Quality Assurance for the Research Team:

Connecting Day-to-Day Operations to a Regulatory Framework

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Objectives

- By applying a regulatory framework to your daily research agenda:
  - Learn how to operate under SOPs
    - Discern which regulations apply to which studies
    - Write and work with your SOPs
  - Learn how to build solid organizational systems
    - Case Study: Regulatory binder
  - Learn how to be rigorous about self-QA
    - Case Study: Consent SOP

SOPs

- Which regulations apply to my research?
- What are SOPs?
- What SOPs do I need?
- How do I work with my SOPs?

Which regulations apply to my research?

- **All studies**
  - **GCPs**, sections 4, 6 and 8 http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf
  - **OHRP Guidance** for Investigators http://www.hhs.gov/ohrp/policy/index.html
  - **OHRP Regulations** ("The Common Rule," 45 CFR 46 - standards for IRB review) http://www.hhs.gov/ohrp/humansubjects/index.html
  - **HIPAA Guidance** for Research http://privacyruleandresearch.nih.gov/clin_research.asp
  - **HIPAA Regulations** for Research ("The Privacy Rule," 45 CFR 164.508) http://edocket.access.gpo.gov/cfr_2010/octqtr/45cfr164.508.htm

Which regulations apply to my research?

- **Drug/Product Intervention Studies**
  - **FDA Guidance** for Investigators http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm113709.htm
  - **FDA Regulations** (21 CFR 50, 54, 56, 312) http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm
- **Device studies**
  - **FDA Guidance** on Medical Devices http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm
  - **FDA Regulations** (21 CFR 50, 54, 56, 812, 820) http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm

What are SOPs?

- Standard Operating Procedures:
  - The **procedures** and processes that people **operate** under, which are **standardized** to ensure things are done the same way each time.
  - Detailed, written instructions to achieve uniformity of the performance of a specific function. (ICH GCPs)
  - General processes common to running all studies
- Why do I need SOPs?
  - Ensures usability of data through compliance
  - Creates efficiency
  - Useful for training

What SOPs do I need?

Examples

1. IRB Review: Initial, Amendments, and Continuing Review
2. Protocol Compliance
3. Recruitment
4. Informed Consent Process
5. Regulatory Recordkeeping
6. Unanticipated Problems, Protocol Deviations, and Adverse Events
7. Study Closure
8. FDA Inspections: Preparation, On-Site, and Post-Inspection
9. Writing, Approving and Revising SOPs

How do I work with my SOPs?

- Beginning:
  - Find and revise institutional templates
    - Versions and dates
  - Train yourself and staff
    - Document
- Ongoing
  - Reference often
    - They can't help you if you don't use them.
  - Annual review
    - Revise
    - Retrain and document

Building a solid organizational system

Case Study: Regulatory Binder

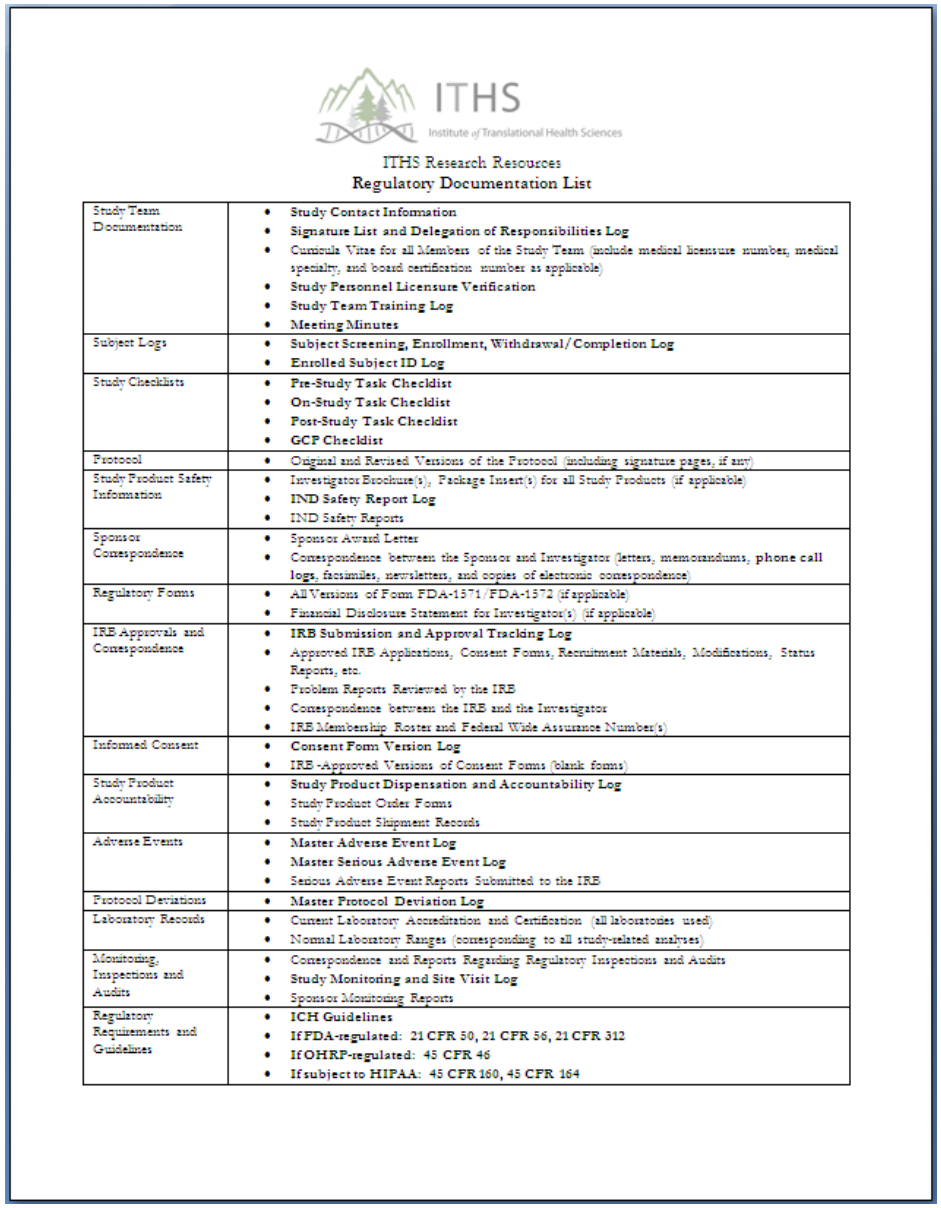
- What is a Regulatory Binder?
  - An organizational system for maintaining all study-related documents
- Why do I need it?
  - Efficiency
    - Compile all study-related documentation in one place
  - Ease of access
    - Resource to retrieve study information
  - Regulatory compliance
    - Ensure compliance with federal and local departments (FDA, HHS, OHRP, IRB) and sponsor (NIH, industry)

Regulatory Binder

- Sample forms online
  - http://www.iths.org/forms

Regulatory binder forms

- Regulatory Binder Contents Checklist
- Study Contact Information
- Signature List and Delegation of Responsibilities Log
- Study Personnel Licensure Verification
- Study Team Training Log
- Meeting Minutes
- Subject Screening Enrollment Withdrawal Completion Log
- Subject ID Log
- IND Safety Report Log
- Phone Call Log
- IRB Submission and Approval Tracking Log
- Consent Form Version Log
- Study Product Dispensation and Accountability Log
- Master Adverse Event Log
- Master Serious Adverse Event Log
- Protocol Deviation Log
- Study Monitoring and Site Visit Log



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Regulatory Documentation List

Study Team Documentation	• **Study Contact Information** • **Signature List and Delegation of Responsibilities Log** • Curricula Vitae for all Members of the Study Team (include medical licensure number, medical specialty, and board certification number as applicable) • **Study Personnel Licensure Verification** • **Study Team Training Log** • **Meeting Minutes**
Subject Logs	• **Subject Screening, Enrollment, Withdrawal/Completion Log** • **Enrolled Subject ID Log**
Study Checklists	• **Pre-Study Task Checklist** • **On-Study Task Checklist** • **Post-Study Task Checklist** • **GCP Checklist**
Protocol	• Original and Revised Versions of the Protocol (including signature pages, if any)
Study Product Safety Information	• Investigator Brochure(s), Package Insert(s) for all Study Products (if applicable) • **IND Safety Report Log** • IND Safety Reports
Sponsor Correspondence	• Sponsor Award Letter • Correspondence between the Sponsor and Investigator (letters, memorandums, phone call logs, facsimiles, newsletters, and copies of electronic correspondence)
Regulatory Forms	• All Versions of Form FDA-1571/FDA-1572 (if applicable) • Financial Disclosure Statement for Investigator(s) (if applicable)
IRB Approvals and Correspondence	• **IRB Submission and Approval Tracking Log** • Approved IRB Applications, Consent Forms, Recruitment Materials, Modifications, Status Reports, etc. • Problem Reports Reviewed by the IRB • Correspondence between the IRB and the Investigator • IRB Membership Roster and Federal Wide Assurance Number(s)
Informed Consent	• **Consent Form Version Log** • IRB-Approved Versions of Consent Forms (blank forms)
Study Product Accountability	• **Study Product Dispensation and Accountability Log** • Study Product Order Forms • Study Product Shipment Records
Adverse Events	• **Master Adverse Event Log** • **Master Serious Adverse Event Log** • Serious Adverse Event Reports Submitted to the IRB
Protocol Deviations	• **Master Protocol Deviation Log**
Laboratory Records	• Current Laboratory Accreditation and Certification (all laboratories used) • Normal Laboratory Ranges (corresponding to all study-related analyses)
Monitoring, Inspections and Audits	• Correspondence and Reports Regarding Regulatory Inspections and Audits • **Study Monitoring and Site Visit Log** • Sponsor Monitoring Reports
Regulatory Requirements and Guidelines	• **ICH Guidelines** • **If FDA-regulated: 21 CFR 50, 21 CFR 56, 21 CFR 312** • **If OHRP-regulated: 45 CFR 46** • **If subject to HIPAA: 45 CFR 160, 45 CFR 164**

Regulatory Documentation List

Table of contents

Name of Study

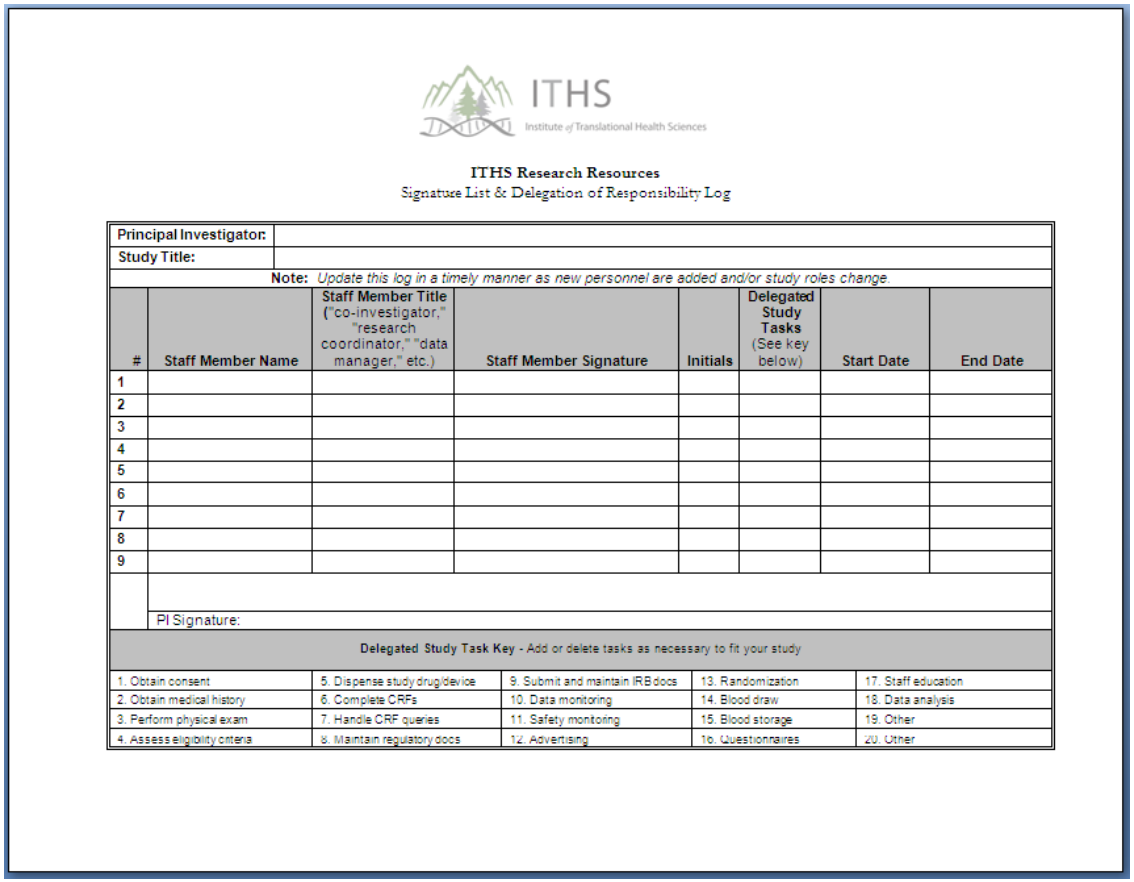
Contact Information

Name	Telephone	Email

Resource	Telephone	Email
24-hour emergency telephone number	206-___ _____	
UWMC Paging	206 598-6190	
UWMC-IDS	206 598-6054	idssam@u.washington.edu
Research Lab Services	206 616-8979	rts@u.washington.edu
UWMC Lab	206 598-6224	lodoran@u.washington.edu
IRB Administator	206 543-0098	
	IRB Approval 07/01/2009 through 06/30/2010 Current consent form date: 07/22/2009	
AAA#/Budget #:		

Study Contact Information

- Be sure to keep it updated as staff change



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Signature List & Delegation of Responsibility Log

Principal Investigator:	
Study Title:	

Note: *Update this log in a timely manner as new personnel are added and/or study roles change.*

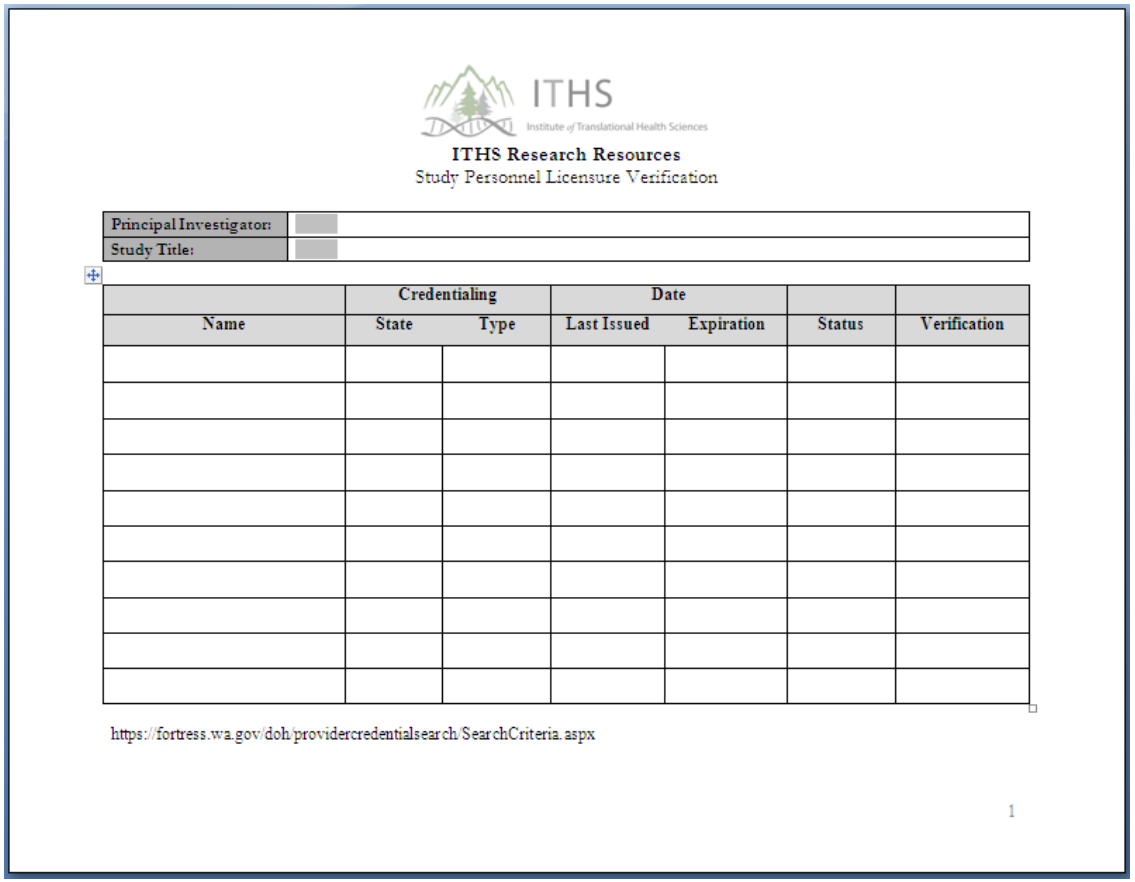
#	Staff Member Name	Staff Member Title ("co-investigator," "research coordinator," "data manager," etc.)	Staff Member Signature	Initials	Delegated Study Tasks (See key below)	Start Date	End Date
1							
2							
3							
4							
5							
6							
7							
8							
9							
	PI Signature:						

Delegated Study Task Key - Add or delete tasks as necessary to fit your study

1. Obtain consent	5. Dispense study drug/device	9. Submit and maintain IRB docs	13. Randomization	17. Staff education
2. Obtain medical history	6. Complete CRFs	10. Data monitoring	14. Blood draw	18. Data analysis
3. Perform physical exam	7. Handle CRF queries	11. Safety monitoring	15. Blood storage	19. Other
4. Assess eligibility criteria	8. Maintain regulatory docs	12. Advertising	16. Questionnaires	20. Other

Signature List and Delegation of Responsibilities Log

- Ultimately, the Principal Investigator (i.e., you) are 100% responsible for the study
- You can't *usually* do it all yourself, so this is the form that documents how you will delegate responsibilities that you will not do yourself
- Again, be sure to update it as staff and responsibilities change



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Study Personnel Licensure Verification

Principal Investigator:	
Study Title:	

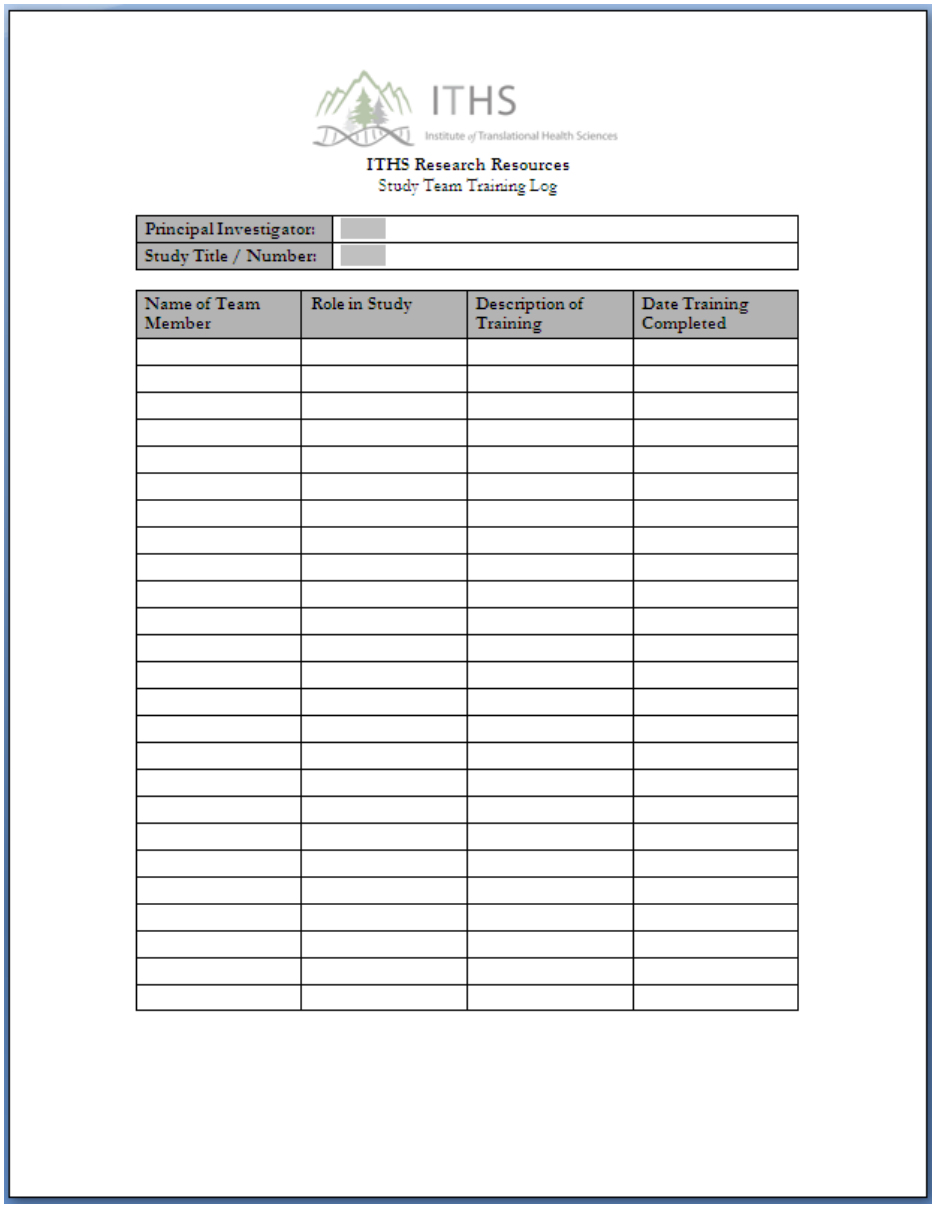
	Credentialing		Date			
Name	State	Type	Last Issued	Expiration	Status	Verification

https://fortress.wa.gov/doh/providercredentialsearch/SearchCriteria.aspx

1

Study Personnel Licensure Verification

- If the study procedures require credentialed staff, there must be documentation that staff have been properly credentialed.
- Keep this list for staff members who will be delegated responsibilities for which credentialing is required (like MDs, NDs, RNs, PharmDs, etc.)
- Again, be sure to update it as staff change



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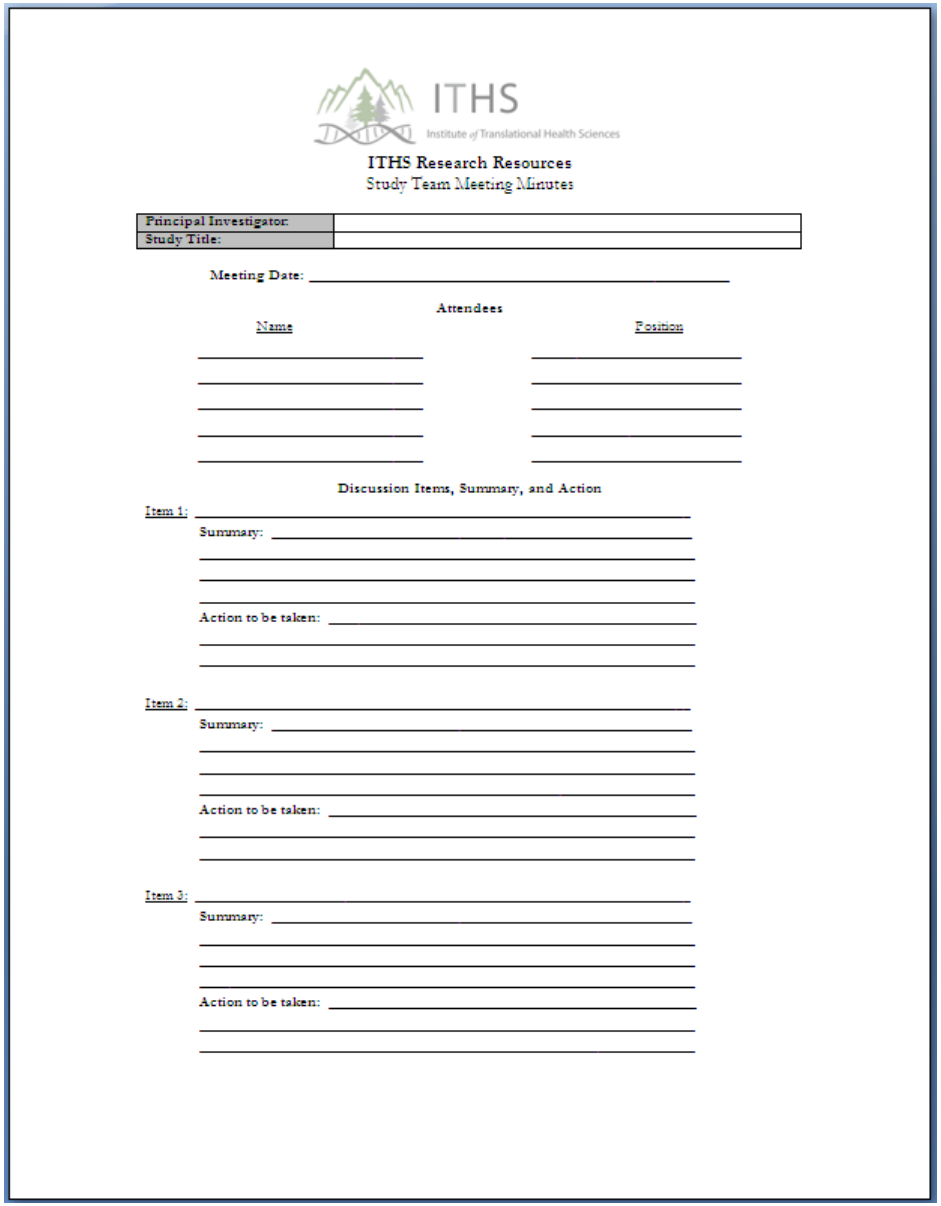
Study Team Training Log

Principal Investigator:	
Study Title / Number:	

Name of Team Member	Role in Study	Description of Training	Date Training Completed

Study Team Training Log

- This log documents the completion of staff training as it relates to delegation of responsibilities from the PI to staff



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Study Team Meeting Minutes

Principal Investigator:	
Study Title:	

Meeting Date: _____

Attendees

Name	Position
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

Discussion Items, Summary, and Action

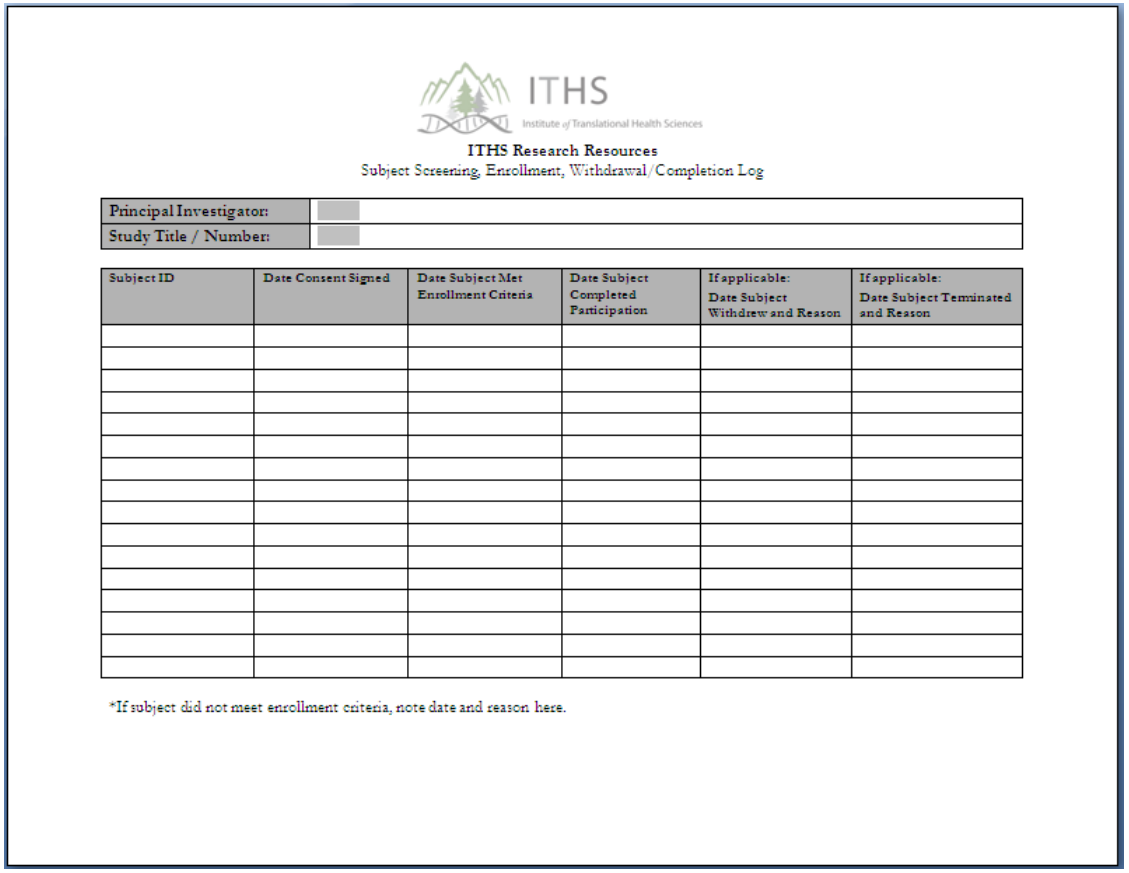
Item 1: _____
Summary: _____
_____
_____
_____
Action to be taken: _____
_____
_____

Item 2: _____
Summary: _____
_____
_____
_____
Action to be taken: _____
_____
_____

Item 3: _____
Summary: _____
_____
_____
_____
Action to be taken: _____
_____
_____

Study Team Meeting Minutes

- A template to document the discussions at team meetings



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Subject Screening, Enrollment, Withdrawal/Completion Log

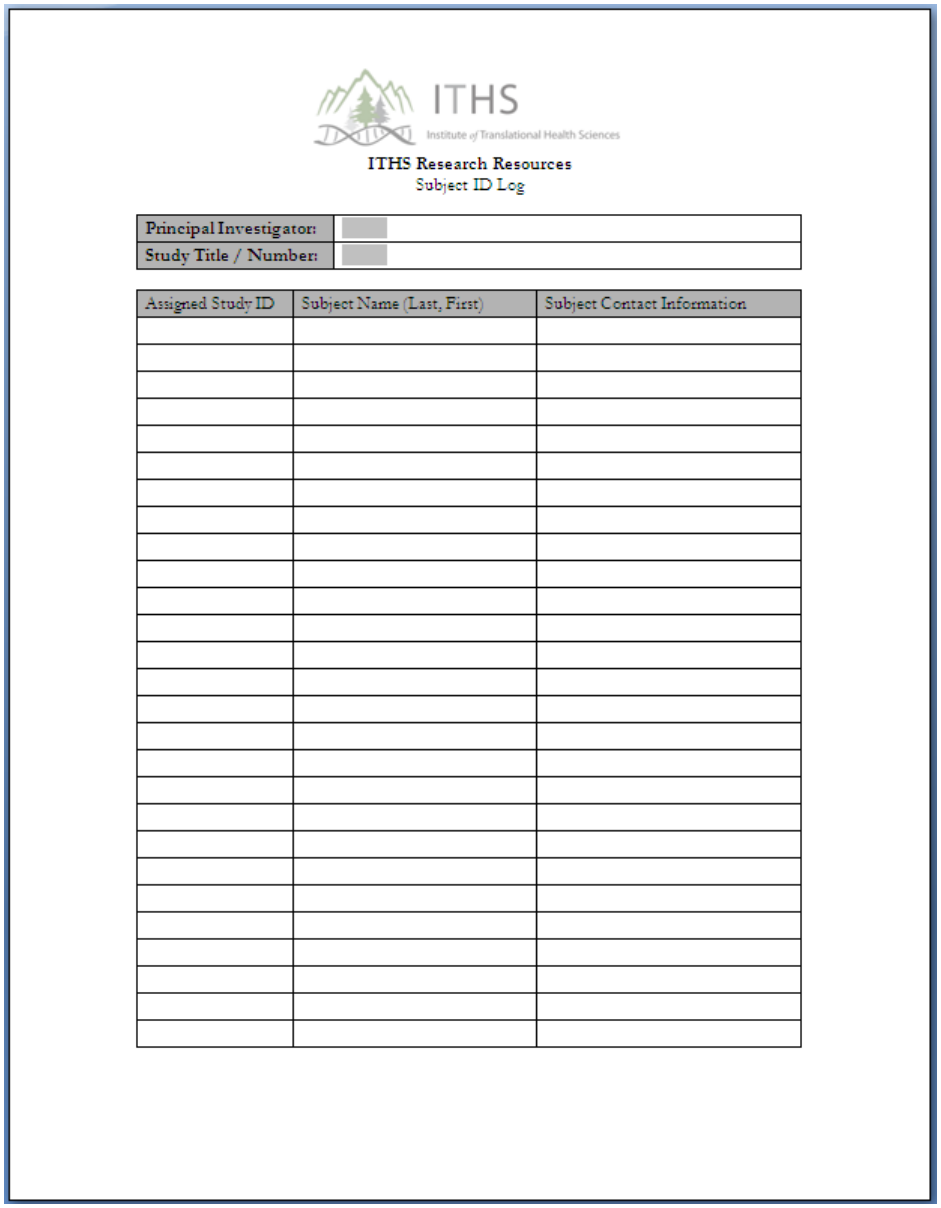
Principal Investigator:	
Study Title / Number:	

Subject ID	Date Consent Signed	Date Subject Met Enrollment Criteria	Date Subject Completed Participation	If applicable: Date Subject Withdrew and Reason	If applicable: Date Subject Terminated and Reason

*If subject did not meet enrollment criteria, note date and reason here.

Screening, Enrollment, Withdrawal, and Completion Log

- This type of log works best as an Excel spreadsheet for a larger study
- It can be maintained electronically but printed in preparation for a monitoring visit



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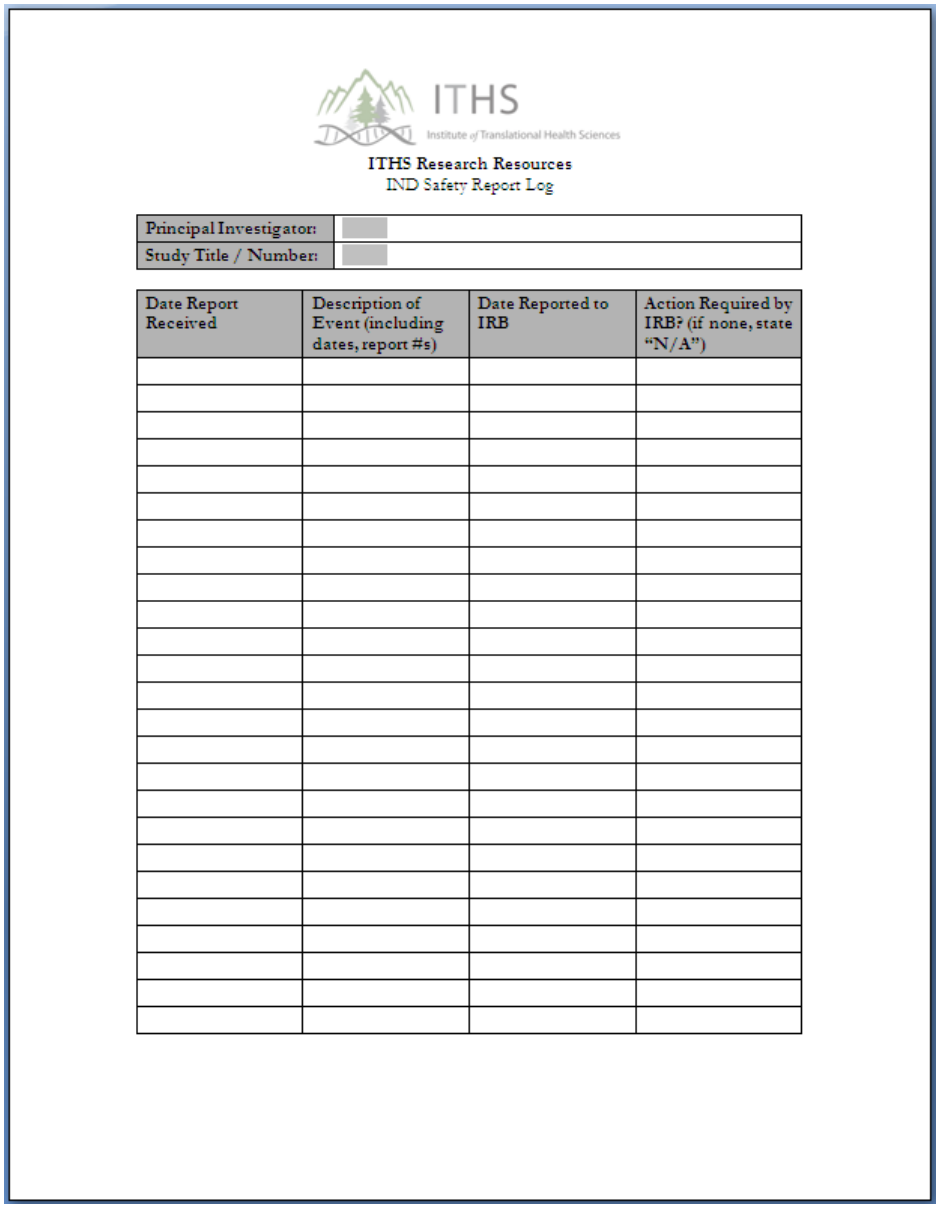
Subject ID Log

Principal Investigator:	
Study Title / Number:	

Assigned Study ID	Subject Name (Last, First)	Subject Contact Information

Subject ID Log

- It should NOT be kept in the Regulatory Binder, but in a separate, secured place as specified in the IRB application
- It should be readily accessible to the members of the study team who need it, as specified in the IRB application



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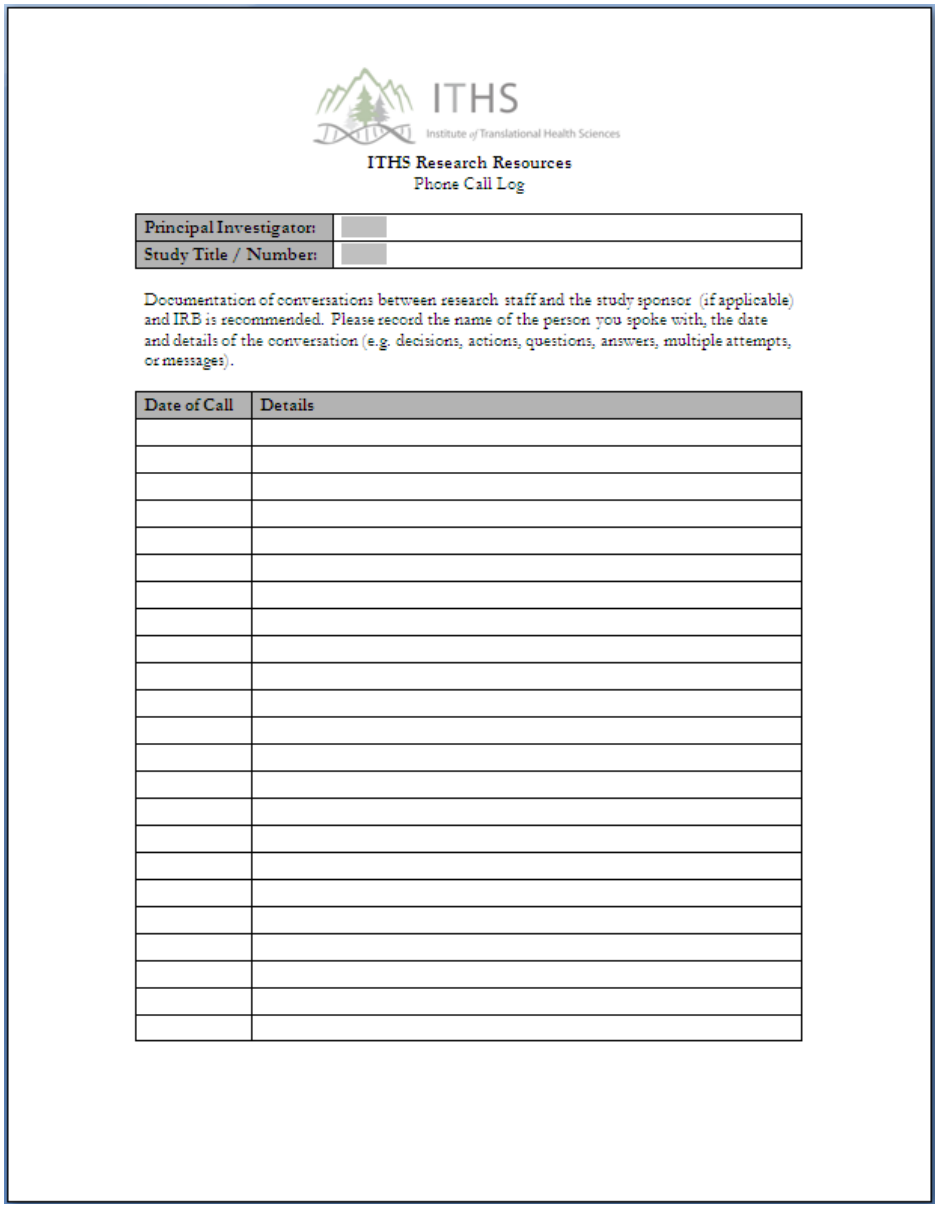
IND Safety Report Log

Principal Investigator:	
Study Title / Number:	

Date Report Received	Description of Event (including dates, report #s)	Date Reported to IRB	Action Required by IRB? (if none, state "N/A")

IND Safety Report Log

- If you are doing an FDA-regulated study with an Investigational New Drug (IND), this log can help you keep track of receipt and reporting of the IND Safety Reports
- Best as an Excel spreadsheet



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Phone Call Log

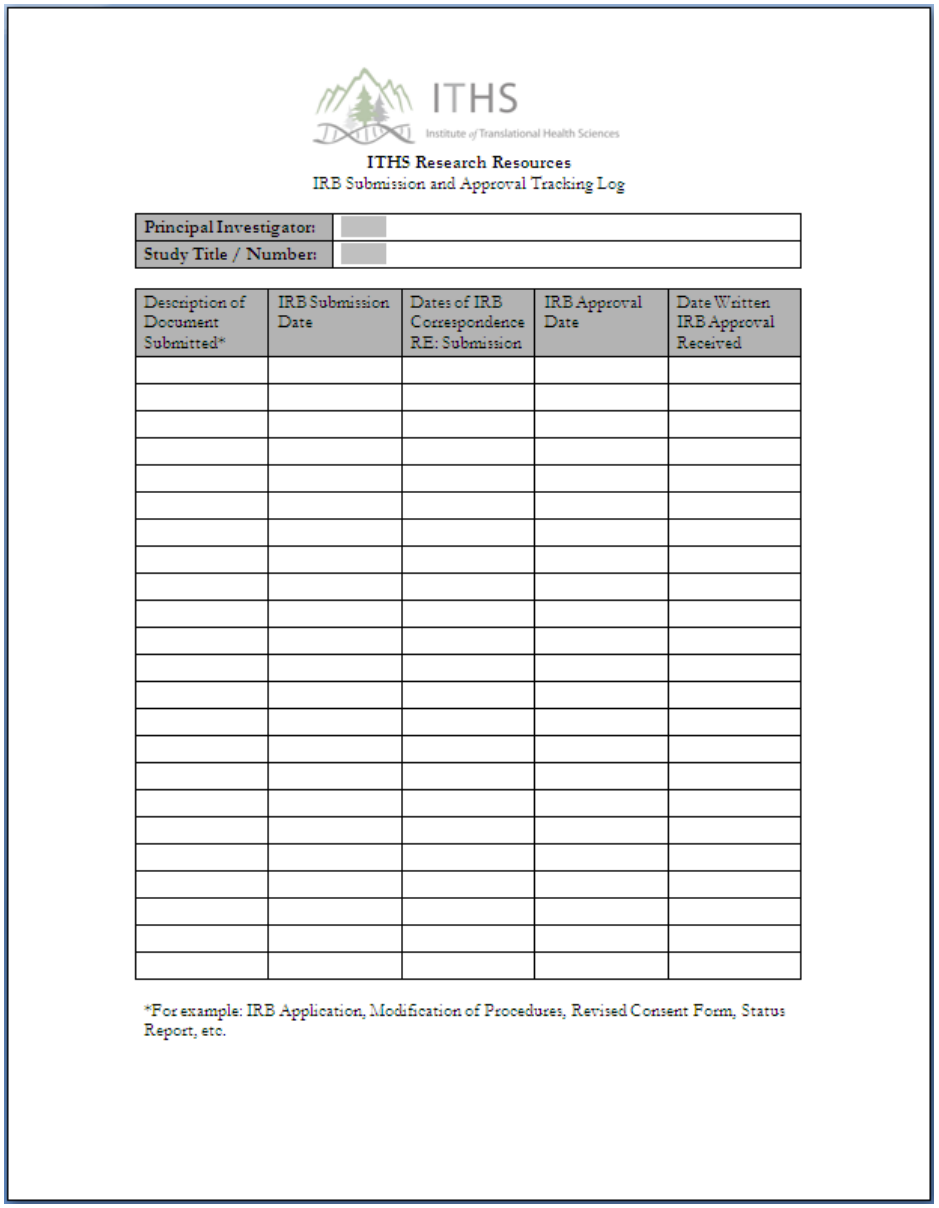
Principal Investigator:	
Study Title / Number:	

Documentation of conversations between research staff and the study sponsor (if applicable) and IRB is recommended. Please record the name of the person you spoke with, the date and details of the conversation (e.g. decisions, actions, questions, answers, multiple attempts, or messages).

Date of Call	Details

Phone call log

- A template to document significant conversations might be with the NIH or other funding agency/sponsor, the IRB, FDA/OHRP, or institutional personnel
- It can be maintained electronically but printed in preparation for a monitoring visit



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IRB Submission and Approval Tracking Log

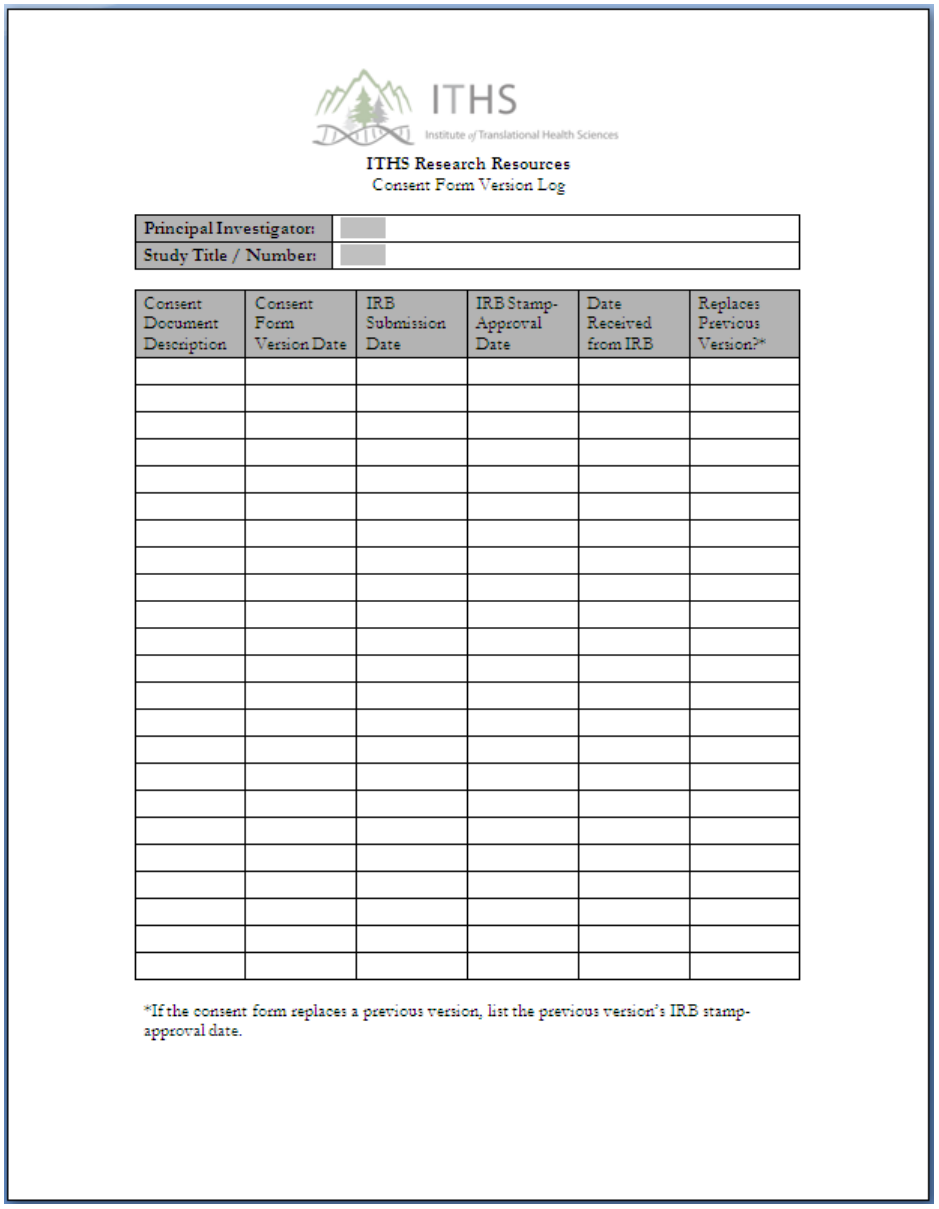
Principal Investigator:	
Study Title / Number:	

Description of Document Submitted*	IRB Submission Date	Dates of IRB Correspondence RE: Submission	IRB Approval Date	Date Written IRB Approval Received

*For example: IRB Application, Modification of Procedures, Revised Consent Form, Status Report, etc.

IRB Submission and Approval Log

- This works best as an Excel spreadsheet that can be printed in preparation for a monitoring visit



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Consent Form Version Log

Principal Investigator:	
Study Title / Number:	

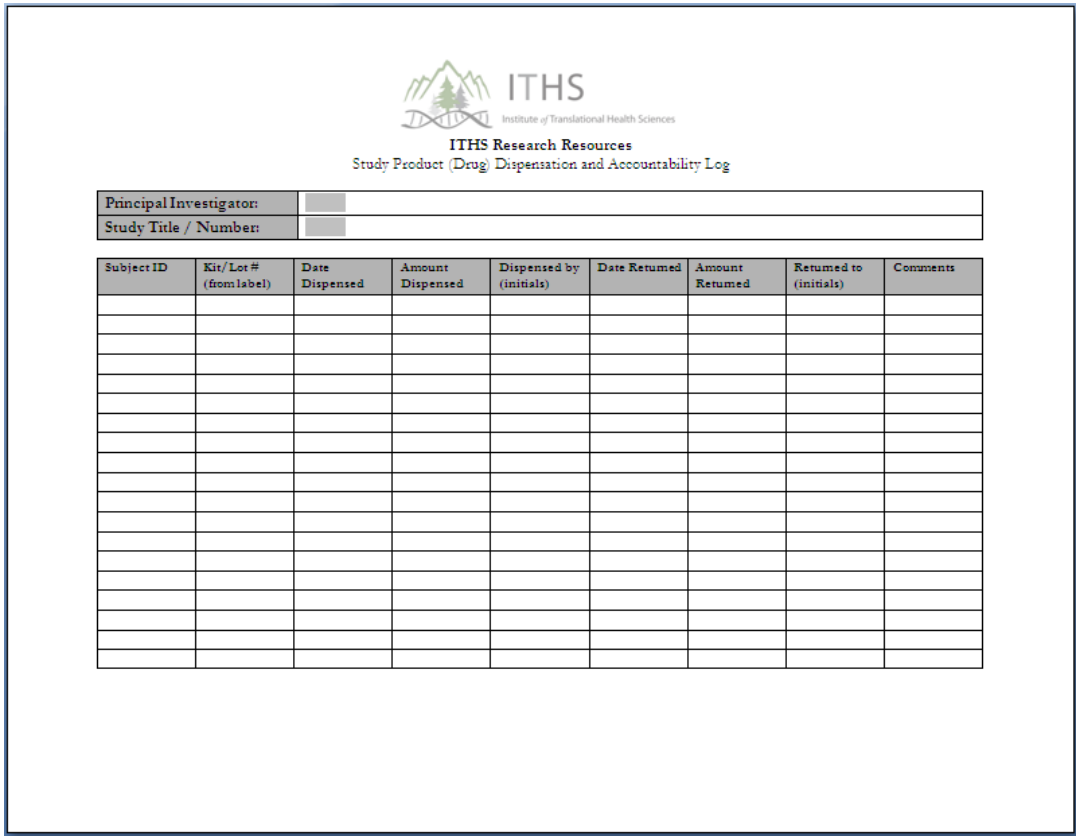
Consent Document Description	Consent Form Version Date	IRB Submission Date	IRB Stamp-Approval Date	Date Received from IRB	Replaces Previous Version?*

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

Consent Form Version Log

- Like the IRB tracking log, this consent version log captures time-specific information on IRB approval status for consent forms
- It may only be necessary to use one of the two logs

Study Product Dispensation and Accountability Log



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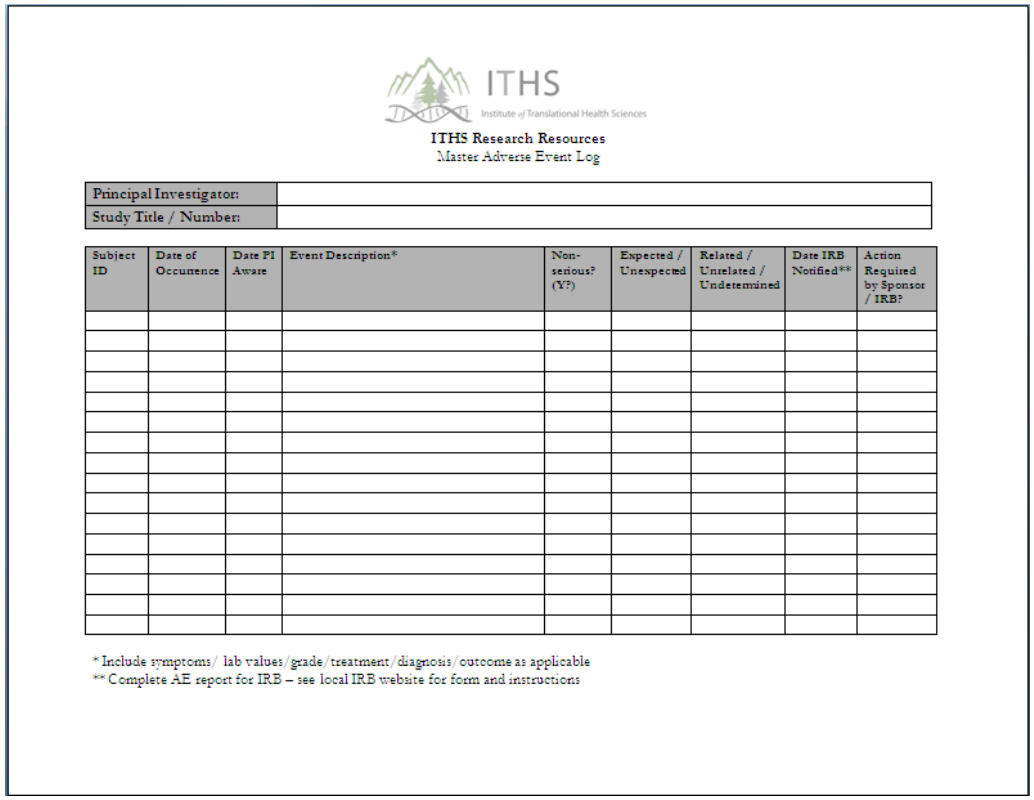
Study Product (Drug) Dispensation and Accountability Log

Principal Investigator:	
Study Title / Number:	

Subject ID	Kit/Lot # (from label)	Date Dispensed	Amount Dispensed	Dispensed by (initials)	Date Returned	Amount Returned	Returned to (initials)	Comments

- If you are administering drugs, devices, supplements, etc. during your study, you are responsible for maintaining detailed records of the use of study product
- This log works best as an Excel spreadsheet and can be printed in preparation for a monitoring visit

Master AE Log



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Master Adverse Event Log

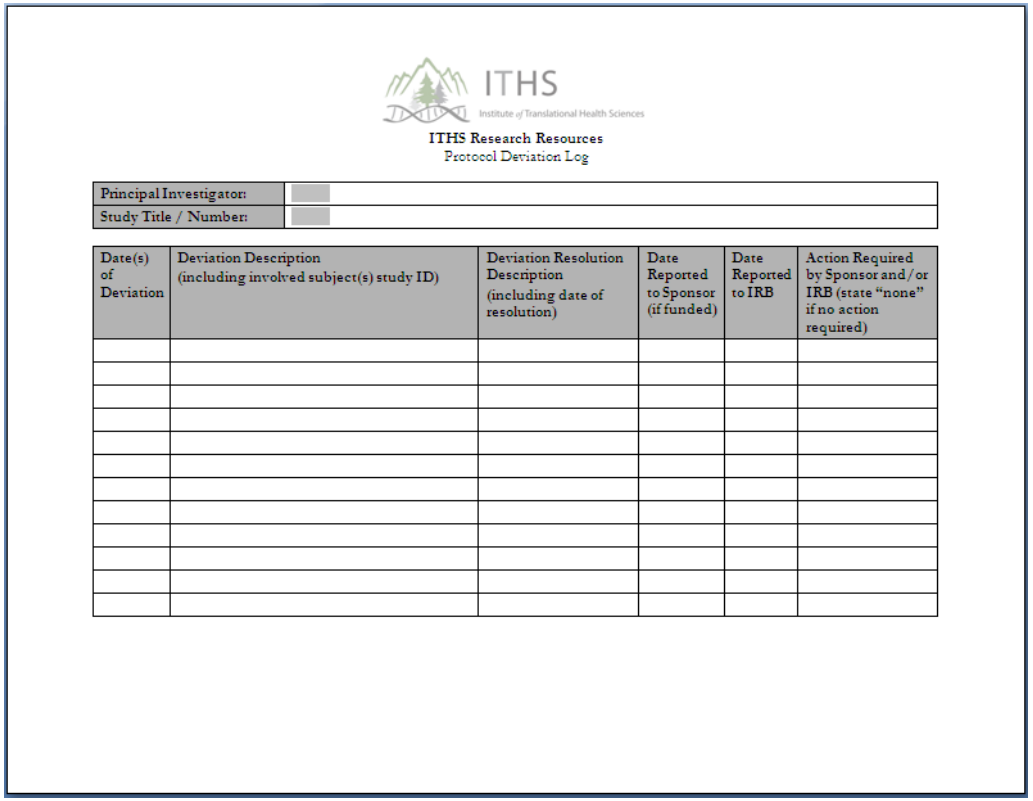
Principal Investigator:	
Study Title / Number:	

Subject ID	Date of Occurrence	Date PI Aware	Event Description*	Non-serious? (Y?)	Expected / Unexpected	Related / Unrelated / Undetermined	Date IRB Notified**	Action Required by Sponsor / IRB?

*Include symptoms/ lab values/grade/treatment/diagnosis/outcome as applicable
**Complete AE report for IRB – see local IRB website for form and instructions

- AEs are always maintained in the participant's individual study record, but there should also be a master AE log where all AEs reported for the entire study are documented as a group
- Some (not all) IRBs require reporting of all AEs annually
- This log works best as an Excel spreadsheet and can be printed in preparation for a monitoring visit

Protocol Deviation Log



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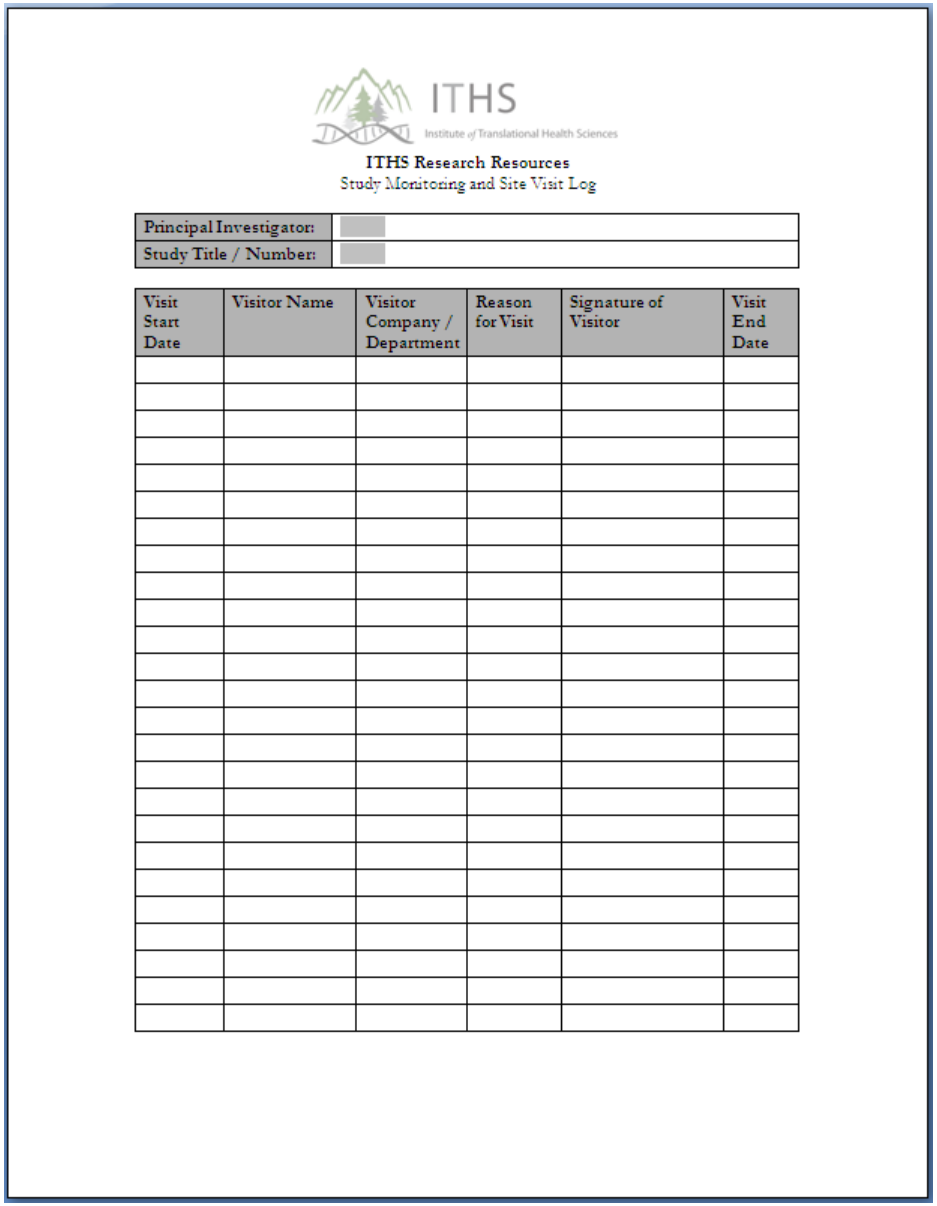
Protocol Deviation Log

Principal Investigator:	
Study Title / Number:	

Date(s) of Deviation	Deviation Description (including involved subject(s) study ID)	Deviation Resolution Description (including date of resolution)	Date Reported to Sponsor (if funded)	Date Reported to IRB	Action Required by Sponsor and/or IRB (state "none" if no action required)

- You should maintain records of all protocol deviations, their resolution and IRB reporting status
- Protocol deviations related to individual participants may be included as a Note to File in the participants' study record, but there should also be a master protocol deviation log where all deviations are recorded for the study as a whole
- Some (not all) IRBs require reporting of protocol deviations annually
- This log works best as an Excel spreadsheet and can be printed in preparation for a monitoring visit



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Study Monitoring and Site Visit Log

Principal Investigator:	
Study Title / Number:	

Visit Start Date	Visitor Name	Visitor Company / Department	Reason for Visit	Signature of Visitor	Visit End Date

Study Monitoring and Site Visit Log

- When a monitor reviews the study, you should have them sign in and out as a record of their visit
- Depending on the results of their review, they may or may not provide a report back to you documenting their visit (they are less likely to if there were no issues noted)
- This can be a problem if there is documentation they had scheduled a visit but issued no report, as it makes it look like you lost the report

Tips for maintaining a Regulatory Binder

- Make a “key” to your filing system for reference
  - Guidance to the Reg Binder SOP
- File new/updated documents as soon as received
- De-identify any participant information
- Keep all versions of documents (protocol, consent, recruitment)
- Know the record retention period for your study and institution/facility

  UW: http://f2.washington.edu/fm/recmgt/retentionschedules/gs/general/uwgs7

  FHCRC: http://www.hvtn.org/events/daidsstorage.html

  Seattle Childrens: Policy ORF-003 Advance Activities (sponsored research), 21 CFR 312.62, 21 CFR 812.140, and any contractual obligations with the sponsor.

Be rigorous about self-QA

Case study – Consent SOP

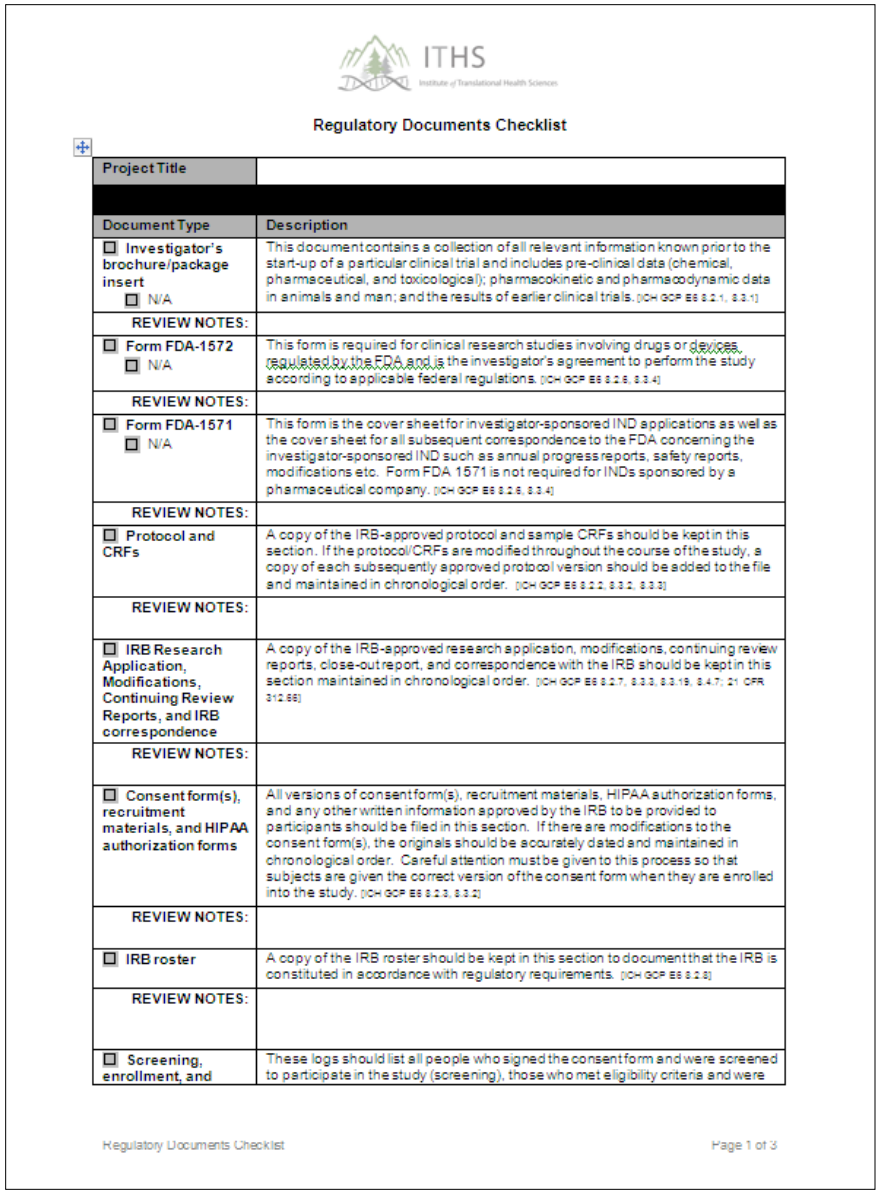
- What is self-QA?
  - Ongoing internal review process to promote successful, streamlined operations
    - Audit of internal recordkeeping practices
    - Systematic way to identify, correct and prevent errors
- Why should I do self-QA?
  - Catch errors early
  - Look for trends in errors and address them systemically
  - Maintain regulatory compliance
  - Maintain data integrity
  - Protect your participants

What do I need for self-QA?

- Sample forms online
  - https://www.iths.org/forms
    - Self-Audit - Regulatory Documents Checklist
    - Self-Audit - Participant Records Checklist

OR

- Build QA into your SOPs



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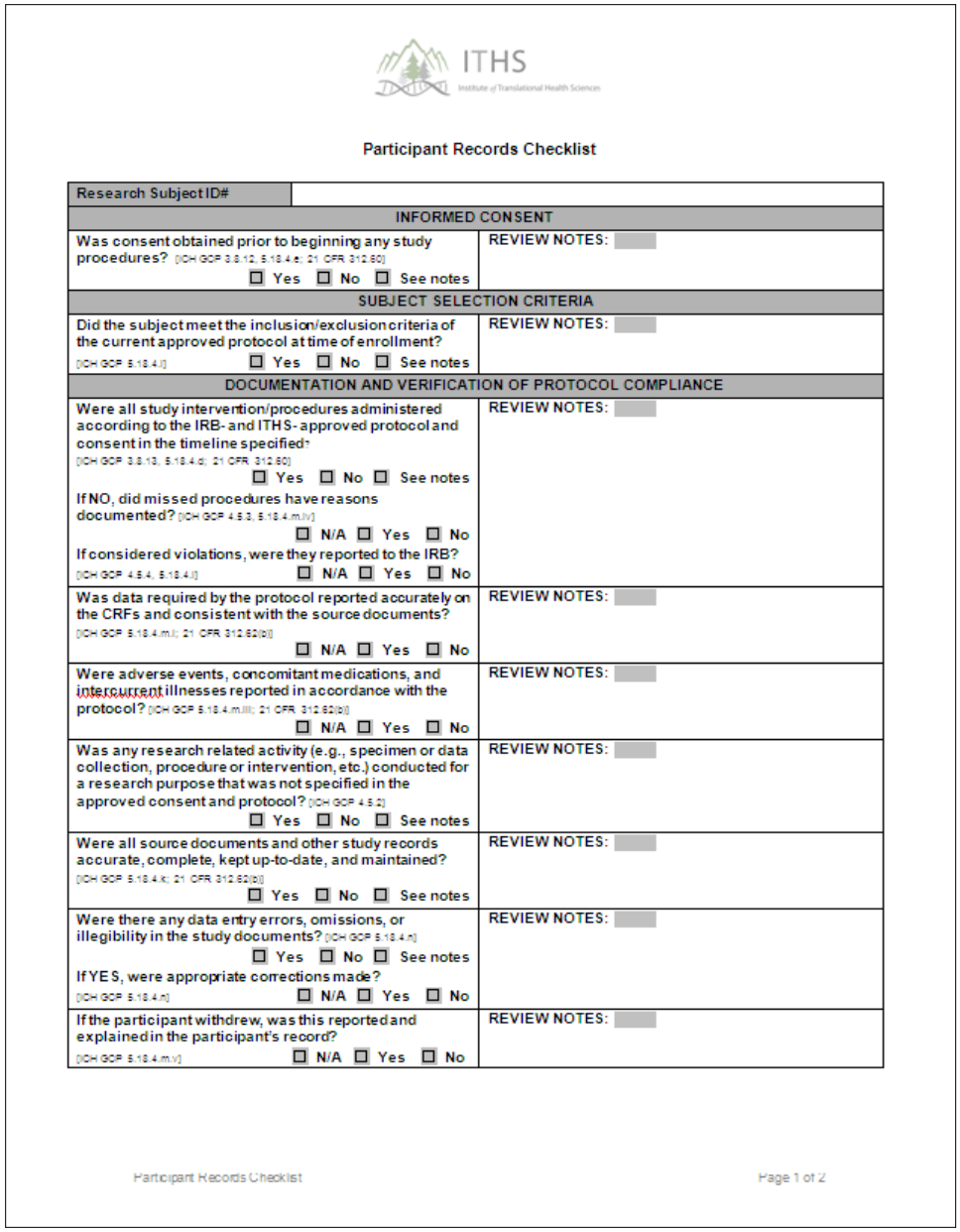
Regulatory Documents Checklist

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**	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

Regulatory Documents Checklist Page 1 of 3

Regulatory Documents Checklist

- Double check your regulatory binder and records at least annually (and in advance of any monitoring or inspection visit)



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Participant Records Checklist

Research Subject ID#	
INFORMED CONSENT	
Was consent obtained prior to beginning any study procedures? [ICH GCP 3.8.12, 5.18.4.e; 21 CFR 312.60] ☐ Yes ☐ No ☐ See notes	REVIEW NOTES:
SUBJECT SELECTION CRITERIA	
Did the subject meet the inclusion/exclusion criteria of the current approved protocol at time of enrollment? [ICH GCP 5.18.4.f] ☐ Yes ☐ No ☐ See notes	REVIEW NOTES:
DOCUMENTATION AND VERIFICATION OF PROTOCOL COMPLIANCE	
Were all study intervention/procedures administered according to the IRB- and ITHS-approved protocol and consent in the timeline specified? [ICH GCP 3.8.13, 5.18.4.d; 21 CFR 312.60] ☐ Yes ☐ No ☐ See notes If NO, did missed procedures have reasons documented? [ICH GCP 4.5.3, 5.18.4.m.iv] ☐ N/A ☐ Yes ☐ No If considered violations, were they reported to the IRB? [ICH GCP 4.5.4, 5.18.4.l] ☐ N/A ☐ Yes ☐ No	REVIEW NOTES:
Was data required by the protocol reported accurately on the CRFs and consistent with the source documents? [ICH GCP 5.18.4.m.i; 21 CFR 312.62(b)] ☐ N/A ☐ Yes ☐ No	REVIEW NOTES:
Were adverse events, concomitant medications, and intercurrent illnesses reported in accordance with the protocol? [ICH GCP 5.18.4.m.iii; 21 CFR 312.62(b)] ☐ N/A ☐ Yes ☐ No	REVIEW NOTES:
Was any research related activity (e.g., specimen or data collection, procedure or intervention, etc.) conducted for a research purpose that was not specified in the approved consent and protocol? [ICH GCP 4.5.2] ☐ Yes ☐ No ☐ See notes	REVIEW NOTES:
Were all source documents and other study records accurate, complete, kept up-to-date, and maintained? [ICH GCP 5.18.4.k; 21 CFR 312.62(b)] ☐ Yes ☐ No ☐ See notes	REVIEW NOTES:
Were there any data entry errors, omissions, or illegibility in the study documents? [ICH GCP 5.18.4.n] ☐ Yes ☐ No ☐ See notes If YES, were appropriate corrections made? [ICH GCP 5.18.4.n] ☐ N/A ☐ Yes ☐ No	REVIEW NOTES:
If the participant withdrew, was this reported and explained in the participant's record? [ICH GCP 5.18.4.m.v] ☐ N/A ☐ Yes ☐ No	REVIEW NOTES:

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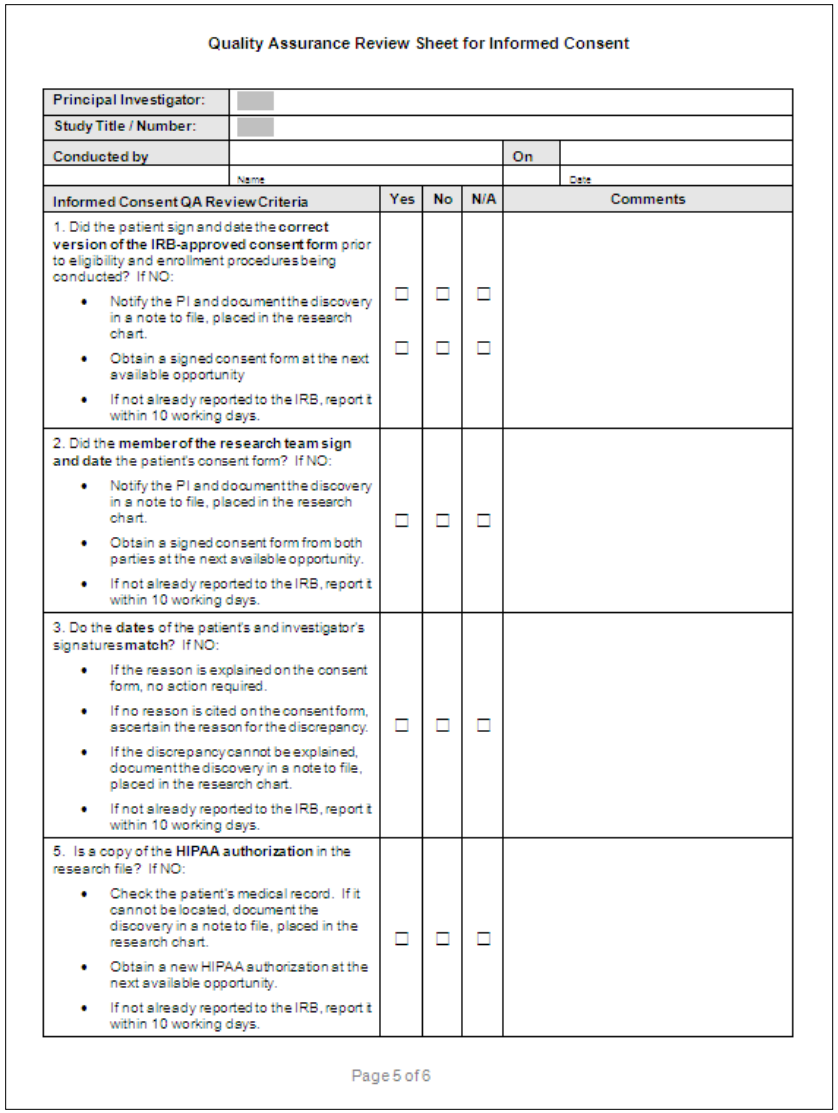
- Double check a percentage of your participant records at least annually (and in advance of any monitoring or inspection visit)
- If there are discrepancies, report them to the IRB/sponsor, document resolution of issues with Notes to File



Quality Assurance Review Sheet for Informed Consent

Principal Investigator:				
Study Title / Number:				
Conducted by			**On**	
	Name			Date
Informed Consent QA Review Criteria	**Yes**	**No**	**N/A**	**Comments**
1. Did the patient sign and date the **correct version of the IRB-approved consent form** prior to eligibility and enrollment procedures being conducted? If NO: • Notify the PI and document the discovery in a note to file, placed in the research chart. • Obtain a signed consent form at the next available opportunity • If not already reported to the IRB, report it within 10 working days.	☐ ☐	☐ ☐	☐ ☐	
2. Did the **member of the research team sign and date** the patient's consent form? If NO: • Notify the PI and document the discovery in a note to file, placed in the research chart. • Obtain a signed consent form from both parties at the next available opportunity. • If not already reported to the IRB, report it within 10 working days.	☐	☐	☐	
3. Do the **dates** of the patient's and investigator's signatures **match**? If NO: • If the reason is explained on the consent form, no action required. • If no reason is cited on the consent form, ascertain the reason for the discrepancy. • If the discrepancy cannot be explained, document the discovery in a note to file, placed in the research chart. • If not already reported to the IRB, report it within 10 working days.	☐	☐	☐	
5. Is a copy of the **HIPAA authorization** in the research file? If NO: • Check the patient's medical record. If it cannot be located, document the discovery in a note to file, placed in the research chart. • Obtain a new HIPAA authorization at the next available opportunity. • If not already reported to the IRB, report it within 10 working days.	☐	☐	☐	

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QA process in the SOPs

- Summarize your QA steps within your SOPs

4. Quality Assurance

a. After the first 10% of patients are enrolled and annually thereafter, a member of the research team not directly involved in daily operations for the study completes a periodic internal review of compliance with the SOP and IRB-approved informed consent procedures for all enrolled participants in the study. The member of the research staff will use the "Quality Assurance Review Sheet for Informed Consent" to conduct the review.

b. The member of research team provides the completed Quality Assurance Review Sheet for Informed Consent to the <<Research Administrator, PI>> for review and determination if immediate corrective actions and long-range process improvements are necessary.

c. If necessary, the team notifies the IRB of any problems identified through the review within ten working days.

Tips for self-QA

- Self-QA for highest impact issues
  - Informed consent
  - Eligibility
  - Adverse events
  - Study product accounting
- Stick to it!
  - Choose a schedule that is easy to follow
  - Choose a reasonable volume (25% vs. 100%)
  - Divide responsibilities equally amongst staff

Summary

Reference regulations and guidance often!

Connect your daily work with the regulations to

- Operate your research program under SOPs
- Create solid organizational systems for your regulatory documents
- Be rigorous about self-QA

These actions ensure the validity and publish-ability of your data (which leads to future funding for more!)

Questions?