The Protocol Review

Presented by Amy Good, PhD

8:30am-9:30am

UW Husky Union Building

Room 145

THE PROTOCOL REVIEW:

How to Read for Both the Big Picture and Your Responsibilities in Implementing a Study

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UW Clinical Trials Office/Institute of Translational Health Sciences

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Learning Objectives

By the end of the session, you will be able to:

- Describe your role as the liaison between the study and the public
- Discuss which components of the protocol are most relevant for study execution by study staff
- Identify components in the protocol that facilitate the creation of study checklists

Protocols

- Industry vs grant funded protocols
- For today, focus is on time of implementation; start-up and approvals are completed

Protocols

Why is the protocol important?

- Road map, source of information for study execution.
- The big picture: you are the liaison between the study team and the participants, and between the study and the public.

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The Why of the Protocol

2. BACKGROUND INFORMATION AND SCIENTIFIC RATIONALE

3. OBJECTIVES/STUDY AIMS

- Primary objective
- The primary objective of this study is to evaluate the effect of a dietary supplement, given as an oral tablet, on muscle energetics as measured by a muscle fatigue test in elderly subjects.

- Secondary objective
- The secondary objectives of the study are to assess the safety and tolerability of a single oral dose of the supplement in elderly subjects.

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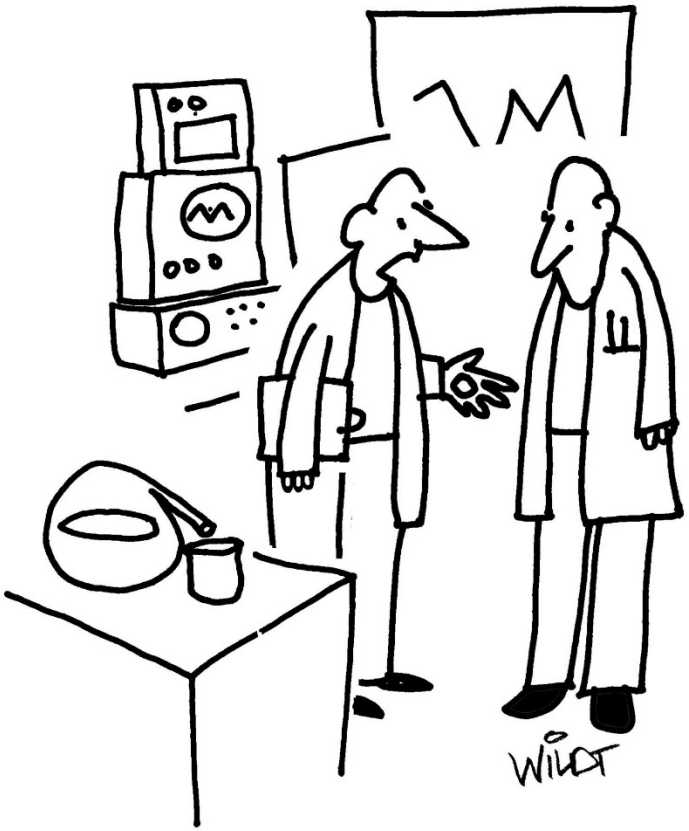
The How of the Protocol

4. STUDY DESIGN



"They want us to double check our methodology.
Your turn to flip."

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The How of the Protocol

STUDY DESIGN

- A Phase 2 randomized, double-blind, placebo-controlled study to evaluate the impact of a dietary supplement on muscle function in the elderly

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The Who of the Protocol

5. PARTICIPANT SELECTION

- Participant Inclusion Criteria
- Participant Exclusion Criteria

6. RECRUITMENT PLAN

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The When, What, and Where

7. **STUDY INTERVENTION**
8. **VISIT SCHEDULE AND ASSESSMENTS**

Assessment specifics

- Familiarize yourself with these
- Can you experience the assessments yourself?
  - Diaries
  - Questionnaires
  - 6-minute walk test
  - Neurocognitive assessments
  - Procedures: can you observe?

Schedule of Events

Parameters	Screening	Baseline Visit 1[a]	Visit 2 (Day 21)	Visit 3 (Day 60)
Informed consent	X			
Pulmonary Function Tests	X			X
6 minute walk test	X			X
Inclusion and exclusion criteria	X			
Medical history	X			
Physical examination	X			X
Height and Weight	X			X
Laboratory – CBC, chemistry panel	X			X
Laboratory – serum biomarkers[b]		X	X	X
Laboratory – liver function tests		X		X
ECG	X			X
Vital Signs[c]	X	X	X	X
Study Product Dispensed		X	X	
Peak Flow Meter[d]	X	X	X	X
Review Exercise Diary		X	X	X
Quality of Life Questionnaires		X		X
Concomittent Medications	X	X	X	X
Adverse Events		X	X	X

a Should occur no more than 14 days after screeing visit
b Participant should be fasting
c To include heart rate, blood pressure, temperature, and respiratory rate
d Peak flow meter dispensed at screening visit for home use; reviewed at study visits

The When, What, and Where

Labs and specimen processing

- Lab medicine vs research testing service (RTS)
- Watch out for aggregate labs
  - Comprehensive metabolic panel

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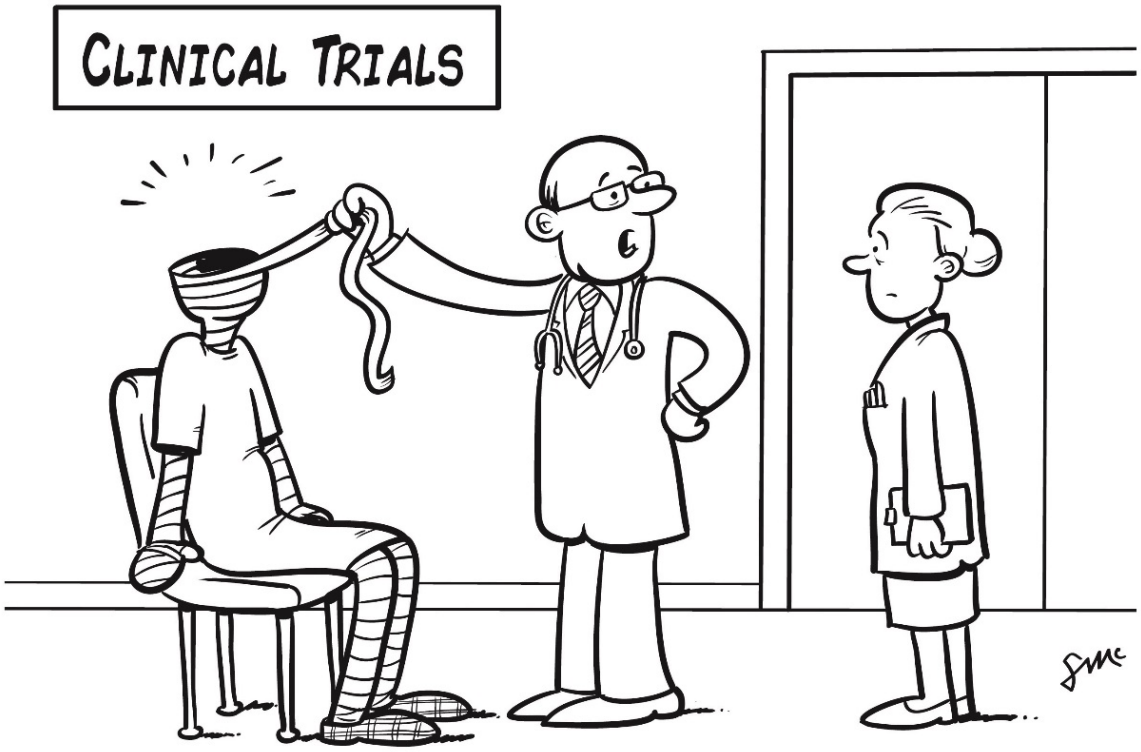
Safety

9. ASSESSMENT OF SAFETY

- **Adverse Event**
- **Serious Adverse Event**

Reporting requirements

- To whom
- By when
- Requirements vary



"So I guess this probably counts as an adverse event."

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Appendices

13. APPENDICES

- Schedule of events
  - Footnotes!

- Lab manual
  - Processing times

Participant Visits

What, who, when, and where?

Mental run-through; think it through.

Where do you start?

- Checklists
- Participant binders
- Equipment, questionnaires, study assessments

Participant Visits

Traveling kit

- Checklists
- Protocol
- Schedule of events
- Extra consent forms
- Post-its and pens
- Assessments/questionnaires
- Lab manual

Learning Objectives

- Describe your role as the liaison between the study and the public
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Increase Study Success Through Integration of Team Science

Presented by Jennifer Sprecher & Nicole Summerside

9:40am-10:40am

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