CLINICAL TRIALS METHODOLOGY WORKSHOP

Course Orientation and Overview

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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

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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

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

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Imaging vs. Therapy

Imaging Template

- **Diagnostic accuracy**
- **Biomarker**
- **Screening**

Therapy Template

- **Treatment**

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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**

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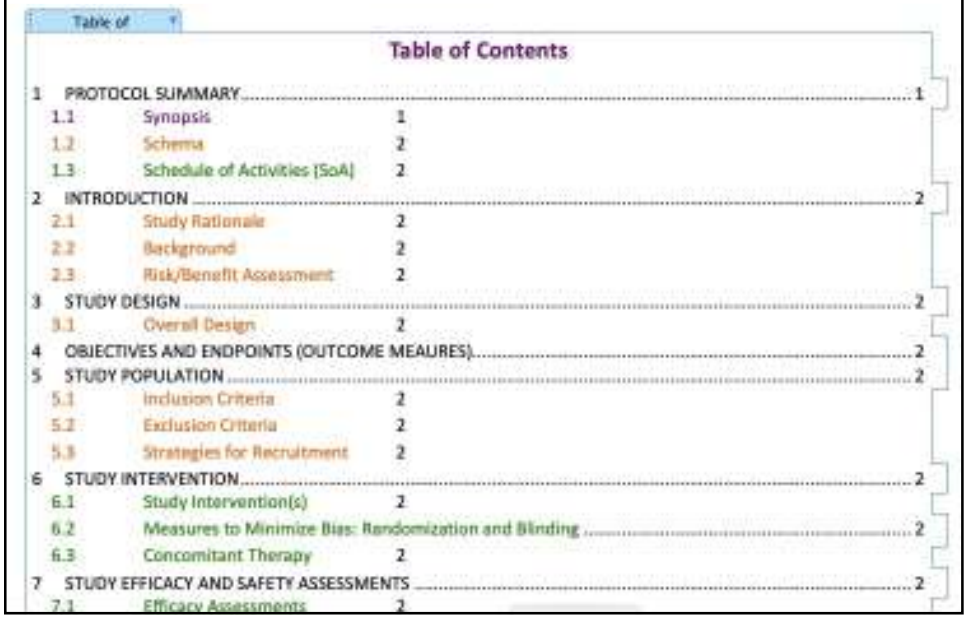
Select TOC by clicking on it



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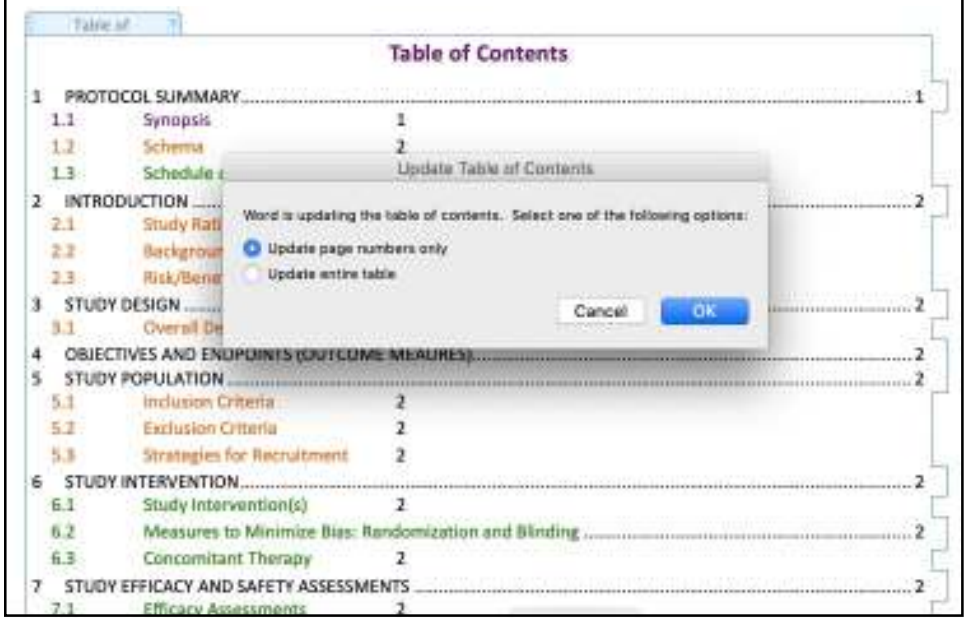
Update page numbers only



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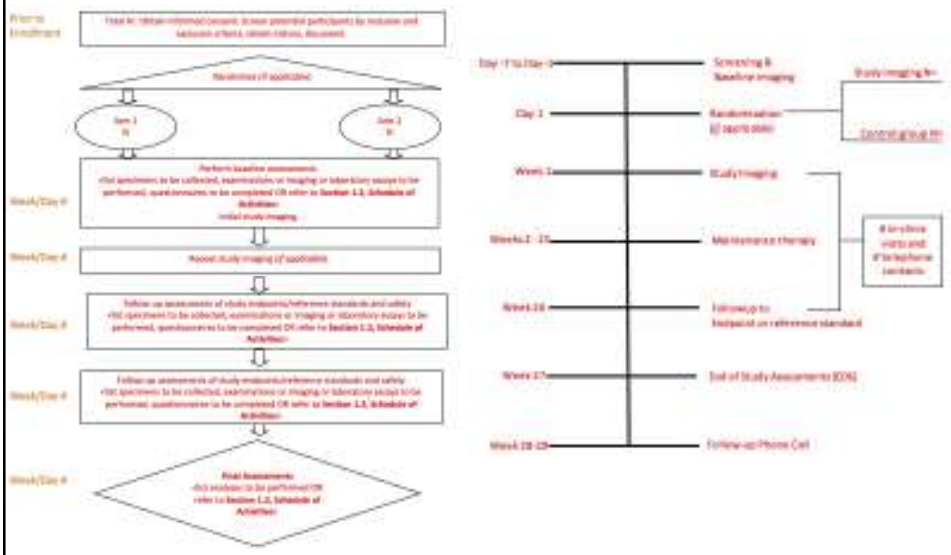
Schema



. . . Or create your own using Powerpoint or yEd

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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 import.

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 discontinuation. Only include procedures that contribute to participant eligibility and study objectives and endpoints. Allowable windows should be stated for all visits.

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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

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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

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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.

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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

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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.

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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*

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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.

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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)

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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

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Protocol Development Groups

PDG 1	Dr. Schnall	*Coronado 7*
PDG 2	Dr. Thomas	*Coronado 2*
PDG 3	Dr. J. Lee	*Coronado 3*
PDG 4	Dr. S. Lee	*Coronado 4*
PDG 5	Dr. Carlos	*Coronado 5*

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