

CLINICAL TRIALS METHODOLOGY WORKSHOP

Course Orientation and Overview

Course Co-Directors:

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1

Schedule Overview

- Lectures each morning
- Protocol Development Groups
 - Daily PDG sessions in late AM/early afternoon
- Schedule has time to work on protocols each day so you can pay attention during the lectures!
- Homework due most evenings

2

Protocol Templates

- Modified NIH templates for imaging trials and interventional trials (<https://osp.od.nih.gov/clinical-research/clinical-trials/>).
- Color-coded by due date:
 - Orange Font: Draft due Sunday
 - Green Font: Draft due Tuesday
 - Blue Font: Draft due Wednesday
 - Purple Font: Final draft due Friday
 - Grey Font: Supplemental Material (Not required for course)
- Major shout-out to Dr. Susanna Lee & team for this

3

2023 RSNA Clinical Trials Methodology Workshop
January 7 – 13, 2023
Coronado Island Marriott Resort & Spa
San Diego, California

LEARNING OBJECTIVES and FINANCIAL DISCLOSURE STATEMENT	
WORKSHOP AGENDA	
INSTRUCTIONS FOR THURSDAY EVENING POSTER SESSION	
2023 CTMW FACULTY & BIOS	
2023 STUDENT CATALOG	
PRE-COURSE REQUIREMENT - CHECKLIST PRE-COURSE RECOMMENDED READING ELIGIBILITY CRITERIA EXAMPLES	SUPPLEMENTAL BIBLIOGRAPHY STATISTICAL CONCEPTS SERIES FUNDAMENTALS OF CLINICAL RESEARCH FOR RADIOLOGISTS
CTMW 2023 STUDENTS	CTMW 2023 FACULTY

Templates and Sample Documents

→ [Guided version \(Detailed instructions included\)](#)

- [Diagnostic Imaging Protocol Template](#)
- [Imaging Therapy Trials Protocol Template](#)
- [Schedule of Activities Template](#)

[Informed Consent](#)
[Template for Basic Elements of Informed Consent](#) [Screenshot](#)

<https://www2.rsna.org/re/CTMW2023/index.htm>

4

Imaging vs. Therapy

Imaging Template

- Diagnostic accuracy
- Biomarker
- Screening

Therapy Template

- Treatment

5

Instructions on Template Use



1. Each section contains
 - a. Explanation of expected content *in italics*. Please read them.
 - b. Sample content imbedded in [brackets]
 - c. <Carrots> indicates where you write content
2. Upon completing each section:
 - a. Remove instructional and sample text
 - b. Change font color to black
3. Update the TOC

6

Select TOC by clicking on it

Table of Contents		
1	PROTOCOL SUMMARY.....	1
1.1	Synopsis	1
1.2	Schema	2
1.3	Schedule of Activities (SoA)	2
2	INTRODUCTION.....	2
2.1	Study Rationale	2
2.2	Background	2
2.3	Risk/Benefit Assessment	2
3	STUDY DESIGN.....	2
3.1	Overall Design	2
4	OBJECTIVES AND ENDPOINTS (OUTCOME MEASURES).....	2
5	STUDY POPULATION.....	2
5.1	Inclusion Criteria	2
5.2	Exclusion Criteria	2
5.3	Strategies for Recruitment	2
6	STUDY INTERVENTION.....	2
6.1	Study Intervention(s)	2
6.2	Measures to Minimize Bias: Randomization and Blinding	2
6.3	Concomitant Therapy	2
7	STUDY EFFICACY AND SAFETY ASSESSMENTS.....	2
7.1	Efficacy Assessments	2

7

Update page numbers only

Table of Contents		
1	PROTOCOL SUMMARY.....	1
1.1	Synopsis	1
1.2	Schema	2
1.3	Schedule of Activities (SoA)	2
2	INTRODUCTION.....	2
2.1	Study Rationale	2
2.2	Background	2
2.3	Risk/Benefit Assessment	2
3	STUDY DESIGN.....	2
3.1	Overall Design	2
4	OBJECTIVES AND ENDPOINTS (OUTCOME MEASURES).....	2
5	STUDY POPULATION.....	2
5.1	Inclusion Criteria	2
5.2	Exclusion Criteria	2
5.3	Strategies for Recruitment	2
6	STUDY INTERVENTION.....	2
6.1	Study Intervention(s)	2
6.2	Measures to Minimize Bias: Randomization and Blinding	2
6.3	Concomitant Therapy	2
7	STUDY EFFICACY AND SAFETY ASSESSMENTS.....	2
7.1	Efficacy Assessments	2

Update Table of Contents

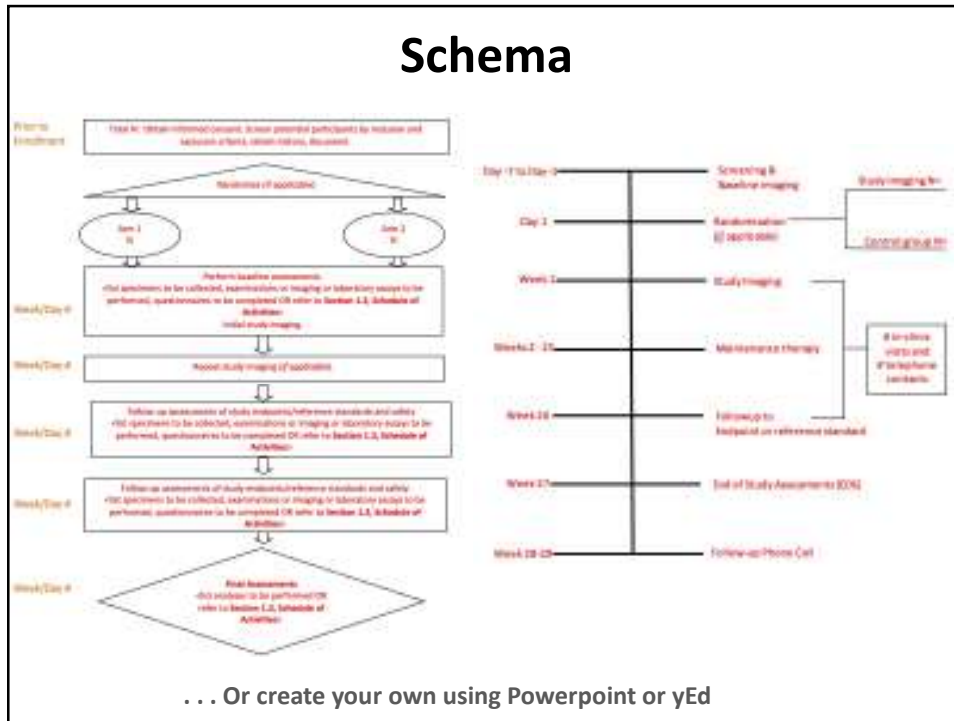
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Update page numbers only

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8



9

Schedule of Activities

1.3 | SCHEDULE OF ACTIVITIES (SOA)

The schedule below is provided as an example and should be modified as appropriate. It is available as a separate Excel file for students to edit and report.

The schedule of activities must capture the procedures that will be accomplished at each study visit, and all contact with study participants e.g., telephone contacts. This includes any tests that are used for eligibility, participant randomization or stratification, or decisions on study allocation. Only include procedures that contribute to participant eligibility and study objectives and endpoints. Allowable activities should be stated for all visits.

	Visit 1 Day 1-3	Visit 2 Day 7-10	Visit 3 Day 14-17	Visit 4 Day 21-24	Visit 5 Day 28-31	Visit 6 Day 35-38	Visit 7 Day 42-45	Visit 8 Day 49-52	Visit 9 Day 56-59	Visit 10 Day 63-66	Visit 11 Day 70-73	Visit 12 Day 77-80	Visit 13 Day 84-87	Visit 14 Day 91-94	Visit 15 Day 98-101	Visit 16 Day 105-108	Visit 17 Day 112-115	Visit 18 Day 122-125	Visit 19 Day 132-135	Visit 20 Day 142-145
Eligibility																				
Screening	X																			
Randomization	X																			
Baseline assessment	X																			
Study Imaging		X																		
Follow-up to hospital or reference standard			X																	
End of Study Assessments (EOS)																				
Follow-up Phone Call																				
Other assessments e.g., laboratory tests, questionnaires	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

10

Deliverables (1)

- Sun PM: Protocol Concepts due
 - Schema
 - Background
 - Objectives
 - Selection criteria
 - Study overview
- Mon PM: Revised Concepts may be due
- Tues PM: Draft Protocol due
 - Edits to concept components
 - Study procedures
 - Data analysis
 - Preliminary statistical plan



11

Deliverables (2)

- Wed PM: Near Final Document
 - Informed consent form (ICF) elements due
 - Revised protocols may be due;
 - Final statistical plan
- Thu PM: Poster due
- Fri AM: Final Protocol due (electronically)
- Course evaluations



12

Protocol Templates

- This template is a comprehensive compilation of all the issues that might need to be addressed in a clinical trial protocol
- Not all of the sections apply to every protocol.
- The Protocol Development Group (PDG) discussions will help you decide which issues are specifically relevant to your protocol.

13

What students struggle with

NIH Definition of a Clinical Trial

- A research study in which human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes

14

What students struggle with: Objectives, Outcomes, and Hypotheses

- **Objectives** are the Aims or Goals of the study
- An **objective** is the purpose for performing the study in terms of the scientific question to be answered. Express each objective as a statement of purpose (e.g., to assess, to determine, to compare, to evaluate) and include the general purpose (efficacy, diagnostic accuracy, safety) and/or specific purpose (superiority to control, effect of an intervention on disease incidence, disease severity, or health behavior).
- One **Primary Objective** drives the study design. May have many secondary and tertiary (exploratory) objectives.

15

What students struggle with: Objectives, Outcomes, and Hypotheses

- An **outcome** measure (or endpoint) is a specific measurement or observation to assess the effect of the study variable (study intervention). Study endpoints should correspond to the study objectives and hypotheses being tested.
- *Give succinct, precise definitions of the study endpoints used to address the study's primary objective and secondary objectives (e.g., specific imaging measures and clinical/pathologic data that define safety or efficacy, clinical assessments of disease status, patient reported outcomes, etc.*
- Every **Objective** has a corresponding **outcome measure**

16

What students struggle with:

Objectives, Outcomes, and Hypotheses

- The Primary Objective must have an associated **hypothesis**. This will determine the statistical methods and sample size required to perform the study.
- Secondary Objectives may or may not have associated hypotheses. Study will not be powered for these. May be exploratory or correlative.

17

Other amazing benefits of this course

- Mon 3:00 – 5:30 PM **One-on-one sessions with faculty**
 - Meet with faculty from other PDGs for advice on protocol or life
- Mon 6:30 – 8:00 PM Informal dinner, students and faculty
- Tues 2:45 – 4:45 PM **More one-on-one sessions with faculty**
- Wed 3:30 – 4:30 PM **One-on-one sessions with Stats faculty**
- Thu 12:00 – 1:00 PM Post-test
- Thu 1:00 – 5:30 PM Set up posters
- Thu 6:00 – 7:00 PM Reception and poster session
- Thu 7:00 – 9:00 PM Closing dinner and Trivia Quiz Reveal
 - Trivia Quiz may be entered individually or as a PDG group
 - Unending glory and cheesy prizes to the winners. This could make your career
- Fri 8:00 AM Final protocols due (electronic submission)



18

Suggestions for a Great Week

- Show up
- Pay attention
- Participate in all discussions – especially in PDGs
- Turn in deliverables on time
- Seek new mentors
- Have fun & meet new people

19

Protocol Development Groups

PDG 1	Dr. Schnall	<i>Coronado 7</i>
PDG 2	Dr. Thomas	<i>Coronado 2</i>
PDG 3	Dr. J. Lee	<i>Coronado 3</i>
PDG 4	Dr. S. Lee	<i>Coronado 4</i>
PDG 5	Dr. Carlos	<i>Coronado 5</i>



20