all AE's, including those that are serious and unexpected reportable events, documented appropriately on the cumulative AE log and followed through to resolution? ○ Yes ○ No ○ N/A - ...n completed

Were any adverse events Serious and Unexpected and Related or the Relationship is "more likely than not"?

Was this event submitted as a reportable event... IRB within 5 days?

Have all AE's been reported appr... and to the Sponsor, if applica... ...o serious/unexpected, no CR has occurred

Does the AE log... in the electr... ○ Yes ○ No ○ N/A - approved through autoexemption tool

ADVERSE E...

List Correcti... if Applicable ...de Suggestions _____

Leave blank if CA... ...eeded

Date Corrected _____

Corrective Actions Performed

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Correspondence

CORRESPONDENCE

Is relevant correspondence (Sponsor newsletters, PI emails, patient letters, phone log, FPDS/IDR report requests etc) available for reference in the study binder?	○ Yes ○ No
Are all previous audits signed by both Dr. Horodyski and the PI and filed in the correspondence tab of the study binder?	○ Yes ○ No (NOTE: Audits do not need to be saved in the G:)
CORRESPONDENCE List Corrective Actions Needed & Provide Suggestions if Applicable Leave blank if CAs are not needed	_____
Date Corrected	_____
Corrective Actions Performed	

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Miscellaneous Items to Consider Checking

- Sponsor information
- Multi-center specifications
- Research agreement
- Training of research team on file
- FDA 1572 required
- Storage of data procedures
- Animal study
- DSMB

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When Completed

Reviewed by:

Director of Research: _____

Date: _____

Principal Investigator: _____

Date: _____

Take Home

- Do you need an audit/assessment method
- What method will work best for you and your research team
- Have you identified the areas you need to improve
  - Begin designing your system with the areas you identified
- Remember - change is inevitable
  - Assessment will change with your studies and staff

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QUESTION – Chat Storm

- Are there any systems that you use at your institution to aid with assessments of your clinical studies?

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BOSTON UNIVERSITY

BUMC/BMC Resources Library

Resources

- Study Documentation Tools
- eConsent
- Self-Assessment Tools
- Institutional Standard Operating Procedures (SOPs)
- Brochures for Participating in Research
- Clinical Research Reference Guide

UF UNIVERSITY of FLORIDA

UF Clinical and Translational Science Institute

Study Related Checklists

- Informed Consent Form checklist
- Protocol Adherence checklist
- Regulatory Records checklist
- Post-approval Monitoring (PAM) tool

The University of Vermont
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Resources

Office of Clinical Trials Research SharePoint

Regulatory Documents and Resources