

How to Read & Review a Clinical Trial Protocol

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Information from Nancy Roach/ACRIN project IMPACT

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Overview

- ❖ Why our review is important
- ❖ Basics
- ❖ Practice

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Why our Review is Important

- ❖ Scientists focus on questions they want answered
- ❖ We provide a reality check on what is actually do able
- ❖ Paper Trail:
 - ❖ Comments on conference calls may not be captured
 - ❖ No record of advocate concerns/support
 - ❖ No way to track if our concerns where incorporated into final protocol
 - ❖ No way to track if our concerns / if not dealt with impact study
 - ❖ No way to capture our accountability to process

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Structure of all Protocols

- ❖ Background / Introduction
- ❖ Study Hypothesis
- ❖ Study Design / Protocol Development
- ❖ Rationale / Study Objective
- ❖ Eligibility
- ❖ Preliminary Statistical Design
- ❖ Feasibility
- ❖ Schema / Flowchart
- ❖ Informed Consent Process
- ❖ Communication Plan
- ❖ Dealing with Results / other

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Background / Introduction

- ❖ What is the question?
- ❖ What is the value of the answer to patients?
- ❖ Will having the answer help patients live longer / live better? If yes, how?
- ❖ How long will it take to complete the trial;
- ❖ Will the answer be relevant when the trial is completed?
- ❖ Does the trial fit into a strategic plan or initiative
 - ❖ Such as NCI Progress Review Group recommendations
 - ❖ ACOSOG committee plan?

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Study Hypothesis

- ❖ Define the Specific Hypothesis: so you understand it
- ❖ Indicate what kind of study it is
 - ❖ Treatment
 - ❖ QOL
 - ❖ Surgery
 - ❖ Imaging
 - ❖ Prevention
 - ❖ New dosing
 - ❖ New order drugs are given
 - ❖ ?

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Study Design / Protocol Development

- ❖ How does the study design compare to standard of care
- ❖ Do you feel that demands on patients are reasonable when compared to standard of care? (Yes/No)
- ❖ Are correlative studies included? Push for them
- ❖ Will this study be conducted in community settings?

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Rationale / Study Objective

- ❖ **What are the formal trial endpoints?**
- ❖ **Do they compare to the goals in the hypothesis?**
 - ❖ For example, if the hypothesis states that the trial will increase survival, but the endpoints don't include survival, why not?

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Eligibility

- ❖ Who's included
- ❖ Who's excluded
- ❖ Do you think that the trial population is representative of the patient population?
- ❖ Will the study be open in sites with diverse populations?

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Preliminary Statistical Design

- ❖ If the trial examines more than one treatment, are participants randomized to a single treatment
- ❖ Is crossover allowed whereby participants may receive some or all of the treatments being studied?
 - ❖ Why or why not
 - ❖ do you agree with the trial design?

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Feasibility

- ❖ Do you think patients will be interested in enrolling? (Yes/No)
- ❖ Do you think the numbers expected to enroll are reasonable? (Yes/No)
- ❖ Are there specific aspects of the trial that you think will make accrual more difficult?
- ❖ Diversity:
 - ❖ Is there a plan to include a diverse population to this study? (Yes/No)
 - ❖ Will the trial be open at sites with diverse populations? (Yes/No)

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Schema / Flowchart

- ❖ Is the schema designed in a patient-friendly form?
- ❖ Reading left to right, not top to bottom? (Yes/No)
- ❖ Other specific comments on how to make it as patient-friendly as possible?

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Informed Consent Process

- ❖ Does the protocol describe the informed consent process to be used and not just include a form? (Yes/No)
 - ❖ Supplemental patient materials? (Yes/No)
 - ❖ Training for CRAs and physicians? (Yes/No)
 - ❖ Follow-up materials? (Yes/No)
- ❖ Is the informed consent based on the new NCI template? (Yes/No)
- ❖ What happens in the event of an injury: who pays? Is this clear?
- ❖ What grade level is the informed consent written at?
- ❖ Any correlative study sections (i.e. tissue or quality of life) should be at the end of the main consent, but before the signature page. Do any tissue consent pages have separate sections to:
 - ❖ Enroll in this study? (Yes/No)
 - ❖ Use patient's tissue for future studies? (Yes/No)
 - ❖ Contact patient / Do not contact patient? (Yes/No)

Communication Plan

- ❖ Has a communication plan been identified? (Yes/No)
- ❖ Have needed communication/recruitment materials been identified? (Yes/No)
- ❖ Has a timeline been established for production and distribution? (Yes/No)
- ❖ Record any suggestions for additional communication materials / strategies.

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Dealing with Results / other

- ❖ What is the plan to communicate trial results to patients and health care professionals?
- ❖ Does this seem appropriate/adequate?
- ❖ Insure that both positive and negative results are published

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Thank You

Coalition of Cancer Cooperative Groups

ACOSOG

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