



SCHOOL OF MEDICINE

North Carolina Translational and Clinical Sciences Institute



UNC

OFFICE OF CLINICAL TRIALS

# CLINICAL PROTOCOL DEVELOPMENT SERIES (DAY 1)

Kim Brownley, PhD, CIP

Joyce M. Lanier, MSRC, RRT, CCRC

# Online Logistics - Questions

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- To avoid connectivity issues, we ask that participants please turn off their video.
- Please enter questions using the chat function. We will be monitoring the chat and saving questions until the end.
- Any questions we do not get to will be compiled into a Q&A document and distributed to registered attendees.

# Objectives for Day 1

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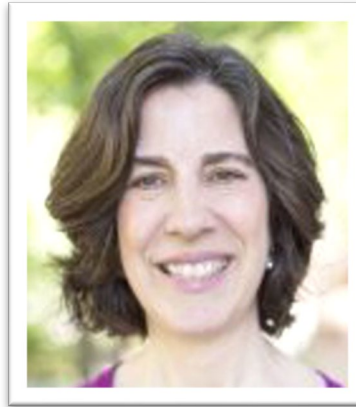
- Understand when and why a clinical protocol is required
- Review how a protocol is helpful to researchers
- Describe the Scientific Review Process
- Review available protocol templates and resources
- Discuss content expectations for sections of the protocol

# Protocol Development Support Team

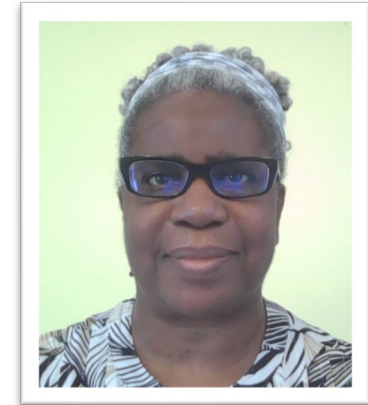
## NC TraCS



**Kim Brownley PhD, CIP**  
*Co-Director*



**Marie Rape RN, BSN, CCRC**  
*Associate Director*



**Joyce M. Lanier, RRT, MSRC, CCRC**  
*Protocol & Quality Assurance Specialist*

## Office of Clinical Trials



**Monica Coudurier, BA**  
*Clinical Trials  
Project Manager*

# Day 1: Background, SRC Review & Process, Protocol Templates

Kim Brownley, PhD, CIP  
Co-Director, TraCS Regulatory Service  
Chair, UNC IRB  
Member, Scientific Review Committee

# Grant Proposal vs Protocol – key differences

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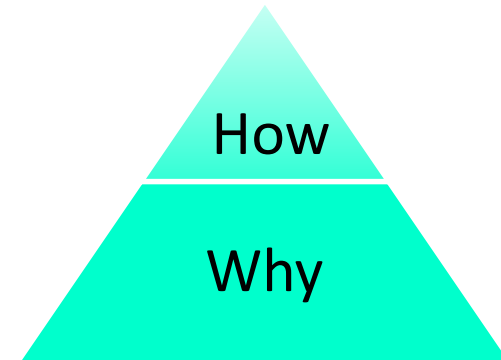
- **Grant proposal:** *rhetorical document, comparable to an artist's painting of a concept car or a rendering of an architectural vision*
  - Page limitations per funding mechanism
  - Document to propose an idea worth funding
  - Summary of clinical plan
  - May include a component for training individual
- **Protocol:** *analytic document, comparable to a schematic drawing or recipe meant to present an effective plan for conducting the study and analyzing the data*
  - No page limitations
  - Sections describe all aspects of clinical plan
  - Roadmap for study teams to implement study
  - Dynamic document (updates, changes)

# What is a Clinical / Research Protocol?

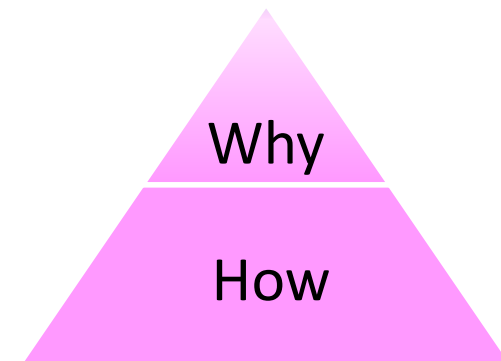
A document that describes:

- **Why** a study will be conducted
  - Background and rationale
  - Objectives and aims
- **How** a study will be conducted
  - Design
  - Methodology
  - Statistical considerations
  - Organization of the project

***Grant Proposal***



***Protocol***



# How is a Protocol Helpful?

- Helps PI translate scientific aims into actionable steps and clear deliverables/outcomes
- Standardizes processes and provides a detailed plan for the study team to implement
  - Clarifies role responsibilities
  - Reduces noncompliance/unanticipated problems
    - ❖ Helps ensure the safety of the trial subjects
    - ❖ Helps ensure the integrity of the data collected
  - Multicenter trials – all sites follow same protocol
- Source material for other submissions (CT.gov, IRB, manuscripts)
- Facilitates IRB Review
  - Maps onto and supports the IRB application
  - Signals attention to detail (“bad” science → unethical)




# Why Require a Protocol?

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- **FDA** IND or IDE submission
- **NIH** clinical trial grant submission (protocol synopsis)
- **Single IRB review** many IRBs require a protocol (not just IRB application)
- **[ClinicalTrials.gov](https://clinicaltrials.gov)** registration & results reporting
- **UNC** = “industry standard” for scientific review

# UNC Scientific Review Policy

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All  **clinical** research conducted at the University of North Carolina at Chapel Hill involving **greater than minimal risk** (full board) must undergo scientific review.

 *Industry-sponsored, multi-site trials generally excluded* 

# Scientific Review – Why?

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Regulatory Criteria for Approval – RISKS ARE:



- *Minimized* through *sound research design*.
- *Reasonable in relation to anticipated benefits* and the *importance of the knowledge* to be gained.



There is ***no acceptable risk*** to human subjects ***in the absence of valid scientific benefit***.

# UNC Scientific Review – Who?

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- Externally by an independent organization that has no COI with the research activity
  - Not NIH study section
  - Not Foundation peer review
- LCCC PRC for oncology research 
- UNC SRC for all other clinical/biomed research 

 **Both require a protocol!!**

# Oncology Protocol Review Committee (PRC) Process

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The PRC reviews local and national research protocols involving cancer prior to IRB submission.

Oncology trials to be reviewed by the PRC must have at least a final protocol and a signed PRC cover sheet (and a statistician signoff, if it is an Investigator Initiated Trial), all of which are sent to the [PRC Coordinator](#). The Protocol Development team is available to assist with any IIT protocols that will be reviewed by the PRC. Visit their website (<https://unclineberger.org/iit/>) for more information.



After submissions have been initially previewed by the PRC Coordinator, they are assigned to the next available PRC meeting (every other week).



Once the protocol has been approved by the PRC, the study team will attach the PRC approval letter to the IRB application and submit it for review.

For more information about the PRC, visit the PRC website (<https://unclineberger.org/protocolreview/>), or contact the [PRC Coordinator](#).



# How Does the SRC Process Work?

<https://research.unc.edu/clinical-trials/src/review-process/>

1. Protocol Submitted through UNC Office of Clinical Trials “*SRC Portal*” (<https://apps2.research.unc.edu/src/index.cfm?event=review.request>)
2. SRC Coordinator Evaluates Protocol
  - a. Shares reviewable protocols with SRC Chairman and with OCT Director and IRB as needed
  - b. If needed, revisions are requested, protocol sent back to PI
3. “Ready” protocols received by Monday at noon
  - a. Scheduled for committee review the following Monday
  - b. Chair assigns three reviewers (primary, secondary, biostatistician)
4. Post review: Investigator advised of next steps
  - a. Revise, resubmit through portal to 3 reviewers only **OR** to the full committee; may include TraCS Protocol Specialist referral
  - b. Proceed to the IRB

# Distinctions Between SRC and IRB Review

## IRB

- Subjects' Rights & Welfare
- Ethical Conduct in Research
- Appropriate Background & Training of Research Personnel
- Transparency Regarding Risks and Benefits of Participation
- Equal Opportunity & Parity
- Adherence to Federal & State laws, OHRP & UNC Policies

### Contact:

UNC Office of Human Research Ethics  
[IRB\\_questions@unc.edu](mailto:IRB_questions@unc.edu)

## SRC

- Scientific Merit & Importance
- Feasibility
- Clearly Stated Aims
- Relevant Outcome Measures
- Appropriate Data Management Plan
- Statistical Integrity
- Adherence to GCP, UNC Research Requirements

### Contact:

[SRC@unc.edu](mailto:SRC@unc.edu)

# • WHO ARE THE CURRENT SRC MEMBERS?

## Chair

**Eric T. Everett, PhD**  
(Oral/Dental/Craniofacial, Genetics)

## Reviewers

- **Kim Brownley, PhD, CIP:** (Psychology, Mental Health, HSR-regulations)
- **Michelle Floris-Moore, MD, MS:** (Infectious Diseases)
- **Marianne Muhlebach, MD:** (Pediatrics, Pulmonology)
- **Gretchen S. Stuart, MD, MPH:** (OB-Gyn)
- **Claudia M. Testa, MD, PhD:** (Neurology, Genetically-based Therapeutics)
- **Michael Wagner, PhD:** (Genetic Medicine, Pharmacogenetics, Genomics)
- **Laura Young, MD, PhD:** (Endocrinology)

## Statistician Reviewers

- **Feng-Chang Lin, PhD**  
(Biostatistics)
- **Jipcy Sulbaran, PhD Candidate**  
(Biostatistics)



# Protocol Templates, Resources & Case Scenarios



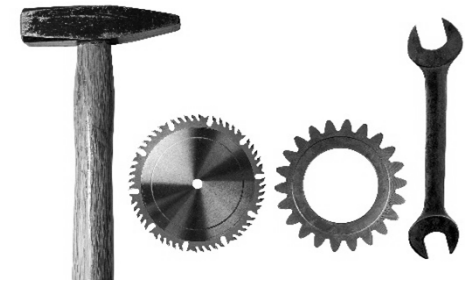
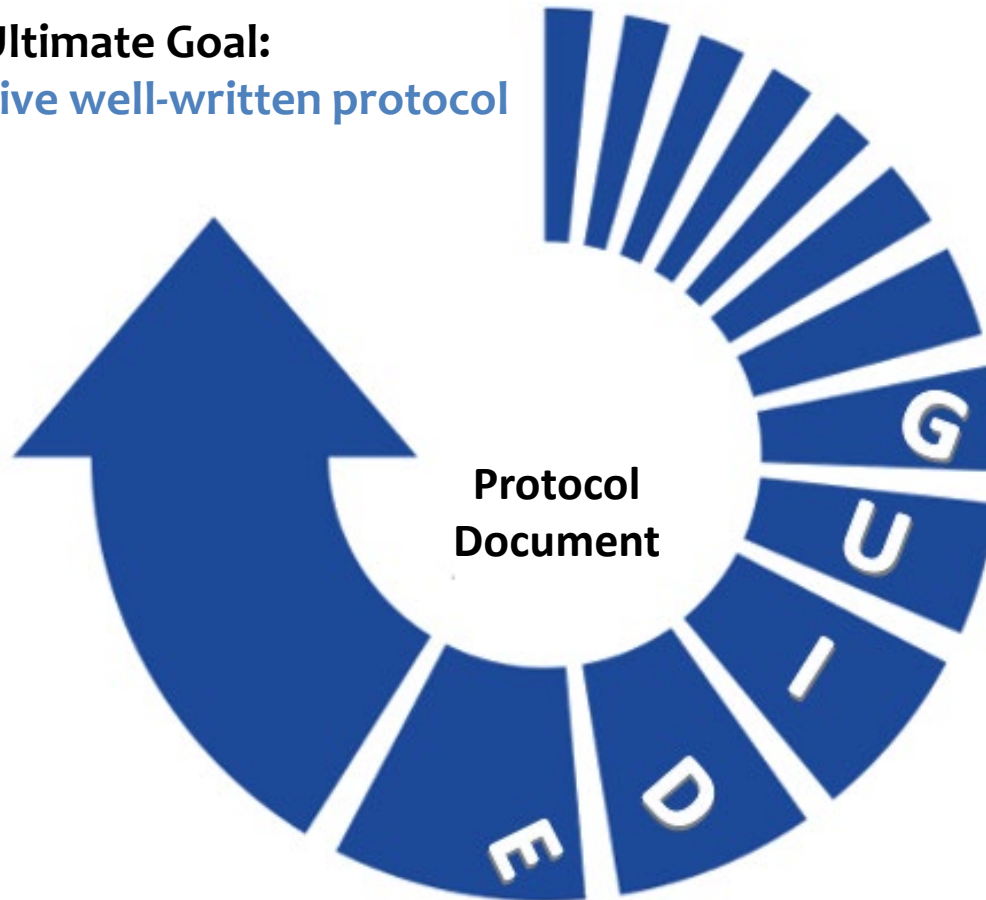
Joyce M. Lanier, MSRC, RRT, CCRC

Protocol & Quality Assurance Specialist

North Carolina Translational & Clinical Sciences Institute

# Why Use a Protocol Template?

**Ultimate Goal:**  
Comprehensive well-written protocol



To guide investigators through the systematic development of the document.

# Protocol Builder Tool

[UNC Research Home](#) / [Office of Clinical Trials](#) / [Training & Resources](#) / Protocol Builder

## Protocol Builder

Protocol Builder is an online tool designed to help investigators develop clinical protocols with all of the elements needed for efficient scientific and ethical review by the UNC Scientific Review Committee and UNC IRB.

Anyone with a UNC ONYEN, including UNC affiliates at other institutions, can [log in and start building a protocol](#).

**Protocol Builder is now available at UNC!**

Log into Protocol Builder

**Link:** <https://research.unc.edu/clinical-trials/training/protocol-builder/>

PB administration contact: [src@unc.edu](mailto:src@unc.edu)

# SRC Protocol Development Tips & Resources

[UNC Research Home](#) / [Office of Clinical Trials](#) / [Scientific Review Committee](#) / Protocol Development

## Protocol Development Tips and Resources



[Download UNC Master Protocol Document Template](#): This document is a comprehensive guide to protocol development for UNC investigators.

<Short Title>  
Protocol Number <#>

Version <x.x>  
<DD Month YYYY>

## Protocol Template for Interventional Studies and Observational Studies

### **Guidance**

Please remove these Guidance pages (i, ii, iii) before finalizing and distributing the protocol. As you complete the protocol, please delete instructions/guidance text, also. The guidance text is GRAY.

<https://research.unc.edu/clinical-trials/src/protocol-development/>

# SRC Protocol Development Tips & Resources

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UNC Master  
Protocol  
Document  
Template


NIH-FDA  
Protocol  
Template

BSSR Protocol  
Template

Registry  
Repository  
Protocol  
Template

<https://research.unc.edu/clinical-trials/src/protocol-development/>

# TIPS for Speedy Scientific Review


- Submit protocol to SRC early
- Pick the right protocol template . . .  grant
- Clearly describe relationships and roles of the:
  - Sponsor
  - Institution
  - Investigator
  - IRB
  - Research Partners
- Clearly describe the investigational drug/device status
- Address all elements per the protocol template
- Be consistent (aims → procedures → measures → analyses)

# Clinical Protocol Templates (LCCC)

UNC SCHOOL of MEDICINE

UNC Lineberger Comprehensive Cancer Center

## Investigator Initiated Trials (IITs)



[Home](#) / [Getting Started](#) / [Initial Protocol Development](#) / Writing Your Protocol

[Getting Started](#) **Writing Your Protocol**

<https://unclineberger.org/protocolreview/forms/>

[Writing Your Protocol - Investigator Initiated Trials \(IITs\) \(unclineberger.org\)](https://unclineberger.org/protocolreview/forms/)

[Investigator Initiated Trials \(IITs\) - Investigator Initiated Trials \(IITs\) \(unclineberger.org\)](https://unclineberger.org/protocolreview/forms/)

# Clinical Protocol Templates (LCCC)

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Chemotherapy  
Treatment  
Protocol  
Template

Cellular Therapy  
Protocol  
Template

Health Services  
Research  
Protocol  
Template

Imaging Study  
Protocol  
Template

Biospecimen  
Protocol  
Template

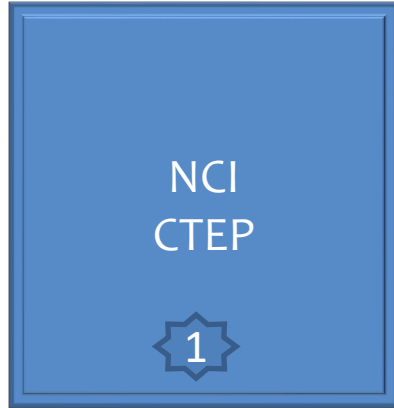
Radiation  
Treatment  
Protocol  
Template

[Writing Your Protocol - Investigator Initiated Trials \(IITs\) \(unclineberger.org\)](http://unclineberger.org)



# Additional Protocol Templates

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- 1 [Protocol Templates and Guidelines | Protocol Development | CTEP \(cancer.gov\)](#)
- 2 [nidcr-clinical-trial-interventional-protocol-template.dotx \(live.com\)](#)
- 3 [Protocols and Informed Consent | NIH: National Institute of Allergy and Infectious Diseases](#)

# Additional Protocol & Template Resources

## Study Record: PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001  
Expiration Date: 09/30/2024

\* Always required field

### Section 1 - Basic Information

### Section 2 - Study Population Characteristics

### Section 3 - Protection and Monitoring Plans

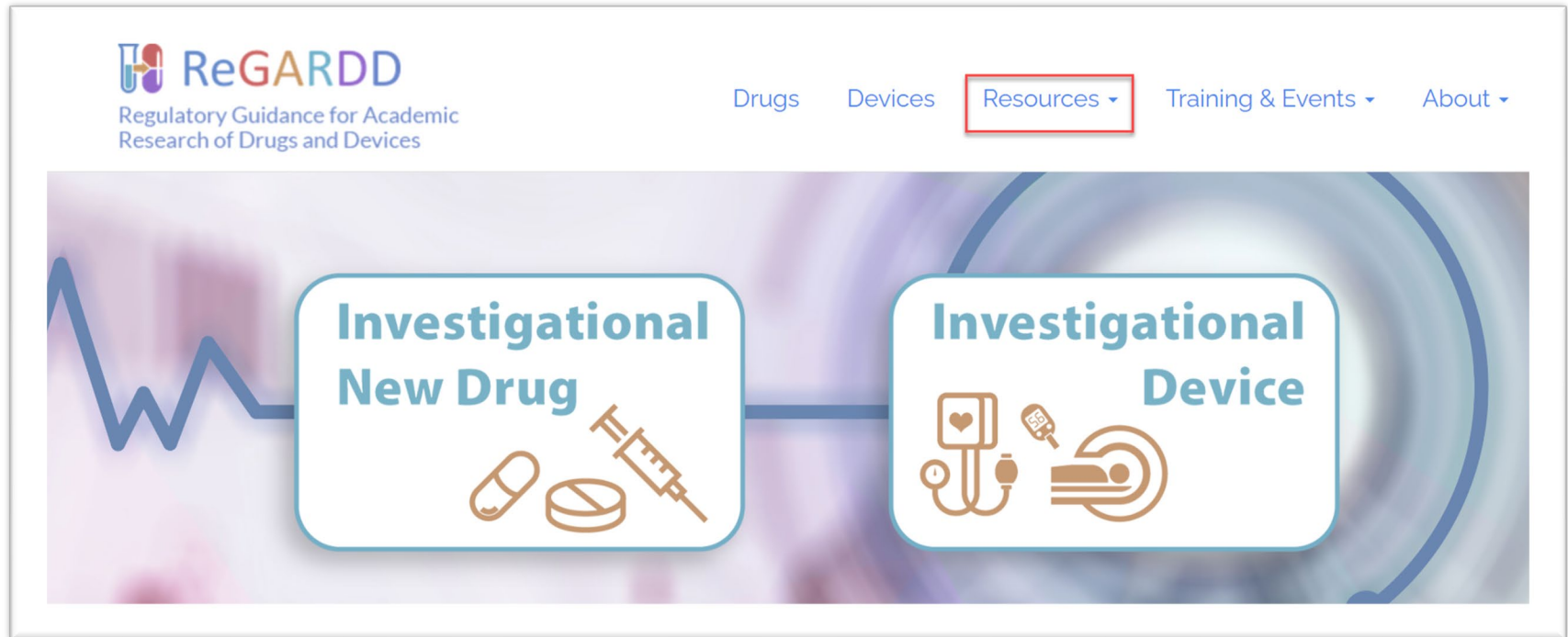
### Section 4 - Protocol Synopsis

#### 4.1. Study Design

##### 4.1.a. Detailed Description

##### 4.1.b. Primary Purpose

# Additional Protocol & Template Resources



[ReGARDD.org \(unc.edu\)](https://regardd.org)

<http://regardd.org/resources>

[ReGARDD - Regulatory Guidance for Academic Research of Drugs and Devices](https://regardd.org)

# Additional Protocol & Template Resources

The screenshot shows the ReGARDD website interface. At the top left is the ReGARDD logo with the text "Regulatory Guidance for Academic Research of Drugs and Devices". To the right is a navigation menu with links for "Drugs", "Devices", "Resources", "Training & Events" (highlighted with a red box), and "About". Below the navigation is a grid of seven institutional logos, each with a corresponding colored button below it: UNC (University of North Carolina at Chapel Hill), Duke University School of Medicine, Wake Forest School of Medicine, MUSC (Medical University of South Carolina), VCU (Virginia Commonwealth University), CTSI (Cancer Therapy Evaluation Program), and RTI International. The background features a decorative pattern of grey dots on the right side.

# Additional Protocol & Template Resources

Support FAQ Contact Us

Courses Organizations Individuals About

Register Log In

What CITI Program is Reading - August 30th, 2022

The Trusted Standard in Research, Ethics, Compliance, and Safety Training

**CITI Optional Module –  
Research Study Design:**  
<https://www.citiprogram.org/>

English

LOG IN LOG IN THROUGH MY ORGANIZATION REGISTER

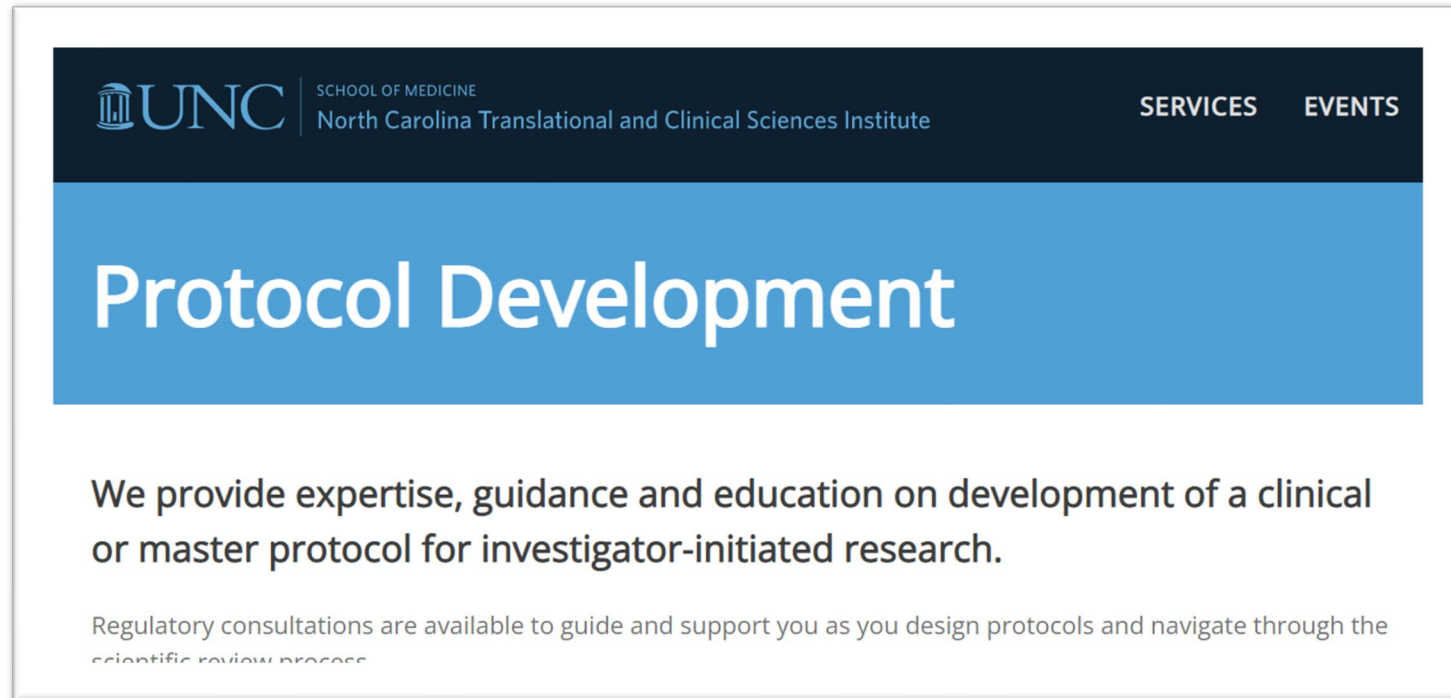
Username [Forgot?](#)

Password [Forgot?](#)

Log In

# Additional Protocol & Template Resources

## TraCS Regulatory:



The screenshot shows a webpage header with the UNC logo and text: 'UNC | SCHOOL OF MEDICINE | North Carolina Translational and Clinical Sciences Institute'. To the right are links for 'SERVICES' and 'EVENTS'. Below the header is a large blue banner with the text 'Protocol Development'. Underneath the banner, the text reads: 'We provide expertise, guidance and education on development of a clinical or master protocol for investigator-initiated research.' At the bottom of the page, it says: 'Regulatory consultations are available to guide and support you as you design protocols and navigate through the scientific review process.'

<https://tracs.unc.edu/index.php/services/regulatory/protocol-development>

# Additional Protocol & Template Resources

## Protocol Development Services

Virtual consultation services

Provide protocol templates

Protocol review with annotated recommendations

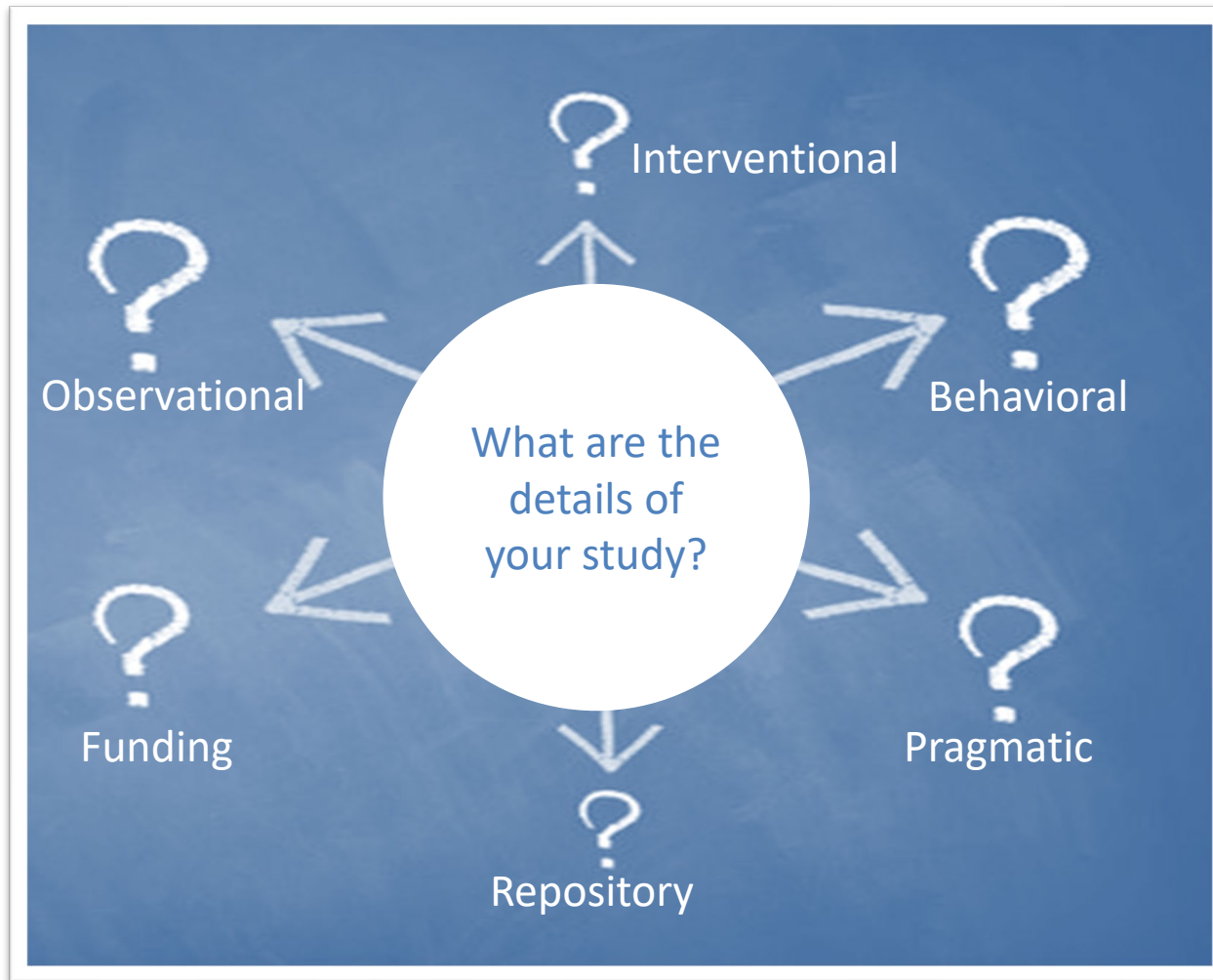
Assist PI & study team with review committee responses

Protocol writing services – *Fee for Hire*



Joyce Lanier (Protocol Specialist) –  
[joyce\\_lanier@med.unc.edu](mailto:joyce_lanier@med.unc.edu)

# Choosing Appropriate Protocol Template





# Interventional vs. Observational Studies

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- **Interventional:** Participants are **assigned** (based on the randomization of the research study) to groups that receive one or more intervention / treatment (or no treatment) so researchers can evaluate the effects of the intervention on biomedical or health related outcomes. Assignments are **determined by the protocol** / study participation (typically prospectively assigned).
- **Observational:** Researchers **observe** the effect of a risk factor, diagnostic test or treatment or other intervention without trying to change who is or isn't exposed to it. Subjects receive treatment via standard of care typically determined by their health care provider (**NOT assigned by study**) .

# Anonymous Case Scenario Poll #1

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**Study 1** is comparing the impact of **Drug A** versus **Drug B** for physiological changes in the liver.

**Study Aim:** To characterize changes in liver microbiome structure

**Inclusion Criteria:** Diagnosis of liver disease; Clinical decision to start Drug A or Drug B

**Study Design:** 4 study visits after starting the drug which includes specimen collection and the administration of questionnaires

*Is this an interventional or observational study?*

# Case Scenario Poll #1 (Revised)

---

**Study 1** is comparing the impact of **Drug A** versus **Drug B** for physiological changes in the liver.

**Study Aim:** To characterize changes in liver microbiome structure

**Inclusion Criteria:** Diagnosis of liver disease; Clinical decision to start Drug A or Drug B where drug has been prescribed by the treating physician as standard of care prior to enrollment.

**Study Design:** 4 study visits after starting the drug which includes specimen collection and the administration of questionnaires

*Is this an interventional or observational study?*

# Pragmatic Trial = Clinical Trial = Interventional

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- ***Pragmatic trial***
  - Typically randomized and controlled, but participants often randomized at the group level (hospital, nursing home, clinic) with a similar group matched as control group.
  - Purpose is to inform decisions about practice
  - Designed to evaluate the effectiveness of interventions in real-world clinical settings.
- Recommend use of an Interventional Protocol Template
- Resource: [Pragmatic Elements: An Introduction to PRECIS-2 - Rethinking Clinical Trials](#)

# Break Time

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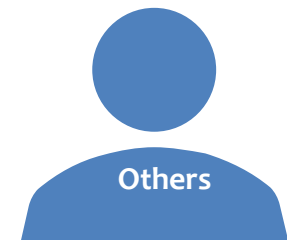
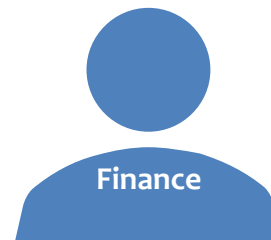
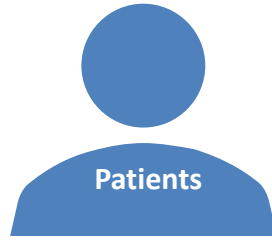
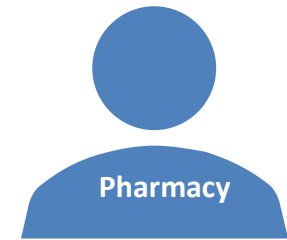
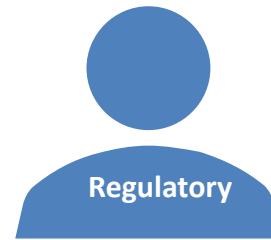
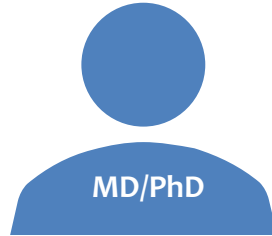
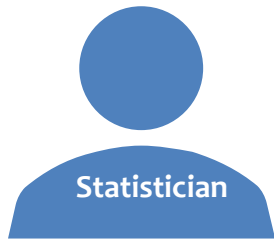
05:00

mins:  secs:  type:

 Breaktime for PowerPoint by Flow Simulation Ltd.  Pin controls when stopped

# How to Develop a Protocol

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Additional tips:

- Anticipate several drafts of the protocol
- Check for consistency across protocol

# Basic Protocol Template Outline

- Title Page
- Table of Contents
- Abbreviations
- Protocol Summary
- Study diagram, SOE
- Introduction (Background, Rationale, Risk/Benefit)
- Study Objectives, Endpoints
- Study Design
- Study Population (I/E criteria)
- Study Intervention Administration
- Assessments & Procedures
- Adverse Event & Safety Management
- Statistical Considerations
- Recruitment Strategy
- Consent Process
- Study Team, Oversight, Monitoring
- Data Collection/Management
- References
- Appendix

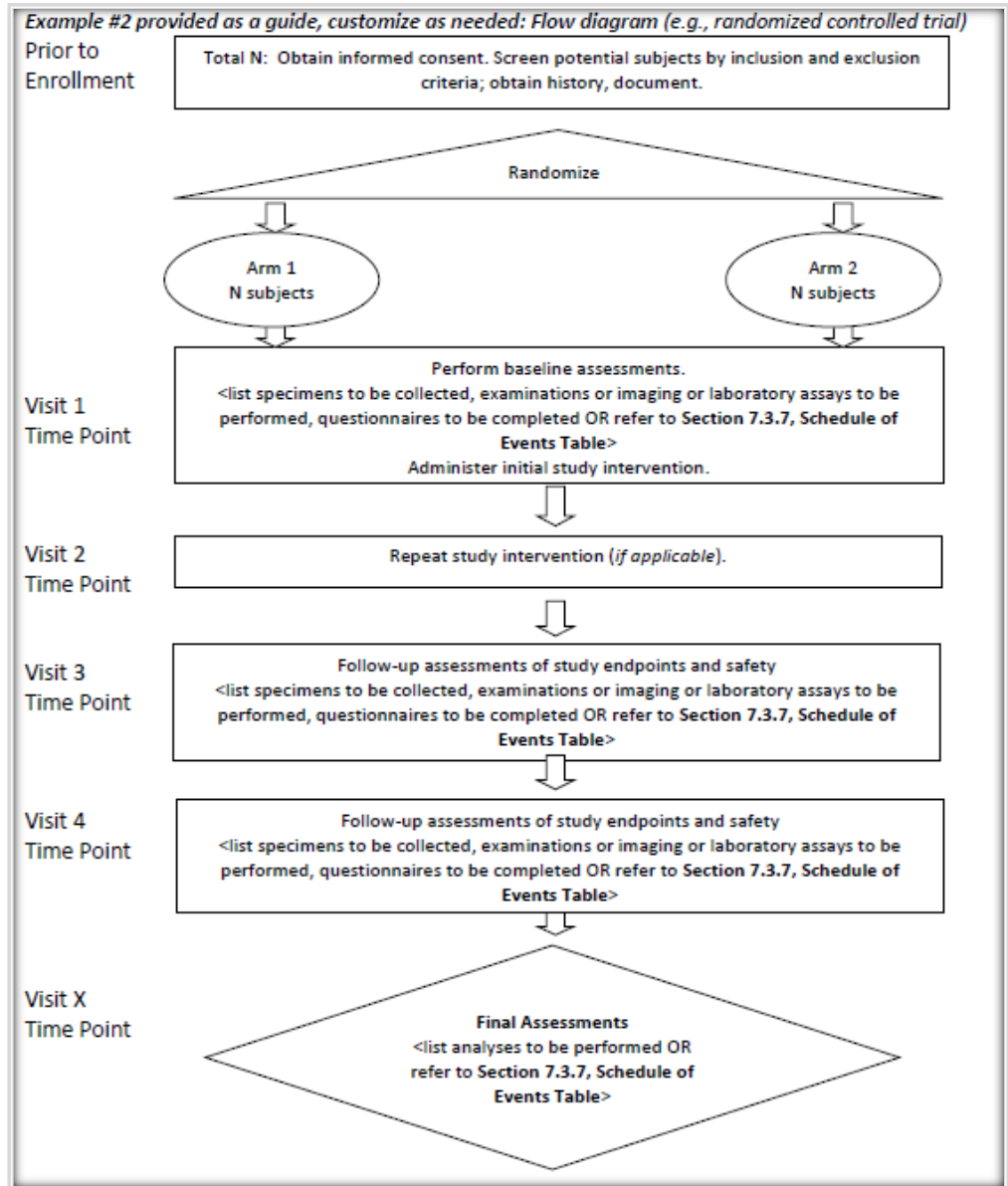
# Protocol Summary or Synopsis

Limit to 1-2 pages – brief, concise, specific

<b>Title:</b>	Include type of trial (e.g., dose-ranging, observational, double-blind)
<b>Phase:</b>	I, II, III, IV
<b>Population:</b>	Include sample size, gender, age, general health status, geographic location
<b>Number of Sites:</b>	3 or fewer, list here; otherwise, list only in Section 1
<b>Study Duration:</b>	Provide time from when the study opens until the monitor completes the close out visit.
<b>Subject Participation Duration:</b>	Provide time it will take to conduct the study for each individual participant.
<b>Description of Agent or Intervention:</b>	Include dose and route of administration
<b>Objectives:</b>	Copy objectives and clinical/laboratory outcome measures from the appropriate sections of the protocol. Include primary/secondary outcome measures and method by which outcome will be determined.  Primary:  Secondary:
<b>Description of Study Design:</b>	This schematic should provide an overview of the study design, including study arms, sample size and schedule of interventions (e.g., vaccine administration), if applicable;



# Study Schema



# Study Schema: Dose Escalation Study (Phase I)

Dose Escalation Schedule	
Dose Level	Dose of [IND Agent]*
Level 1	
Level 2	
Level 3	
Level 4	
Level 5	

\* Doses are stated as exact dose in units (e.g., mg/m<sup>2</sup>, mcg/kg, etc.) rather than as a percentage.

# Schedule of Events / Activities (SOE)

	Pre-screening (Pre-consent)	Visit 1 Day 1	Visit 2 Day 14 ±7	Visit 3 Day 28 ±7	Visit 4 Day 42 ±7	Visit 5 Day 56 ±7	Visit 6 Day 365 ±30	Unscheduled Visit
EMR Review Eligibility	X							
Informed Consent		X						
Demographics		X						
Clinical history		X					X	
Height & Weight		X	X				X	
Outcome Evaluation								
Assessment		X			X		X	X
Questionnaire		X	X	X	X	X	X	
Randomization		X						
Control & Experimental Interventions		X	X	X	X			
Adverse Events Reporting		X	X	X	X	X	X	X

# Introduction

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## Study Rationale

*(state the problem or research question)*

## Background

*(summary of relevant clinical research)*

## Known Risks

*(potential risks from clinical or nonclinical studies )*

## Known Potential Benefits

*(relevant published data)*

# Background/Rationale

## Before:

Condition P is common and causes enormous human suffering and societal cost. P is the leading cause of psychiatric morbidity among minority US women. There is a need for culturally sensitive P treatments that can reach large numbers of women. This study proposes to use a mobile device app to deliver intervention for P.

# Background/Rationale

## What SRC Reviewers Look For...

There must be **thoughtful justification** for conducting a study. It should draw upon results from **previous or pilot studies** and investigator experience to identify knowledge gaps, and devise a strategy to answer one or more questions - while maximizing resources and minimizing burden on participants.

# Background/Rationale

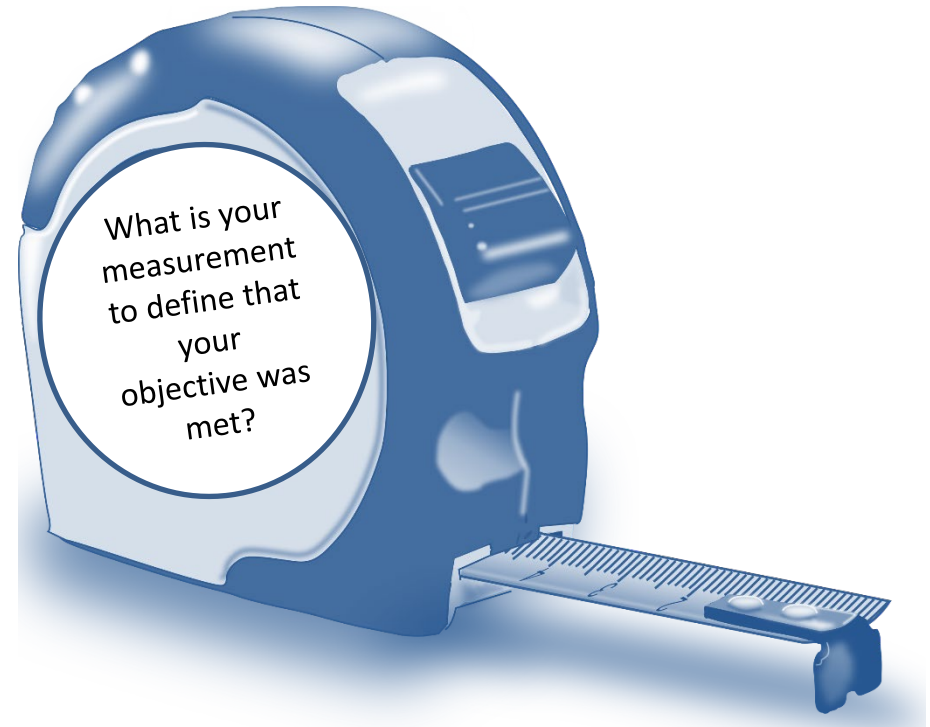
## After:

Childbirth is a potent trigger for the condition, P, with potentially harmful outcomes for mother and child. Prevalence of P is estimated at 5% in Western societies but may be as high as 35% in minority women living in the southeastern US, especially among women in rural counties. The main feature of P is depression. Six of 8 women in our pilot feasibility study found the mobile app (called P-I) easy to use and helpful for dealing with feelings of depression. This study will assess feasibility and efficacy of P-I for mothers with P living in rural NC.

# Study Objectives & Endpoints



What answers are you searching for through the conduct of your study?





# Study Design

## General Overview of the Study Features

**Type:** Randomized Clinical Trial, Observational, Cross-sectional, Parallel arm, Open-label  
Single site or multi-site (and # sites)

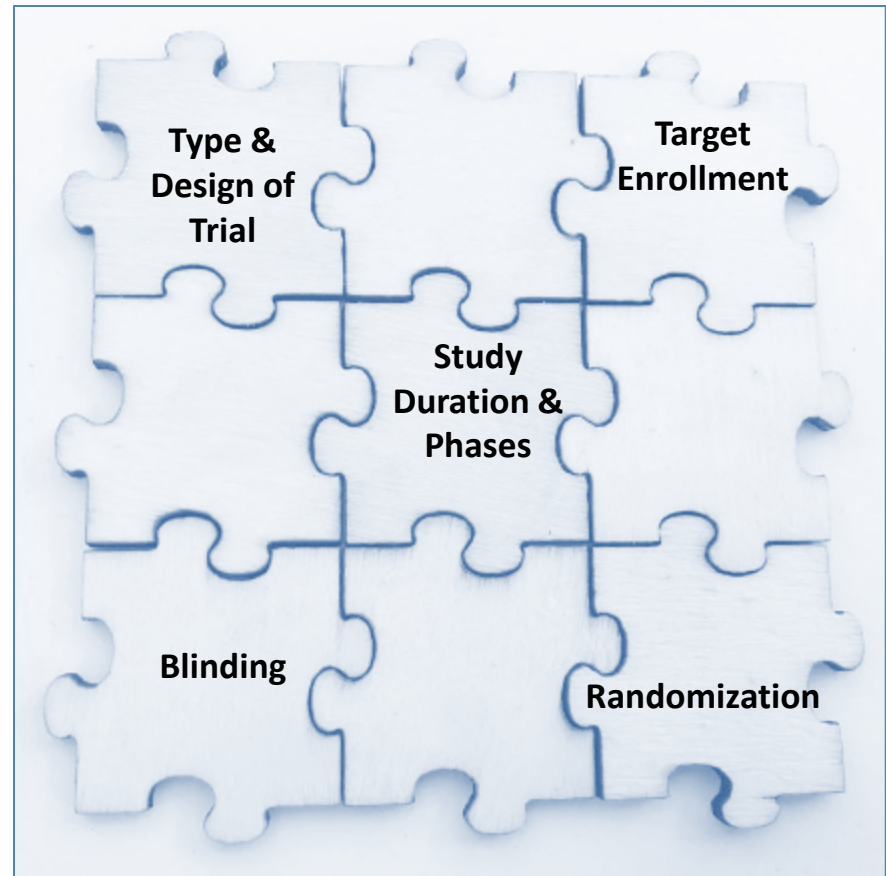
**Target:** # of participants, # of groups/arms

**Randomization:** method for assigning participants to study groups/arms

**Blinding:** Will there be blinding, who blinded (PI, subjects?)

**Duration:**

- Screening/baseline
- Intervention/treatment
- Follow up, Unscheduled visits



# Study Population

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## Eligibility Criteria

### Inclusion & Exclusion Criteria

- All aspects of selection procedures
- Specific criteria on who is and is not eligible
- I/E criteria both for scientific and safety purposes

## Recruitment Retention

### Strategies

- Summarize, can refer to detailed plan in manual of procedures
- TraCS Support
  - ❖ Recruitment Specialist (Emily Olsson)
  - ❖ Community & Stakeholder Engagement (Alicia Bilheimer)

# Recruitment Strategy

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What are the strategies for achieving adequate participant enrollment in order to reach the proposed sample size?



# Study Intervention

## Drug



## Device



## Behavior Modification



This section has sub-sections to describe.....

- administration of the study intervention, dosing, or info on the experimental manipulation
- preparation handling and storage of the product or device,
- randomization & blinding, placebo/control
- intervention compliance

# Study Assessments and Procedures

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- **Efficacy Assessments** (evaluations done to support determination of **efficacy of the intervention** on study endpoints)
  - Biological specimen collection, PKs, physical measures
  - Assessments of intervention adherence
  - Survey and interview data
  
- **Safety Assessments** (study procedures and evaluations done to **monitor safety**)
  - Physical Exams, Vital signs, EKGs, X-rays
  - Laboratory evaluations
  - Adverse event monitoring

# Adverse & Serious Adverse Event Section

---

Include descriptions **specific** to your study (not boilerplate)

- Plan on how AEs / SAEs will be assessed by study team
- Specific events to monitor, based on what is known & expected from intervention (e.g., kidney or liver affects)
- Events that lead to stopping intervention in participant
- Events leading to stopping entire study
- Classification scale to evaluate severity of adverse events
  - e.g., GI side effects → nausea, vomiting, hosp. for dehydration

# Evaluating Severity of AEs

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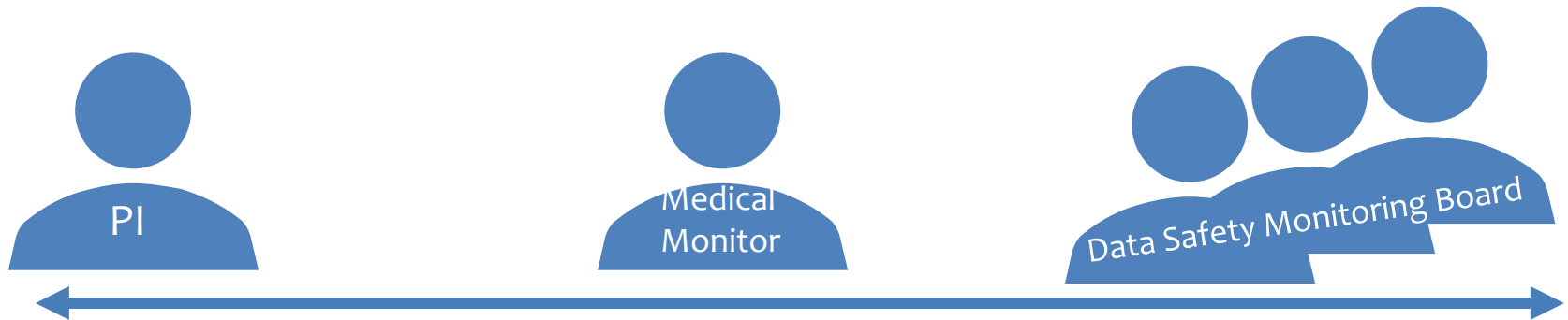
When it comes to evaluating adverse events, you should have a scale to grade the **severity**, a **classification scale**.

- Mild-Moderate-Severe Scale
- CTCAE scale (5 levels of severity)
- DAIDS AE Grading Table
- Other Specific Scale

The classification scale should be described in the protocol and used consistently for all subjects and by all investigators.



# Safety Oversight



- Who would be providing the safety oversight?
- What are their responsibilities?
- What are the frequencies for when the reviews would be done?
- What data would they review to decide if the study was safe to continue?



# Safety Management-Monitoring

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## Before:

No new safety evaluations will be implemented as the intervention is a reduction of doses compared to current practice. We do not anticipate any moderate or severe AEs from the intervention as compared to the usual care group. However, AEs will be monitored and recorded in both treatment groups.

# Safety Management - Monitoring

## What SRC Reviewers Look For...

When conducting a high risk research study, it is recommended to have independent Data Safety Monitoring (board or medical monitor) with *a priori* stopping rules. Such stopping rules should be **safety based** and not necessarily based on statistical numbers at interim review. This is especially important when the sample size is small and the literature suggests large variations in response.

# Safety Management - Monitoring

## After:

Dr. [x] and Dr. [y], both board-certified and not otherwise involved in the study or treatment decisions, will serve as independent safety monitors. AEs will be reported to the IRB and safety monitors through regular progress reports. In addition, AE reports will be generated every 3 mo. or after 20 participants are enrolled, whichever comes first. If any of the following are met in either arm we will suspend the study to investigate: death at 30 days-20%; pleural hemorrhage-15%; increase in pain medications-50%.

# Consent Process

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- Where will participants be consented?
- Is there any consent training required for the staff?
- Does your consent process require any waivers?
- Will interpreters be needed?
- Are you enrolling decisionally impaired individuals?
- What is the process for re-consent?



# Study Team, Oversight, Monitoring

- What does your study team consist of? (PI, SC, research nurse etc...)
- Is there a manual of procedurals (MOP)?
- How is the conduct of the study being monitored?
- Who is responsible for monitoring your study?
- What is your process for ensuring the rights & welfare of study participants?
- Is there a clinical monitoring plan?



# Questions/Discussion

Any questions we do not get to will be compiled into a Q&A document and distributed to registered attendees.

Also, email [joyce\\_lanier@med.unc.edu](mailto:joyce_lanier@med.unc.edu) if you would like to submit a question for the Q&A document or be included in distribution.

Thank you!

# Protocol Development Workshop – Day 2

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Study Design

Statistics

SRC Problem Spots

CT.gov Registration & Results reporting

# Workshop Evaluation

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- Please use the link provided to complete the online evaluation. Your comments are especially helpful as we update and improve the workshop for future sessions.
- If you would like an attendance certificate, which includes the equivalent of 2.0 Clinical Research Education Contact Hours, please complete the evaluation and email [joyce\\_lanier@med.unc.edu](mailto:joyce_lanier@med.unc.edu)



# Workshop Evaluation QR Code

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## Workshop Evaluation Link:

[https://unc.az1.qualtrics.com/jfe/form/SV\\_5zhykCE1KeVtaSO](https://unc.az1.qualtrics.com/jfe/form/SV_5zhykCE1KeVtaSO)

Thank you!

# Websites, Links, Resources

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- PRC Website: <https://unclineberger.org/protocolreview/>
  - [kaitlin\\_morrison@med.unc.edu](mailto:kaitlin_morrison@med.unc.edu); [stacy\\_maxwell@med.unc.edu](mailto:stacy_maxwell@med.unc.edu),  
[christinegrace\\_narag@med.unc.edu](mailto:christinegrace_narag@med.unc.edu)
- SRC Website: <https://research.unc.edu/clinical-trials/scientific-review-committee/>
- UNC CT.gov information: <https://research.unc.edu/clinical-trials/clinical-trials-gov/overview-policy/>
  - Monica Coudurier - [m\\_coudurier@unc.edu](mailto:m_coudurier@unc.edu)
  - Melahat Canter - [gmelahat@email.unc.edu](mailto:gmelahat@email.unc.edu)
- Recruitment Resources at TraCS:
  - Recruitment Specialist (Summer Choudhury, [summer.choudhury@unc.edu](mailto:summer.choudhury@unc.edu))
  - Community & Stakeholder Engagement (Alicia Bilheimer, [alicia\\_bilheimer@med.unc.edu](mailto:alicia_bilheimer@med.unc.edu))
  - Inclusive Science Program (Laura Villa Torres) [villal@unc.edu](mailto:villal@unc.edu)
  - UNC Health Science Library guide  
<https://guides.lib.unc.edu/c.php?g=787212&p=5636824>

# References

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- Best Practices in Clinical Research Protocol Writing: Eight tips from an IRB member. [10 Kinetiq WP BestPracticesinClinicalResearchProtocolWriting-EighttipsfromanIRBmember\\_020416-1.pdf \(usc.edu\)](http://www.kinetiq.com/wp-content/uploads/2016/02/BestPracticesinClinicalResearchProtocolWriting-EighttipsfromanIRBmember_020416-1.pdf)
- Minnesota Department of Health. Different Ways to Write SMART Objectives. <http://www.health.state.mn.us/divs/opi/qi/toolbox/objectives.html>
- SPIRIT Group:
  - <http://www.spirit-statement.org/about-spirit/>
  - <http://www.spirit-statement.org/publications-downloads/>
- Protocol Writing in Clinical Research. [J Clin Diagn Res](#). 2016 Nov; 10(11): ZE10–ZE13. Published online 2016 Nov 1. doi: [10.7860/JCDR/2016/21426.8865](https://doi.org/10.7860/JCDR/2016/21426.8865). PMID: [28050522](https://pubmed.ncbi.nlm.nih.gov/28050522/)
- Rho Protocol Design presentation: <https://www.slideshare.net/BrookWhitePMP/protocol-design-development-what-you-need-to-know-to-ensure-a-successful-study>
- Workshop by Paul Stewart: [Designing Your Research Study: Essential concepts, Best practices, Pitfalls, Speedy IRB approval](#)