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CANCER CONSORTIUM

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At Least It's Not the FDA : *Strategies & Tools to Successfully Navigate Sponsor Audits*

"For Cause" Sponsor Audits

- Usually Triggered By:
  - Serious Noncompliance "Event" (or Trend of Events)
  - Significant Backlog of Data Entry
  - Perceived Lack of PI Oversight
- Assume That Some Post-Audit Corrective Action Will Be Requested

TOOL KIT
- **Informed Consent Version Log**
- **CAPA Plan Template**

Pre-FDA Sponsor Audits

(For High Enrolling Sites / Sites Likely to be Reviewed for IND, BLA, PMA Audits)

- Sponsors Typically Select High Enrolling Sites or Those Who Participated In the Most Studies of IP
- Sponsors and Site Prepare Together to Ensure Site is "FDA Audit-Ready"
- Good Opportunity to Prepare PI and Study Staff Ahead of a Visit From FDA

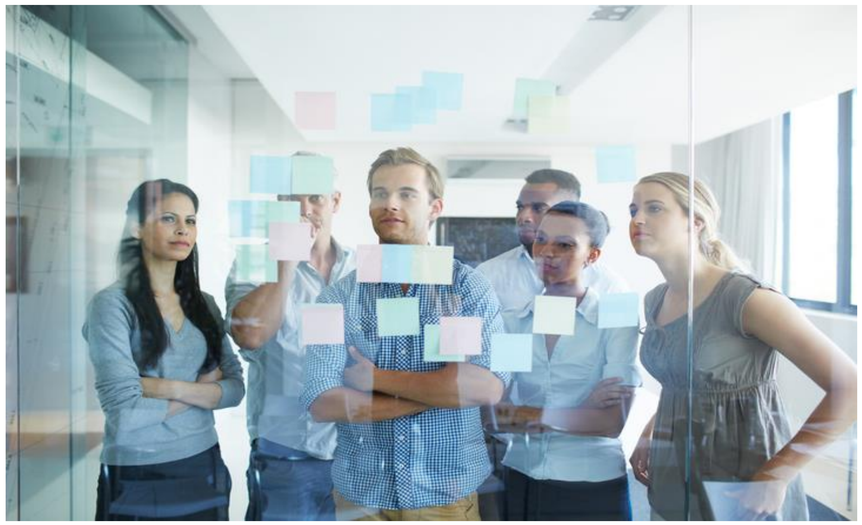
TOOL KIT
- **Investigator Questionnaire**
- **Regulatory Documents Checklist**

Acknowledgements

Clinical Research Support at Fred Hutch / University of Washington Cancer Consortium; ITHS – Institute of Translational Health Sciences; Bojana Askovich, PhD; Reina Hibbert, CCRC; Sarika Wegner; Annie Dang

BEST PRACTICE:

Utilize Time & Tools to Thoroughly Pre-Review Study Materials. The Goal Is, NO SURPRISES!



PREPARATION STRATEGIES:

- Review 100% of Main Informed Consent Forms
- Review Eligibility of ALL Patients Who Underwent Study-Related Treatment & Procedures
- Review Protocol Deviations to Pre-Identify Trends and/or Deviations That Were Not Reported
- Review Monitor Visit Reports to Identify Longstanding and/or Overdue Action Items
- Assign Someone From the Study Team to Take Notes of the Questions the Auditor Asks to Use as Reference
- Pre-review Major Issues Of Noncompliance With The PI And Key Study Team Ahead Of Audit – Make Sure Any Issues Can Be Spoken About Consistently

CRO/Monitor-Focused Sponsor Audits

- Geared Towards QA of Site Monitor and/or CRO to Demonstrate Sponsor Oversight
- Typically Involve:
  - Less Intense Review of Source Docs
  - Thorough Review of CRA-Generated Documentation (Monitor Reports, Data Queries, Use of Template Docs & Logs)

TOOL KIT
- **PI Oversight Meeting Log**
- **Eligibility Checklists**

Sponsor Oversight Audits

(Required by a Health Authority)

- Allow Sponsors to Demonstrate Oversight of Clinical Trial Sites During Life Cycle of Study (Not Just At Time of FDA Filing)
- Usually Sponsors Choose to Review High Enrolling Sites
- Not Necessarily Indicative of Site 'Issues' But Are Good Opportunity to Get Study "Audit-Ready"

TOOL KIT
- **Conditionally Formatted Staff Database To Highlight Training Expiration Dates**

Outcomes

- Tools That Our Site Has Used, Adapted, and Implemented Have Successfully Guided Us Through Over a Dozen Sponsor Audits In The 10 Years That Our Phase 1 Program Has Existed

Adverse Events

This Log is the Most Current and Up to Date Version of the Subject's Adverse Events to Date and Supersedes All Previous Versions
This Adverse Event Log is Reviewed with the Patient and Investigator During the Clinic Visit and is Routed to the Investigator Upon Completion of the Visit

Adverse Event	**Date of Onset**	**Date Resolved**	**SAE?** Y=Yes N=No	**CTCAE v4.03 Grade** 1=Mild 2=Moderate 3=Severe 4=Life-threatening 5=Death	**Possibly Related to Study Drug?** 1 = Not Related 2 = Unlikely Related 3 = Possibly Related 4 = Probably Related 5 = Yes, Related		**If Not Related, Other Suspected Cause** 1=Disease Under Study 2=Concomitant Treatment 3=Other Illness (Specify) 4= Other (Specify)	**Action Taken with Study Drug** 1 = No Action Taken 3 = Study Drug Dose Reduced 4 = Study Drug Held Temporarily 5 = Study Drug Held Permanently		**Other Actions** 1= No Action Taken 2= Subject Withdrawn 3= Treatment Given (Specify) 4= Other (Specify)
					Drug 1	Drug 2		Drug 1	Drug 2	
Intermittent chills		□								
Constipation baseline- miralax		□								
Right flank pain baseline- norco, acetaminophen		□								
Anorexia baseline		□								
Int fatigue G1 baseline		□								
Hydralazine allergy		□								
Oxycodone allergy		□								
Statin allergy		□								
Anemia- blood tx baseline		□								
Nasal congestion baseline- Sudafed, flonase		□								
enoxaparin		□								
Hydration C1D1-C1D3		□								
Hyperlipidemia baseline		□								
Hypertension baseline- HCTZ		□								
Renal stones baseline		□								
Peptic ulcer disease baseline		□								
Fluid overload		□								
Dry mouth		□								
Hearing changes		□								
		□								
		□								
		□								
		□								
		□								
		□								
		□								
		□								

Signature: _____ Date: _____

Adverse Events

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					Drug 1	Drug 2		Drug 1	Drug 2	
		□								

Signature: _____ Date: _____

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Clinical Research Support
CAPA Implementation Review Template

Corrective and Preventive Action Implementation Review for *(enter name of PI, program, or department implementing CAPA)*

Initial CAPA Date _____ **Review Date** _____ **Prior Review Date** _____ **Check here if final review** ☐

Instructions *(Remove before finalizing)**:***

- *Create an implementation review document for each set of corrective/preventive actions. Multiple events requiring the same actions may be addressed in a single assessment.*
- *Briefly summarize the event, corrective action, and preventive action from the original CAPA plan.*
- *Add lines to "next steps" as needed. Schedule further implementation review in "next steps" section if any actions or assessments are not complete.*
- *Check as "final review" if all actions and assessments are complete and there has been no recurrence of issue. If all actions and assessments are complete and the issue is not resolved, include development of a new CAPA plan as part of "next steps."*
- *Signatures: "Implementation review conducted by" includes all individuals involved with review assessment and determining next steps. "Implementation review approved by" must be signed by the PI.*

Issue/Event Summary	Corrective Action	Corrective Action Completed?
		☐ Yes (Date: _____) ☐ In progress ☐ No
Purpose(s) of Preventive Action	**Procedures/Tools Required for Preventive Action**	**Procedures/Tools Developed?**
		☐ Yes (Date: _____) ☐ In progress ☐ No

Preventive Action Status	Method(s) to Assess Preventive Action	Preventive Action Results
☐ Fully implemented with any necessary training completed and documented ☐ Implemented with training and/or further improvements continuing ☐ Implementation in progress ☐ Not yet implemented	☐ 100% source data or study data verification related to issue/event ☐ Partial source data or study data review related to issue/event ☐ No assessment method identified ☐ Other:	☐ No recurrence of issue/event to date ☐ Decrease in occurrence of issue/event ☐ Improved response to occurrences of issue/event (e.g., timely identification and reporting of events) ☐ No improvement observed upon assessment ☐ No assessment completed yet

Next Steps	Responsible Party	Anticipated Completion Date

Comments

Implementation review conducted by (add lines as needed):

Printed Name and Role	Signature	Date

Implementation review conducted by (add lines as needed):

Printed Name and Role	Signature	Date

Implementation review approved by:

Printed Name (Principal Investigator)	Signature	Date

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Corrective and Preventive Action Plan
Clinical Research Support Template

Corrective and Preventive Action Plan for *(enter name of PI, program, or department implementing CAPA)* **Dated** _____

Instructions *(Remove before finalizing)**:***

- *Create a separate table for each issue*
- *Group issues together that can be grouped together (e.g., documentation of training on different studies)*
- *Comments: Any comments you may have to further clarify the issue and the process surrounding the corrective/preventive actions.*
- *Conclusion/Signature: The PI is only required to sign once, at the end of the entire document. There should only be one conclusion section for the entire document (i.e., page 1 of 1, one signature and conclusion; page 1 of 5, one signature and conclusion).*

Issue/Event ***Issue that needs to be resolved***	**Root Cause** ***The underlying cause of the issue***

Corrective Action ***How immediate issue will be resolved***	**Preventive Action** ***How to keep the issue from reoccuring***	**Comments**

Conclusion *(follow-up action items, accountability, time frame for completing items/initiating process*):

Principal Investigator Signature

Date of Signature

Principal Investigator Printed Name

CORRECTIVE and PREVENTATIVE ACTIONS (CAPA) FORM

Section I

Identified Issue:

Section II

Causal Analysis:

Section III

Proposed Resolution(s):

Section IV

Final Root Causal Analysis

Issued Resolved On: _____
Continuing to be Reviewed: _____ Next Planned Assessment: _____

CORRECTIVE and PREVENTATIVE ACTIONS (CAPA) FORM

Section V
Members Required to Attend Retraining
Attach Attendance Sheet with Minutes

Documentation of Staff Retraining:

Section VI

Continual Process Improvement:

Event Reoccurrence:
Address reoccurrences and further preventative measures and retraining and process improvements.

Section VII

Investigator's Review or Corrective Action Plan and Acknowledgement of Continual Improvement:

_____ _____

Corrective Action Plan Preparer's Signature **Date of Signature**

_____ _____

Clinical Investigator's Signature **Date of Review and Approval**

Form Example - Completed CAPA

CLINICAL INVESTIGATOR'S CORRECTIVE ACTION RESOLUTION FORM

Protocol: ABC 479
CRC: R. Jackson

Investigator: A. Johnson
Date of Report: May 3, 2005

Section I

Identified Issue:
Subject NSM – 004 is a subject of child bearing potential and began study participation on December 13, 2004. During an ABC sponsor audit, Dr. Johnson was made aware that subject 004 did not have a screening pregnancy test completed.

Section II

Causal Analysis:
This incident is being reported on May 3, 2005 which is five (5) months after the pregnancy testing with no corrective action regarding the lack of a pregnancy test being documented. The issue has been noted in a monitoring follow-up letter dated March 17, 2005. There was no documentation on file that the IRB was informed of the deviation. Records were reviewed and end of the study pregnancy results indicated the subject was not pregnancy by urine testing. There was no documentation to indicate the employees involved were retrained or corrected on preventative measures. Review of this incident indicates that the lab requisition was not marked as childbearing potential/that a pregnancy test was requested.

Section III

Proposed Resolution(s):
Monitoring letters will be reviewed for all protocol deviations upon receipt to address corrective and preventative issues. Retraining of employees involved will be completed. CRCs will be responsible for issuing orders for all labs. All protocol deviations will be reported in a timely manner to the IRB. Subjects will be asked to return to the site for testing when critical testing is missed. Tracking of deviations will be instituted on a Protocol Tracking Log and maintained by the Clinical Research Director per study.

Section IV

Final Root Causal Analysis:
The lab requisition was not completed properly that led to subject 004 not have a screening serum pregnancy result.

Continuing to be Reviewed: May 3, 2005

Next Planned Assessment: May15, 2005

Section V

Documentation of Staff Retraining:
All clinical research team members were retrained on lab requisition procedures for completing lab test request, monitoring visit procedures, and reporting protocol deviations. The training was documented in each employee file. Signature sheet for attendees are attached.

Members Required to Attend Retraining
Attach Attendance Sheet with Minutes

Section VI

Continual Process Improvement:
Continual review will be completed to review each incoming monitoring letter for protocol deviation and significant performance study issue. Subject safety will continue to be reinforced at weekly staff meetings. Lab tests will only be scheduled as designed by the protocol by CRCs. Protocol deviations will be reviewed and tracked by the Clinical Research Director for root causal analysis for compliance concerns.

Event Reoccurrence:
Address reoccurrences and further preventative measures and retraining and process improvements.

Section VII

Clinical Investigator's Review or Corrective Action Plan and Acknowledgement of Continual Improvement:
I, Dr. Johnson, have read and agree with the CAPA plan and acknowledge my agreement to supervise and implement immediate corrective action to secure compliance. My staff was retrained on May 10, 2005 and I was in attendance to participate and receive retraining. We will again measures how we are progressing on May 15, 2005 and I will receive continue to review monitoring letters and compliance issues since this last occurrence to measure our compliance outcomes.

_____ _____
Clinical Investigator's Signature **Date of Review**

_____ _____
Corrective Action Plan Preparer's Signature **Date of Signature**

Issue Completion Tracking Log

Assessment Date: Reviewer(s): _____
Investigator: _____ Prepared By: _____ Date: _____

Protocol Number(s): _____

Corrective Action Review:

Clinical Research Director: _____ Date: _____

Clinical Investigator: _____ Date: _____

Observation(s)	Recommendation	Corrective Action	Completion Target Date	Responsible Person(s)	Completion Date

Documentation of Consenting Process

Study: (Sponsor) (Protocol #)

Principal Investigator:

Was the subject given ample time to review the consent documents?	☐ Yes ☐ No If no, please indicate reason in comments section	Comments: _____ _____ _____ _____	
Were all of the subject's questions answered prior to signing the consent documents?	☐ Yes ☐ No If no, please indicate reason in comments section	Comments: _____ _____ _____ _____	
Was the subject given a copy of the signed consent documents?	☐ Yes ☐ No If no, please indicate reason in comments section	Comments: _____ _____ _____ _____	
Were any study procedures performed prior to signing of the consent documents?	☐ Yes If yes, please indicate reason in comments section ☐ No ☐ Re-Consent	Comments: _____ _____ _____ _____	
Did the subject verbally acknowledge understanding of the consent discussion?	☐ Yes ☐ No If no, please indicate reason in comments section	Comments: _____ _____ _____ _____	
Does the subject agree to use two effective birth control measures throughout the duration of their participation in the study?	☐ Yes ☐ N/A If N/A, please explain ☐ Re-Consent	Subject is Female ☐ Prior Hysterectomy ☐ Prior Tubal Ligation ☐ Post Menopausal For More Than Two Years ☐ Other	Subject is Male ☐ Prior Vasectomy ☐ Other

List Staff Members Participating in the Informed Consent Discussion:

1. _____
2. _____
3. _____

☐ Re-Consent

☐ 2nd RC check_____

_____ _____

Signature of Investigator Obtaining Consent Date

PT.NO

NAME PLACE EPIC LABEL HERE

DOB

(Insert Program Information)

Signed Copy of Consent Document Submitted to Medical Records on _____ by _____

Documentation of Consenting Process

Study: (Sponsor) (Protocol #)

Principal Investigator:

PT.NO

NAME PLACE EPIC LABEL HERE

DOB

(Insert Program Information)

Signed Copy of Consent Document Submitted to Medical Records on _____ by _____

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Clinical Research Support Eligibility Checklist

Principal Investigator:		Sponsor:	
Protocol Number:		Sponsor Study #:	
Title or Brief Description:			
Subject ID:		Subject Initials:	

All subjects enrolled must meet eligibility criteria based on the inclusion/exclusion criteria detailed in the most current IRB-approved protocol and listed below. All subject files must include supporting documentation to confirm subject eligibility. This documentation may include, but is not limited to clinical summaries, physical exams, laboratory results, and radiology reports.

PROTOCOL VERSION: _____

Inclusion Criteria The subject is not eligible for the study if any inclusion criterion is checked **NO**.	**YES**	**NO**	**N/A**
1.	☐	☐	☐
2.	☐	☐	☐
3.	☐	☐	☐
4.	☐	☐	☐
5.	☐	☐	☐
6.	☐	☐	☐
7.	☐	☐	☐
8.	☐	☐	☐
9.	☐	☐	☐
10.	☐	☐	☐

Exclusion Criteria The subject is not eligible for the study if any exclusion criterion is checked **YES.**	**YES**	**NO**	**N/A**
1.	☐	☐	☐
2.	☐	☐	☐
3.	☐	☐	☐
4.	☐	☐	☐
5.	☐	☐	☐
6.	☐	☐	☐
7.	☐	☐	☐
8.	☐	☐	☐
9.	☐	☐	☐
10.	☐	☐	☐

Principal Investigator:		Sponsor:	
Protocol Number:		Sponsor Study #:	
Title or Brief Description:			
Subject ID:		Subject Initials:	

STATEMENT OF ELIGIBILITY:

I confirm that the information recorded above is true and correct.

This subject is: ☐ **Eligible** ☐ **Ineligible** for participation in the study

PERSON COMPLETING THE FORM		
PRINTED NAME	SIGNATURE	DATE
PI or MD REVIEW		
PRINTED NAME	SIGNATURE	DATE

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Clinical Research Support
ICF Discussion Documentation Form - INITIAL CONSENT

Person Consenting:		Consent Version:	
Protocol Number:		Subject Initials:	
Subject ID:			

Date Consent Obtained:	Time of Consent:

How was the informed consent discussion conducted? Check all that apply:
☐Oral discussion in private clinic/hospital/consult room ☐Telephone ☐Email

Subject was given adequate time to read and review the informed consent form?	☐Yes	☐No
The following was thoroughly explained to the subject, including but not limited to: • Purpose of the study • Possible risks and benefits • Other options to participation • Expected duration of treatment and procedures required • Costs of participation • Compensation and coverage for injury • Confidentiality • The ability to withdraw from the study at any time without penalty or loss of treatment or benefits • Contact information	☐Yes	☐No
The subject agrees to use birth control as required per protocol (if applicable)? ☐N/A	☐Yes	☐No
Subject agreed to discontinue any prohibited medications?	☐Yes	☐No
Any and all questions from the subject were answered prior to obtaining the subject's signature on the informed consent form?	☐Yes	☐No
Subject voluntarily signed their name in all applicable sections and included date (& time if required)?	☐Yes	☐No
Signed copy of the informed consent form provided to the subject and additional copy placed in the subject's clinical chart?	☐Yes	☐No
Informed consent form signed and dated (and all check boxes have been fully marked) by the subject prior to any study-specific procedures being performed?	☐Yes	☐No
Is the person consenting authorized to do so (e.g., delegated responsibility on the DOA log, and role described in IRB application)? Please note any unusual circumstances in the comments.	☐Yes	☐No
Any special circumstances regarding this consent discussion? (e.g., non-English speaking, LAR, etc.) If "yes" is checked, please note additional forms or procedures that were used and document in the comment section below.	☐Yes	☐No

Comments:

Signature of person obtaining consent

Signature Date

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Clinical Research Support
ICF Discussion Documentation Form - RE-CONSENT

Person Consenting:		Consent Version:	
Protocol Number:		Subject Initials:	
Subject ID:			

Date Re-consent Obtained:	Time of Re-consent:

How was the informed consent discussion conducted? Check all that apply:
☐Oral discussion in private clinic/hospital/consult room ☐Telephone ☐Email

Subject was given adequate time to read and review the revised informed consent form?	☐Yes	☐No
New information and changes as specified in the revised informed consent form were reviewed with the subject. See comments below for a detailed description.	☐Yes	☐No
The subject agrees to use birth control as required per protocol (if applicable)? ☐N/A	☐Yes	☐No
Any and all questions from the subject were answered prior to obtaining the subject's signature on the informed consent form?	☐Yes	☐No
Subject agreed to continue their participation in the study and voluntarily signed their name in all applicable sections and included date (& time if required)?	☐Yes	☐No
Signed copy of the revised informed consent form provided to the subject and additional copy placed in the subject's clinical chart?	☐Yes	☐No
Subject was re-consented prior to any study specific procedures being performed?	☐Yes	☐No
Is the person re-consenting authorized to do so (e.g., delegated responsibility on the DOA log, and role described in IRB application)? Please note any unusual circumstances in the comments.	☐Yes	☐No
Any special circumstances regarding this consent discussion? (e.g., non-English speaking, LAR, etc.) If yes is checked, please note additional forms or procedures that were used and document in the comment section below.	☐Yes	☐No

Comments:

Signature of person obtaining consent

Signature Date

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Clinical Research Support
Informed Consent Log

Principal Investigator:		Sponsor:	
Protocol Number:		Sponsor Study #:	
Title or Brief Description:			

Informed Consent								
Version #				v1	v2	v3	v4	v5
Version Date								
Consent Form Release Date								
IRB Approval Date								
Re-consent Instructions (e.g., all subjects, subjects on active tx, etc.)								
Subject ID	Subject Initials	Treatment Start Date	Treatment End Date	Date ICF Signed or N/A	Date ICF Signed or N/A	Date ICF Signed or N/A	Date ICF Signed or N/A	Date ICF Signed or N/A

INVESTIGATOR QUESTIONNAIRE

GCP Compliance

Investigator:
Compound/Protocol:
Monitor(s):
Center Number:
Auditor(s):
Audit Number:
Others Present:
Date of Interview:

Staff

1. Who carried out the study, what specific study procedures and other aspects of the study was each person responsible for and how was each person's involvement documented?
    a. Principal Investigator
    b. Research Nurse/Study Coordinator
    c. Pharmacist
    d. Other
2. Were there any changes in staff during the study?
3. How were the changes in PI/Sub-Investigators documented?
4. How was the sponsor notified?
5. How long has the investigator been conducting clinical trials?
6. Did you have any other studies running at the time of this study?

Responsibilities

1. Who determined the patient's overall eligibility?
2. Does the investigator (physician) see the patients at each visit?
3. If no, at what visits does he see the patients?

Ethical Committee/IRB

1. Who is responsible for the EC/IRB interaction?
2. What documents were submitted to the EC/IRB prior to the study start?
3. What documents were approved?
4. Were any of the following submitted and approved or receipt acknowledged?
    a. Protocol Amendments
    b. Modifications
    c. Consent Changes
    d. Safety Letters
5. Did the EC/IRB request that changes be made to any documents?
6. Do you have complete records of communication with the EC/IRB?
7. When is the EC/IRB re-approval required during the study?
8. When are EC/IRB progress reports required to the filed?
9. Were other approvals (e.g. hospital, pharmacy, regional, national) also required/obtained?

Recruitment

1. How were patients recruited?
2. Did you advertise?
3. Was the advertisement approved by the EC/IRB?
4. Were patients compensated for their participation including travel reimbursement?
5. Was the compensation approved by the EC/IRB?
6. Was the compensation included in the consent form?

Consent

1. What was the procedure for obtaining consent?
    a. Who/Where/When?
    b. What were patients told?
2. What written information was given to the patient?
3. Were patients given a copy of the signed consent?
4. In what language is the consent form?
5. Were translations necessary?
6. If oral consent was given, who would normally be the witness?
7. Were any consents signed by parents or guardians?

Facilities

1. Where in the facility were patients seen?
2. Were study visits limited to specific days?
3. Were any satellite locations used as part of this center?

Study Medication

1. Where were/are the drugs stored?
2. Who has access to the drugs?
3. Were written orders/prescriptions used?
4. Who dispensed (administered) the study medication?
5. What dispensing records were kept?
6. Who is responsible for keeping the records?
7. What happens/happened to unused supplies?
8. Who checked patient compliance? How?
9. What do you do if the patient does not return medication?

Adverse Events

1. Were there any serious adverse events during the study?
2. What was the reporting procedure (EC/IRB)?
3. Who determines whether or not the AE is related to the study drug?
4. Who determines if abnormal labs are related or not-related?
5. Was the blind broken at any time? If yes, why?

Labs

1. Who obtained blood samples? Other samples?

2. What laboratories performed analyses? Certifications on file?
3. When did you receive the results (verbal and reports)?
4. What action was taken regarding abnormal results?
5. Where are the lab specimens stored before picke up?
6. What arrangements do you have for lab courier pick up? Any problems?
7. How were pregnancy tests carried out (where necessary)?
8. Were any clinical tests performed by an outside service or lab?
9. How were the results reported?

Source Documentation

1. Do you maintain separate source documents for each patient?
2. Are these files/charts the only records you have for the patients? List others.
3. When are the SDs completed in relation to the visit?
4. Do you keep notes of telephone communications between the investigator/staff and patients?
5. Did patients complete a medical history form? If yes, is it in the chart?
6. Where are the history and physical exam findings recorded?
7. If a patient was hospitalized, what documentation from the hospital records is available?
8. Is there a key linking patient identification with study number?

Case Report Forms

1. Who completes the CRFs?
2. When is the CRF completed in relation to the visit?
3. What is completed first, the file/chart or the CRF?
4. Was any information entered directly into the CRF? What?
5. How frequently does the investigator review the CRFs?
6. When does the investigator sign the CRFs?

Patient Diaries

1. Who instructed the patients on the completion of the diary?
2. Who reviewed the completed diaries?
3. When were the diaries reviewed?
4. Was the patient present at the review?
5. What action was taken if errors or inconsistencies were found?
6. How were corrections made?

Interaction with the Sponsor

1. Who did the monitor routinely see during their visits?
2. Did you have any protocol exceptions (e.g. inclusion criteria, qualification to continue on study)?
3. Were the exceptions to the protocol approved before allowing the patients to continue?
4. Do you have documentation of approvals?

Documentation Retention

1. Where do you (or did you) keep the study documents during the study?
2. How long must you keep the source data, CRFs and other study documentation after the study is over?
3. Where will the archived data be stored?
4. What happens to the patient records if the patient dies or leaves the clinic/practice?
5. What happens to your archived study records if you leave the hospital/practice?

Withdrawals

1. Did any patients withdraw from the study? Why?
2. How do you follow-up withdrawn patients?

General

1. Were there any study procedures that presented problems?
2. Were there any other problem areas?

ITHS Research Resources

Consent Form Version Log

Principal Investigator:	
Study Title / Number:	

Consent Document Description	Consent Form Version Date	IRB Submission Date	IRB Stamp-Approval Date	Date Received from IRB	Replaces Previous Version?*

*If the consent form replaces a previous version, list the previous version's IRB stamp-approval date.

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Accelerating Research. Improving Health.

Regulatory Visit
Regulatory Documents Checklist

Researcher Name	
Project Title	

Document Type	**Description**
☐ **Investigator's brochure/package insert** ☐ N/A	This document contains a collection of all relevant information known prior to the start-up of a particular clinical trial and includes pre-clinical data (chemical, pharmaceutical, and toxicological); pharmacokinetic and pharmacodynamic data in animals and man; and the results of earlier clinical trials. [ICH GCP E6 8.2.1, 8.3.1]
REVIEW NOTES:	
☐ **Form FDA-1572** ☐ N/A	This form is required for clinical research studies involving drugs or devices regulated by the FDA and is the investigator's agreement to perform the study according to applicable federal regulations. [ICH GCP E6 8.2.6, 8.3.4]
REVIEW NOTES:	
☐ **Form FDA-1571** ☐ N/A	This form is the cover sheet for investigator-sponsored IND applications as well as the cover sheet for all subsequent correspondence to the FDA concerning the investigator-sponsored IND such as annual progress reports, safety reports, modifications etc. Form FDA 1571 is not required for INDs sponsored by a pharmaceutical company. [ICH GCP E6 8.2.6, 8.3.4]
REVIEW NOTES:	
☐ **Protocol and CRFs**	A copy of the IRB-approved protocol and sample CRFs should be kept in this section. If the protocol/CRFs are modified throughout the course of the study, a copy of each subsequently approved protocol version should be added to the file and maintained in chronological order. [ICH GCP E6 8.2.2, 8.3.2, 8.3.3]
REVIEW NOTES:	
☐ **IRB Research Application, Modifications, Continuing Review Reports, and IRB correspondence**	A copy of the IRB-approved research application, modifications, continuing review reports, close-out report, and correspondence with the IRB should be kept in this section maintained in chronological order. [ICH GCP E6 8.2.7, 8.3.3, 8.3.19, 8.4.7; 21 CFR 312.66]
REVIEW NOTES:	
☐ **Consent form(s), recruitment materials, and HIPAA authorization forms**	All versions of consent form(s), recruitment materials, HIPAA authorization forms, and any other written information approved by the IRB to be provided to participants should be filed in this section. If there are modifications to the consent form(s), the originals should be accurately dated and maintained in chronological order. Careful attention must be given to this process so that subjects are given the correct version of the consent form when they are enrolled into the study. [ICH GCP E6 8.2.3, 8.3.2]
REVIEW NOTES:	
☐ **IRB roster**	A copy of the IRB roster should be kept in this section to document that the IRB is constituted in accordance with regulatory requirements. [ICH GCP E6 8.2.8]
REVIEW NOTES:	
☐ **Screening, enrollment, and participant ID logs**	These logs should list all people who signed the consent form and were screened to participate in the study (screening), those who met eligibility criteria and were enrolled (enrollment), and who were assigned a participant code (participant ID). In cases where the person was determined to be ineligible at screening, the reason for the subject's ineligibility should be recorded on the screening log. [ICH GCP E6 8.3.20-22, 8.4.3]

REVIEW NOTES:	
☐ **AEs, SAEs, Protocol Deviations, and Other Reports** ☐ N/A	Copies of all correspondence necessary to document any agreements or significant discussions regarding study conduct, protocol deviations, adverse events (AEs and SAEs), and other reports should be maintained in this section. All documentation pertinent to adverse events and participant-specific protocol deviations should be filed in this section as well as in the individual participant's research record. [ICH GCP E6 8.3.11, 5.18.4.l; 21 CFR 312.66]
REVIEW NOTES:	
☐ **Study Product Accountability** ☐ N/A	The study product accountability records must include: • Copies of labels (sample) to document compliance with applicable labeling regulations and appropriateness of instructions provided to participants • Instructions for study product handling to document proper storage, packaging, dispensing and disposition of study product and study-related materials • Shipping records to document shipment dates, batch numbers, and method of shipment of study product and study-related materials. Allows tracking of product batch, review of shipping conditions, and accountability • Certification of analysis of shipped product to document identity, purity, and strength of strength of study product • Process for documenting how, in case of an emergency, identity of blinded study product can be revealed without breaking the blind for the remaining participants' treatment, and any decoding that occurs during the study • Master randomization log to document method for randomization of participants • Documentation that study product was used according to the protocol • Documentation that accounts for the receipt of study product at the site, dispensation of product to participants, product returned to the site by participants, and product returned to sponsor/manufacturer • Documentation that accounts for the destruction of unused study product by site or sponsor These records may be kept in another location during the active study period. At the conclusion of the study, the records should be placed in this section of the regulatory file. [ICH GCP E6 8.2.13-18, 8.3.8-9, 8.3.23, 8.4.1-2, 8.4.5]
REVIEW NOTES:	
☐ **Sponsor Correspondence** ☐ N/A	All correspondence between the sponsor and researcher pertaining to the conduct of the study should be included in this section, including site initiation and close-out visit reports and all sponsor/external monitoring visit/audit correspondence. [ICH GCP E6 8.2.19-20, 8.3.10, 8.4.4-5]
REVIEW NOTES:	☐ **Monitors to sign in/out of monitoring log**
☐ **Laboratory Certification** ☐ N/A	Copies of current laboratory certifications for all labs involved with the study should be included in this section to document competence of facility to perform required test(s) and support reliability of results. As the certifications expire, they must be replaced with the updated copies. [ICH GCP E6 8.2.12, 8.3.7]
REVIEW NOTES:	
☐ **Range of Normal Values** ☐ N/A	If blood work is required, the range of normal values for the laboratory performing the analyses must be included in this section to document normal values and/or ranges of the tests. This may be part of the protocol. [ICH GCP E6 8.2.11, 8.3.6]
REVIEW NOTES:	
☐ **Signature List**	This is a list of all members of the research team. It designates each person's responsibility and who has authority to enter, delete, or change data. It should consist of each person's printed name as well as their signature. [ICH GCP 8.3.24, 5.18.4.h]
REVIEW NOTES:	
☐ **Investigators'**	The qualifications of the researcher as well as the other members of the research team are required to be documented. This includes physicians, nurses, research assistants, research coordinators, and other staff

CVs	responsible for working with research subjects and/or their information and/or samples. [ICH GCP E6 8.2.10, 8.3.5]
REVIEW NOTES:	

FRED HUTCH
UNIVERSITY OF WASHINGTON
CANCER CONSORTIUM

Clinical Research Support
Principal Investigator Oversight Meeting Log

Principal Investigator:		Sponsor:	
Protocol Number:		Sponsor Study #:	
Title or Brief Description:			

The purpose of this log is to document study relevant meetings held with the Principal Investigator (PI) to review study status, adverse events (AEs), lab results, and other protocol related issues.

Date of Discussion	Topics Discussed	Research Staff Name	Research Staff Signature	PI Initials/ Date
Example: 12/24/14	*Example: Quality & Compliance team meeting (see minutes attached)*	*Example: Quality & Compliance Team*	*Example: Q&C rep (one sig)*	
Example: 1/1/15	*Example: UW14048 Adverse Events*	*Example: Stephanie Porter, CRC*		

Principal Investigator Signature: _____ Date: _____

- Adverse Events Log*
- CAPA Plan – Template*
- CAPA Template – HANDOUT
- CAPA Implementation Review – Template*
- Documentation of Consenting Process Checklist*
- Eligibility Checklist*
- ICF Discussion Documentation Form – Initial Consent*
- ICF Discussion Documentation Form – Re-Consent*
- Informed Consent Log*
- Investigator Questionnaire for the Purpose of Audit Preparation
- ITHS Research Resources-Consent Form Version Log
- ITHS Self QA Regulatory Documents Checklist
- Investigator & Staff Database (Conditionally Formatted Excel Spreadsheet)
- PI Oversight Meeting Log*

**Indicates that template can be customized and/or reformatted to fit your program's artwork*