



Research Program Coordinator Orientation

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TOPICS

RESEARCH COORDINATOR TRAINING
NOTICE OF AWARD
STUDY COORDINATION
TRACKING
REGULATORY BINDER
STANDARD OPERATING PROCEDURES
DATA COLLECTION
RECRUITMENT & RETENTION
PARTICIPANT COMMUNICATION
BUDGET MONITORING
INCENTIVES
RESOURCES
CERTIFICATION
CAREER PROGRESSION



COORDINATOR TRAINING

- Complete IRB Human Subjects compliance modules (on the IRB homepage; training link on left menu) Bookmark IRB page
- Attend the eIRB 101 course (eIRB homepage; training link on left menu; eIRB training)
- Good Clinical Practice (GCP) Training -- (IRB homepage; training link on left menu)
- Fundamentals of Research Coordination
(<https://learn.nursing.jhu.edu/face-to-face/courses/research-coordinator/>)
- Introduction to Clinical Research (Intermediate to Advanced course)
https://ictr.johnshopkins.edu/study_team/training-education/introduction-to-clinical-research-summer-course/



THE GRANT HAS BEEN FUNDED

- PI Receives the Notice of Award
- Read the grant
- Draft SOP's based on grant application sections: recruitment, intervention, data collection (the grant describes **what** you're going to do; the SOP's describe **how** you're going to do it – who, what, where, when, how, with what)



STUDY COORDINATION

- Create basic file folders; grant, recruitment, data, intervention, manuscripts, articles, IRB, sponsor, SOP's, Regulatory Binder, study instruments
- Obtain names of the key players to arrange the weekly Study Team meeting (Teams Board, Zoom)
- Arrange quarterly meetings with you, the PI and Budget Analyst. Ask Sr. GCA to explain the monthly statement to you; spending limits; types of supplies ok'd for purchasing
- Ask the Business Office about options for purchasing supplies, services and participant incentives needed to carry out the study
- Order supplies/services for recruitment, intervention, data collection
- With assistance of the PI and study team, begin fine tuning SOPs drafts. If using technology, take screenshots for the operations manual
- Create a manual of operations and procedures using the SOPs
- The PI may want your assistance with the IRB application. Forms such as eForm A, consents, telephone scripts can be found on the IRB website, forms link.
https://www.hopkinsmedicine.org/institutional_review_board/forms/



TRACKING (Milestones and IRB Actions)

Milestones

Activity	Date	Notes
Notice of Award		
Funding End		
IRB Approval		
Clinical Trials Approval	2/26/2020	NCT 04286568
Hire Staff		
Recruitment began		
Recruitment ended		
First subject consented		
Intervention began		
Intervention ended		
Date last intervention delivered for primary outcome		
DSMB meeting(s)		

IRB Actions

	A	B	D	E	F	
1	Sponsor:					
2	Principal Investigator:					
3	Study Title:					
4	IRB number:					
5	This protocol expires:					
6						
7						
8	Date Submitted	Action Requested	Forms Submitted	Description of Action	Approval Date	Expiration
9	1/26/2017	Change in Research	flyer, consent, eform	Participant age range, flyer, consent, eformA	Approval Letter 4/18/17	
10	4/25/2017	Change in Research	consent forms e form	Change to study team members: John doe. 3 revised consent forms, revised eFormA	Approval Letter 5/25/17	
11	12/17/2018	Change in Research	consent, eform	Study Team member change, revised consent, revised eFormA 2/11/19. Passport to Freedom 2 P2F2 - eForm A, Consent Form; eligibility includes previous history of incarceration	Approval Letter 3/25/2019	
12	6/17/2019	Change in Research	eform, consent		Approval Letter 8/6/2019	
13	9/11/2019	Continuing Review	summary		Approval Letter 11/13/2018	11/5/2019
14	10/17/2017	Continuing Review	summary		Approval Letter 12/4/17	
15						

Training Study team member

	trained staff on data collection
	trained staff on recruitment
	trained on consenting
	Human subjects certification
	trained on delivering intervention
	telephone script
	nursing license



TRACKING

SOURCE DOCUMENT

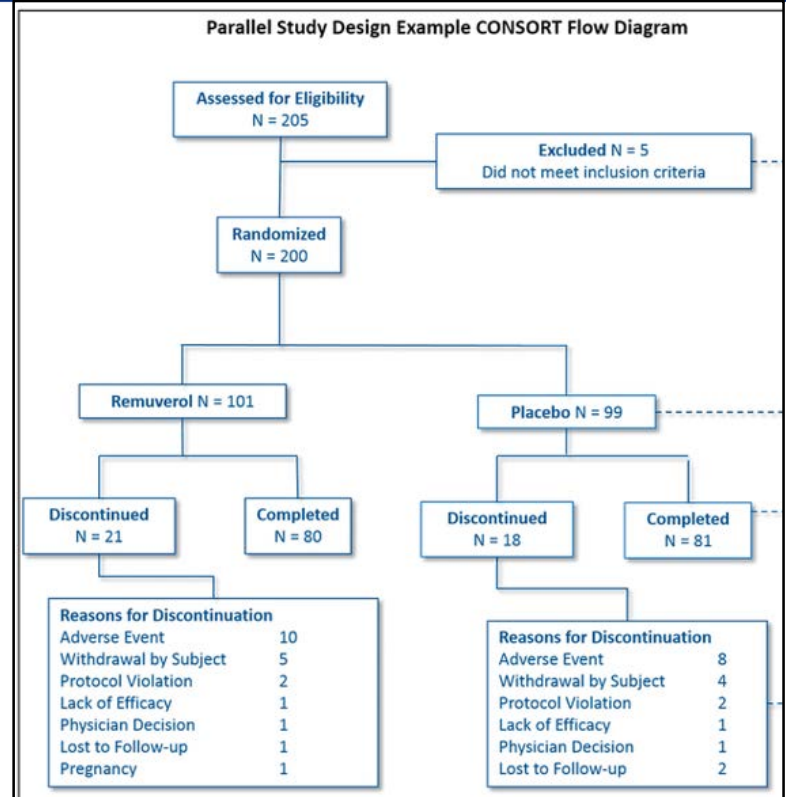
- Used to record all participant communications. Create a table/form for each participant. Should be shared on a platform like OneDrive so that it can be updated by study team members.
 - Name
 - Date
 - Nature of communication; when calling about data collection, record the data collection time point

TRACKING

RECRUITMENT TRACKING

Some of the categories below will be important for IRB reporting, clinical Trials reporting and paper writing, and consort flow diagram

- Assessed for Eligibility/Screened
- Recruitment Source
- Excluded/Ineligible (why)
- Randomized (if applicable)
- Number randomized to each group (if applicable)
- Intervention dates for each subject
- Number completed intervention
- Number discontinued after randomization





TRACKING

Manuscript Table
Study Name

Manuscript Table >

	Article Title (Submitted & Planned)	Journal (& backup)	Article, Abstract or Manuscript.	Status: Accepted, In Review Pending	Date of Conference, Presentation or Manuscript	Lead & Co-Authors
1	Xxx	MATERNAL AND CHILD HEALTH	Abstract ID#			Author(s):
2	Xxx	FAMILY VIOLENCE PREVENTION CAUCUS	Abstract ID# (password:			
3	xxx	MATERNAL AND CHILD HEALTH	Abstract ID# (password:			Author(s):
4		PUBLIC HEALTH NURSING	Abstract ID# (password:			

Protocol Number: _____ Sample Location: _____

PI: _____

Title: _____


Specimen Collection >

	Date Specimen obtained:	Time Sample Obtained	Date/Time Logged	Specimen type	Subject Initials	Subject #	Quantity		
1									
2									
3									



TRACKING

Protocol Deviation- used to record minor departures from the protocol such as missed study visits; consent issues;

 <p>FORM R.F.4: PROTOCOL DEVIATION SUMMARY SHEET</p> <p>Use to report administrative and minor departures from the IRB approved protocol that “does not affect the scientific soundness of the plan or the rights, safety, or welfare of human subjects.” See IRB Guidance at: http://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/protocol_deviations.html.</p> <p>Submit to JHM IRB: Use this form to answer the question 3.1 in the eIRB Continuing Review.</p>				
<p>JHM IRB Application Number: Principal Investigator: Protocol Expiration Date: Sponsor: Sponsor Protocol Number: Date Submitted to the IRB:</p>				
Date of Deviation	Study ID (No PHI, please)	Description of Deviation (attach extra pages, if needed)	Reason for Deviation and Corrective Action Plan	Sponsor Notification Date (required for IND/IDE studies)

Protocol Deviation Codes:

- A – Consent Procedures
- B – Inclusion/Exclusion Criteria
- C – Concomitant Medication/Therapy
- D – Laboratory Assessments/Procedures
- E – Study Procedures
- F – Serious Adverse Event Reporting/Unanticipated Adverse Device Effect
- G – Randomization Procedures/Study Drug Dosing
- H – Visit Schedule/Interval
- I – Efficacy Ratings
- J – Other

Checklists and Templates-

https://www.hopkinsmedicine.org/institutional_review_board/about/compliance_monitoring/researchers_tool_kit/templates_checklists_logs.pdf



TRACKING

Adverse Events – Attach to Continuing Review Report. A adverse events form can be created in your study database in addition to this form

Note to File

Used to add the protocol deviation in the participants record

Memorandum

Note To File

Date:

To: Regulatory Binder

RE: Protocol No. , entitled, *****

Event: [Description of details of a study related event or accounting of information requiring an organizational change to the protocol or needing clarification]

Response: [Description of the immediate response to the event referred to above and/or what steps have been taken to implement a change or to clarify a study concern]

Corrective Action: [Description of the general systematic response to eliminate or minimize the described event or to improved the overall quality of the study]

FORM R.F.3: ADVERSE EVENT REPORT SUMMARY SHEET (to be uploaded with the eIRB Continuing Review application)

Directions:

1. This form should be used to record all adverse events. These occurrences include:
 - a. Anticipated problems/events that are described in the protocol, informed consent form, and/or investigator's brochure, and
 - b. Problem/events that meet with JHM IRB prompt reporting requirements.

For information about the JHM IRB policy on Prompt Reporting of Problem/Events please refer to: https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/organization_policies/prompt_reporting_policy.html

2. Upload this form where prompted in the eIRB Continuing Review Application.

Note: If a sponsor requires immediate reporting of an adverse event to the IRB, but it does not meet the JHM IRB requirements for prompt reporting, please complete and submit a Problem Event Report in eIRB, selecting the last box, indicating the sponsor's requirement and add to this log.

DO NOT USE FOR SPONSOR GENERATED IND SAFETY REPORTS

JHM IRB Application Number:

Participating Site Name (if applicable):

Principal/Participating Site Investigator:

Date of Problem/Event	Subject ID (No PHI)	Description of Event (attach extra pages, if needed) and Outcome (if applicable):	Was the event reported to the IRB during the past approval period? If yes, provide date of the Problem Event Report and JHM IRB review determination.	Date problem/event was reported to the sponsor or FDA (for IND/IDE studies only)



REGULATORY BINDER

The regulatory binder can be a physical binder or it can be digital. If it's digital it should contain the same sections as a physical binder.

Additionally, add sections for DSMB and randomization. Create a table and include study team training documentation in the *binder* (consenting, screening, intervention, data collection, license & certification renewals, etc). DSMB and Randomization

JHU SOM eIRB Path to Sample Forms:

IRB homepage, about the IRB, Compliance Monitoring Program, Researcher's Toolkit, Standard Operating Procedure Templates and instructions

https://www.hopkinsmedicine.org/institutional_review_board/about/compliance_monitoring/researchers_tool_kit/index.htm
!

REGULATORY BINDER – Recommended Contents

The Principal Investigator and authorized Study Team Members are responsible for:

1. Assembling a binder or electronic database in which to file all regulatory documentation. The minimum recommended material included should be:
 - a. A Table of Contents
 - b. A copy of the original human subjects research application submitted to the JHM IRB (and, if applicable, the application may be located in eIRB)
 - c. A copy of the sponsor's protocol (if applicable)
 - d. A copy of the federal grant application (if applicable)
 - e. A copy of the investigator's brochure for an investigational new drug (if applicable)
 - f. A copy of the investigational device exemption information (if applicable)
 - g. A copy of an investigator-initiated IND or IDE application (if applicable)
 - h. A copy of the IRB approved Informed Consent form (if applicable)
 - i. A copy of all correspondence with the IRB, sponsor, funding source, FDA, or others
 - j. Monitoring/Auditing documentation
2. Filing the documents in date order.
3. Maintaining the binder, for paper records, in a secure location.
4. Maintaining secure electronic records from which regulatory documents may be retrieved, viewed, and printed, if necessary for monitoring/auditing purposes.

REGULATORY BINDER

Table of Contents:

- ◆ Protocol
- ◆ IRB (Submissions, correspondence, amendments, advertisements, reports, approved consent forms, materials & HIPAA forms)
- ◆ Investigator's Brochure
- ◆ FDA Form 1572 (Investigator's Statement)
- ◆ Sponsor Communications (written, phone, fax, email)
- ◆ Monitoring Log (every visit, every report)
- ◆ Subject Screening Log/ Master randomization list
- ◆ Study Drug (shipping, accountability, storage, batch numbers, dates)
- ◆ AE, SAE Reports / protocol deviations and violations, IND Safety Reports
- ◆ All relevant communications (letters, e-mails, phone notes, meeting minutes)
- ◆ Study CRFs, data collection forms
- ◆ Documentation of edits (audit trail)



STANDARD OPERATING PROCEDURES/OPERATIONS MANUAL

SOPs serve as a reference of detailed procedures. Useful for new team members; creates uniformity in study procedures; demonstrates adherence to institutional guidance; lends itself to intervention fidelity and replicable research. A protocol should be developed for all study procedures. Typical operating procedures:

- Screening/Eligibility Assessment
- Protocol Deviations
- Adverse Events
- Consenting and Documentation of Consent
- Data Collection
- Biospecimen collection (if applicable)

Source -

https://www.hopkinsmedicine.org/institutional_review_board/about/compliance_monitoring/researchers_tool_kit/standard_operating_procedure.pdf



DEVELOPING STANDARD OPERATING PROCEDURES/OPERATIONS MANUAL

Sample User Standard Operating Procedure	Version:
Status:	Revised by:
Original Date:	Approved By:
Revision Date:	Approval Date:

Standard Operating Procedures: Writing Standard Operating Procedures (SOPs)

The Principal Investigator or authorized Study Team Member should delineate study procedures and regulatory processes in a standard format:

1. Structure Elements
 - a. Use a header, which may include the principal investigator's name, and department information; page number, the SOP's title, version number, approval date, and the name of the person authorized to approve the SOP.
 - b. An optional "Purpose" section may be used to summarize how to use the SOP.
 - c. An optional "Scope" may be used to indicate to whom the SOP applies.
 - d. Develop a detailed "Procedures" section to delineate all the steps to perform a specific procedure.
2. Documentation Organization and Quality Assurance
 - a. The site should use the most current versions of the SOPs
 - b. Previous versions of the SOPs should be available for Quality Assurance audits, using the Version Number to provide an "audit trail."
 - b. A binder or electronic file should contain copies of all SOPs.
 - c. The Principal Investigator should review the SOPs for adequacy and applicability.

SAMPLE Standard Operating Procedure for Obtaining Informed Consent

Original Date: December 3, 2019

Revision Date:

Version:

Revised by:

Approved by: Kimberly Hill

Approval Date: December 3, 2019

Purpose: Define General informed consent process

Scope: This procedure applies to all staff involved in obtaining informed consent

Materials: Most recent IRB stamped version of the Informed Consent, black pen

Responsibilities:

The approved study team members, the Project Coordinator or Research Assistant, are responsible for:

- Assuring you are using the most recent IRB stamped version of the consent.
- Discussing the informed consent form with the potential subject and presenting the potential research subject with the opportunity to discuss the entire informed consent form in a private setting at the recruitment site before it is signed.
- Giving them as much time as needed to reach a decision about participating.
- Assessing and confirming the subject's comprehension of the content in the Informed Consent by asking opened questions about their understanding of the study.
- Allowing the subject the time and opportunity to ask questions about the study.
- If the subject agrees to participate, the study team member will witness the subject signing and dating the consent prior to any study specific procedures. The study team member will sign and date the consent form.
- The subject will be given a copy of the consent form.
- The original will be filed in the subject's research record.

Training:

Each staff member responsible for obtaining informed consent will be adequately trained and qualified by education, training, experience, and knowledge of the trial prior to obtain consent. Training is documented.

DEVELOPING A MANUAL OF OPERATIONS / PROCEDURES MANUAL

Use the table of contents as guide to developing your Operations Manual and developing SOPs >>

Excerpted from: National Institute of Arthritis and Musculoskeletal and Skin Diseases

Website for pdf of complete manual:
<https://www.niams.nih.gov/grants-funding/conducting-clinical-research/trial-policies-guidelines-templates/data-safety-monitoring-guidelines-policies/clinical-study-templates-forms>

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DATA COLLECTION

- **Redcap** – <https://redcap.jhu.edu/>
 - 3 pricing plans; bronze, silver, gold (should have been budgeted for in the grant proposal)
 - different levels of support; bronze has low level support- a group zoom meeting held once or twice per month. Silver and Gold plans can receive support through ticket system within the platform
 - Great for longitudinal studies
 - ask for a development account so you can practice
 - Training videos available within the platform; also on Youtube



DATA COLLECTION

- **Qualtrics**
 - Contact IT to set up account; found at myJH under School of Nursing tab
 - Free to use for SON
 - Great for small pilot studies; pre-post assessments
 - Support is within the platform (Help button, single sign-on, nursingjhu)



DATA COLLECTION

Recruitment:

- Screening & Enrollment data can be collected in Qualtrics, Redcap, or Excel
- Typical Fields: Recruitment source, eligibility status, screening status, study status, randomization group, date of screening, consent date, intervention completion status

Retention Methods:

Continued contact outside of data collection and intervention allows you to keep contact information up to date which is especially useful for longitudinal studies and transient populations. You'll be aware of change in contact information between data collection periods and may have a better chance of reaching backup contacts to get a message to the participant.

- Holiday, Birthday, Special Occasion via cards/text/email
- Incentives
- Data Collection Reminders
- Intervention reminders
- Backup contacts (at least 2 people)



Participant Communication Options

Video Call Options:

- Zoom (HIPAA compliant)

Audio Call Options: comparison video <https://www.softwaresuggest.com/compare/grasshopper-vs-telzio>

- Grasshopper
- Telzio
- Ring Central



In-person Participant Visits

Discuss Mileage and Overtime/Extra Hours with the PI

- **Non-exempt employees are paid for all hours worked.** Non-exempt employees will receive additional compensation for hours worked over their assigned work schedule. For example if you are hired and scheduled to work a 28 hour work week and are approved to work additional hours you will be compensated accordingly. Supervisors must send an email to son-hr@jhu.edu to report the additional hours worked so the employee will be compensated.
- Track **mileage** on a spreadsheet (at a minimum, date, miles, participant name/number should be documented) Contact Judi Damask or Ronnie Medina for mileage reimbursement rate and how often you should submit documentation for reimbursement.
- For **safety**, visits should be conducted in pairs. If that isn't possible, the PI and another team member should be informed of who you're visiting and where they live, especially if you're conducting participant visits during non-work hours. This should be part of your visit standard operating procedure.



STUDY BUDGET

Create a budget folder

- Sr. Grants and Contracts Analyst and study can be used as a guide to what supplies and services are allowable/unallowable; understanding your monthly statement; understanding fringe, f&a, effort.
- Purchasing goods and services; options for incentives – Judi Damask and Ronnie Medina
- Use excel to document Incentives dispersed (participant, vendor, when, how much, description)
- Use excel to document Purchases and payments to vendors/independent contractors (vendor, amount, quantity, description)
- Create folder for Vendors. Store independent contractor invoices, contractor agreements. Document date paid, amount, description of service. Read the contract and be mindful of contract period and that invoices are paid on time and within the contract period
- Save Receipts
- Monitor expenditures to assure expenses appear on the monthly statements, and amounts on the statements match the receipts. If not let your Sr. GCA know immediately
- Keeping your budget on track: use your grant application as a guide as to what you said you would purchase.

Things that can impact the study budget: Delays in hiring staff, not hiring staff at capacity listed in application, delays in paying incentives, delays in purchasing goods and services.



Participant Incentive options

- eGiftcards
- Giftcards (Visa*, Amazon, Target, Walmart)
- Tango cards (bulk purchase of eGiftcards)
- Bank of America debit cards
- Giant Foods & Safeway
- Sam's Club (plastic & e-card)

Contact Judi Damask in the Business office for procedure to purchase and other available options



CERTIFICATION

- ACRP - <https://acrpnet.org/certifications/>
- SOCRA – <https://www.socra.org/certification/at-home-ccrp-testing/>
- Science of Clinical Investigation Training Program - https://ictr.johnshopkins.edu/study_team/training-education/science-of-clinical-investigation-soci-training-program/

RESEARCH ADMINISTRATION

- Society of Research Administrators International - <https://www.srainternational.org/home>



RESEARCH COORDINATOR PROGRESSION

- Research Program Coordinator
- Sr. Research Program Coordinator
- Sr. Research Program Coordinator II
- Other succession options after Research Coordinator:

Research Administration, Program Administrator, Project Manager, Data Manager, Data Analyst, Research Associate, Regulatory Specialist, Compliance Specialist, Statistician, and positions within the ICTR, IRB

WHEN THE FUNDING ENDS



- Coordinators usually start looking to transition to another position 6 months – 1 year before the funding ends



RESOURCES

- **Kimberly Hill**, khill2@jhu.edu, Research Startup Specialist, Nursing Office of Research Administration
- **IRB Questions** – jhmeirb@jhmi.edu
- **eIRB Researcher's Toolkit** (checklists, logs and SOP templates and instructions, GCP checklist)
https://www.hopkinsmedicine.org/institutional_review_board/about/compliance_monitoring/researchers_tool_kit/index.html
- **SAFE Desktop** – Cloud based HIPAA compliant platform to analyze and share data
https://ictr.johnshopkins.edu/programs_resources/programs-resources/i2c/secure-research-data-desktop/
- **Clinical Trials.gov Registry** - to register human subject trials that assess a health outcome. (your PI may or may not ask you to assist with– must first email to request log-in information [Go to PRS-ClinicalTrials.gov](#))
- **NORA** (formerly OSI) son-innovation@jhu.edu;
https://nursing.jhu.edu/faculty_research/research/osi/
- **Welch Library classes**- <https://welch.jhmi.edu/featured/classes>
- **Assistance with literature reviews** – Stella Seal
- **How to write an article** – contact me for a Powerpoint
- **Data Services classes** - <https://dataservices.library.jhu.edu/training-workshops/>
- **ICTR Resources** - https://ictr.johnshopkins.edu/study_team/training-education/



EVALUATION

Please answer 4 short questions to help us better serve you.
If this link doesn't work, please copy and paste into your browser

https://nursingjhu.qualtrics.com/jfe/form/SV_ePMJfXpOxzliroG

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