Introduction to Clinical Research **Boot Camp 2021**

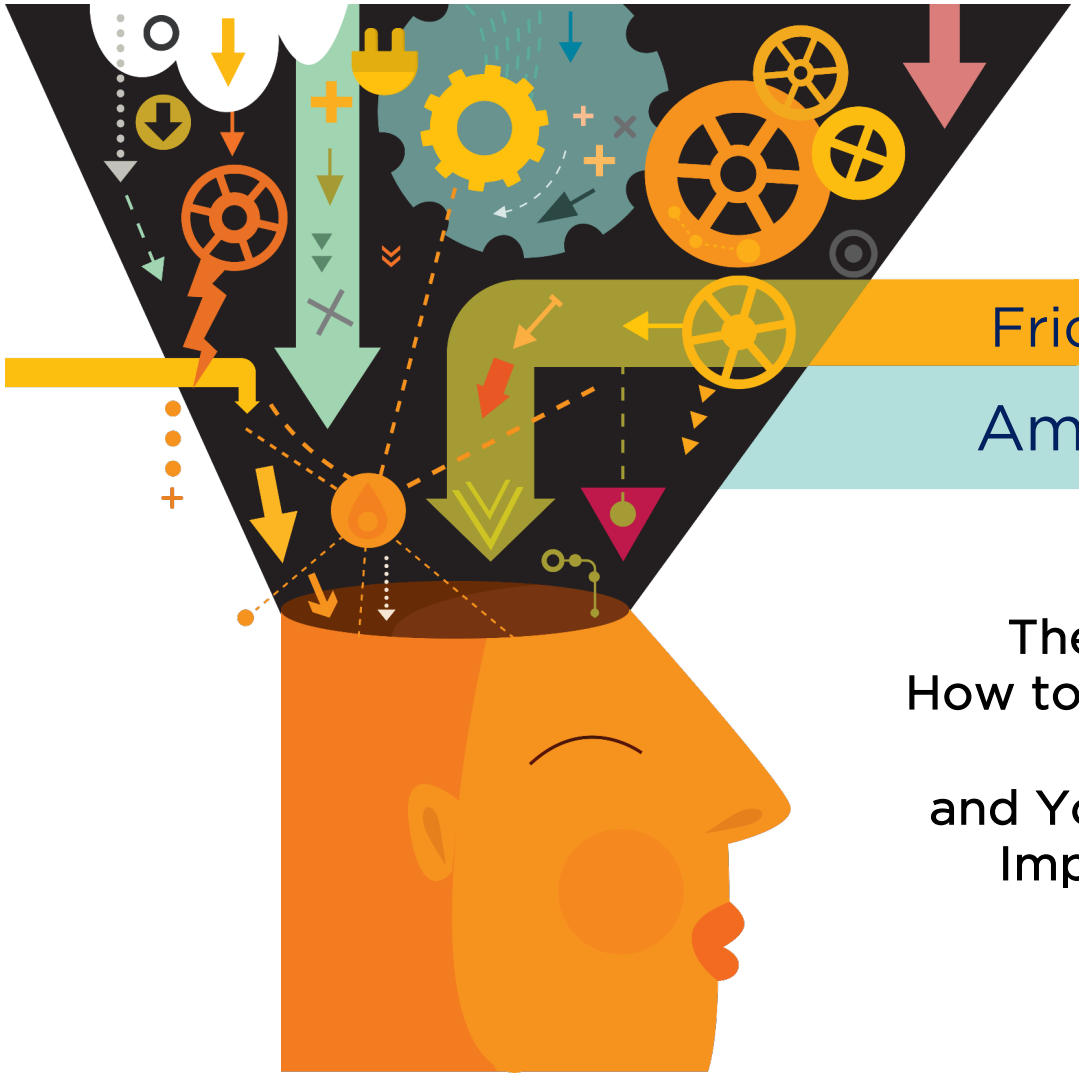
Research Staff

July 19-23

12:00-1:00pm PDT

ITHS | Institute of Translational Health Sciences

ACCELERATING RESEARCH. IMPROVING HEALTH.



Friday, July 23, 2021

Amy B. Good, PhD

The Protocol Review: How to Read for Both the Big Picture and Your Responsibilities in Implementing a Study

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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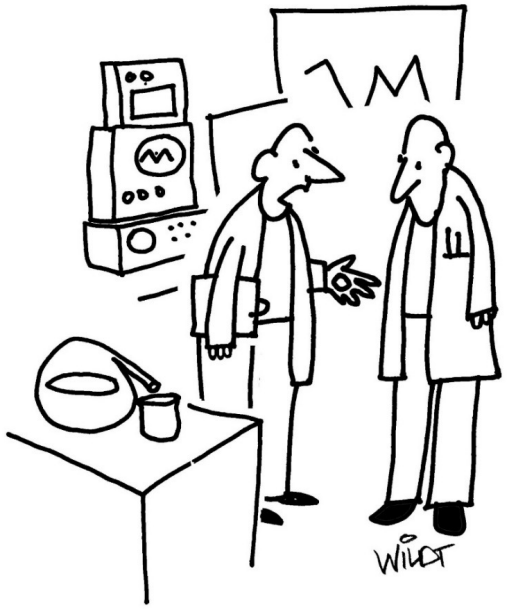
The How of the Protocol

4. STUDY DESIGN



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

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 Criter
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?

APPENDIX 1 - 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
Concomitant 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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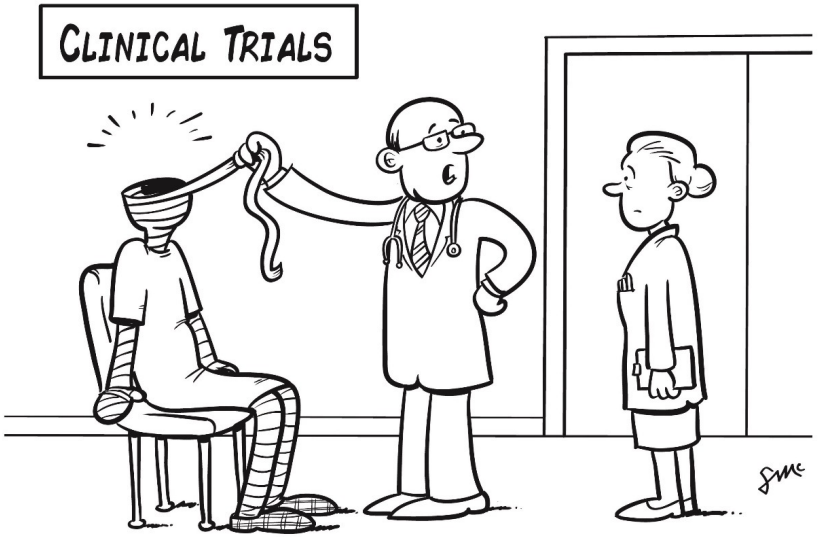
Safety

9. ASSESSMENT OF SAFETY

- Adverse Event
- Serious Adverse Even

Reporting requirements

- To whom
- By when
- Requirements vary



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

CartoonStock.com

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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

Questions For You

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1. SAM-E PLASMA PHARMACOKINETICS SAMPLE PREPARATION

SAM-E PK Plasma Samples	
Blood Volume	4mL
Anticoagulant	EDTA
Blood Collection Times	Per the Protocol: Baseline and at: 2, 6, and 10 hrs post-drug ingestion.
Processing of Samples	Process all blood samples within 30 minutes of collection. All blood samples are to be kept on crushed ice (do not use chilling blocks or allow to freeze) until centrifuged.
Centrifuge	Sample should be centrifuged at 2000 x g for 15 minutes in a refrigerated centrifuge (4°C).

PK Plasma Sample Shipping Instructions (QPS Lab):

Note: Aliquot 1 and Aliquot 2 of each sample set at each time point should be sent separately frozen on dry ice. Please send Aliquot 1 first.

Once shipment receipt acknowledgement from ABC lab is received, then Aliquot 2 may be shipped.

!! DO NOT SHIP ON A FRIDAY!!

2. SAM-E SERUM OXIDATIVE STRESS BIOMARKERS SAMPLE PREPARATION

SAM-E Biomarker PLASMA Samples	
Blood Volume	5mL
Tube	Serum Separator (RedTop) Tube
Blood Collection Times	Per the Protocol: Baseline and at: 2, 6, and 10 hrs Post-drug ingestion.
Processing of Samples	Allow samples to clot for two hours at room temperature.
Centrifuge	Sample should be centrifuged for 20 minutes at approximately 1000 x g.
Plasma Storage Tubes	3 mL polypropylene tubes with screw caps.
Plasma Samples after Separation	2-3mL of plasma should be placed in to plasma storage tube.
Storage	Once placed in the plasma storage tube, the plasma samples should be storedat-20°Cor -80°C upright until shipped. Avoid repeated freeze/thaw cycles.

REMINDERS 1-2 DAYS BEFORE VISIT

- ☐ Call to subject:
  - Please bring in all meds
  - Questions re: mailing?
  - **Eat breakfast or fast depending upon visit**
- ☐ Subject binder: Tag places for PI signature
- ☐ Lab slips and orders signed by PI
- ☐ Lab Requisition slips completed (subj name, DOB, U number)
- ☐ All orders completed for TRU nursing unit (Subj. name, DOB, U number on forms) & highlighted for visit
- ☐ Reminders to PIs (and IDS on Visit 2) about subject schedule
- ☐ Who will walk subject from TRU to imaging lab

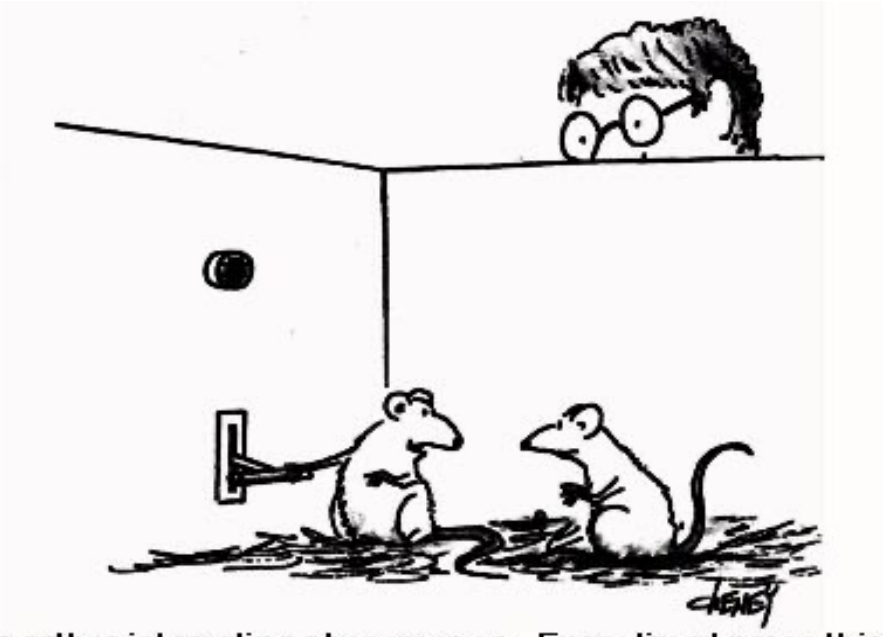
VISIT 1 -- Screening Day

- **Be sure to have:**

- ☐ Subject binder
- ☐ Traveling kit
- ☐ ID Badges
- ☐ Subject phone screen
- ☐ Copier code: 123456
- ☐ Note re: subject reimbursement info
  - SSN
  - Address
- Snack for subject

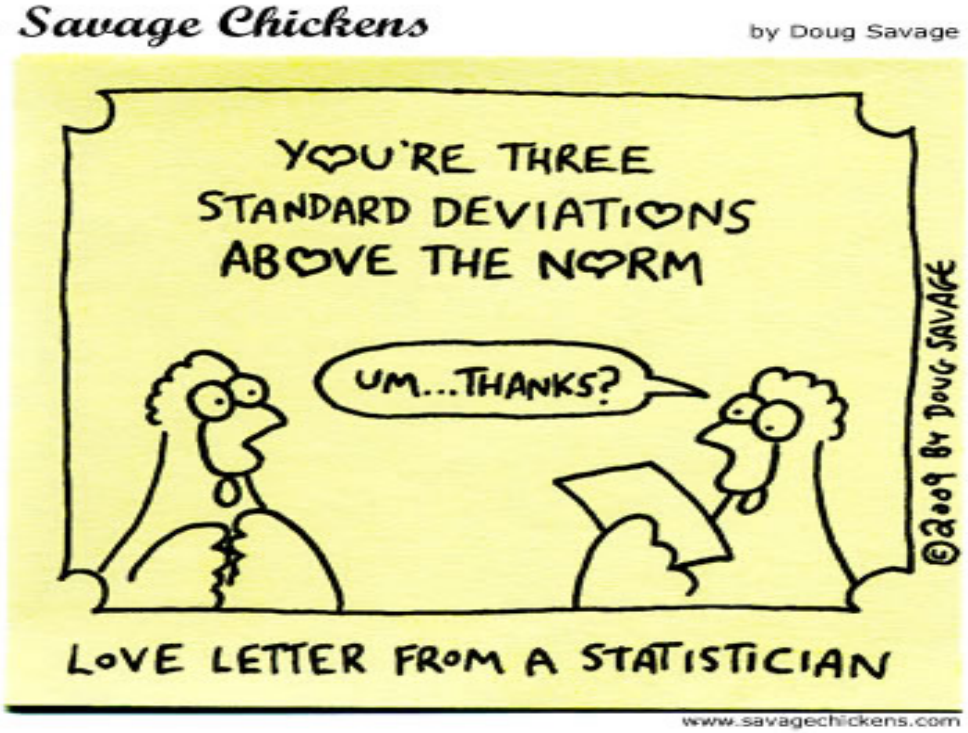
The How of the Protocol

4. STUDY DESIGN

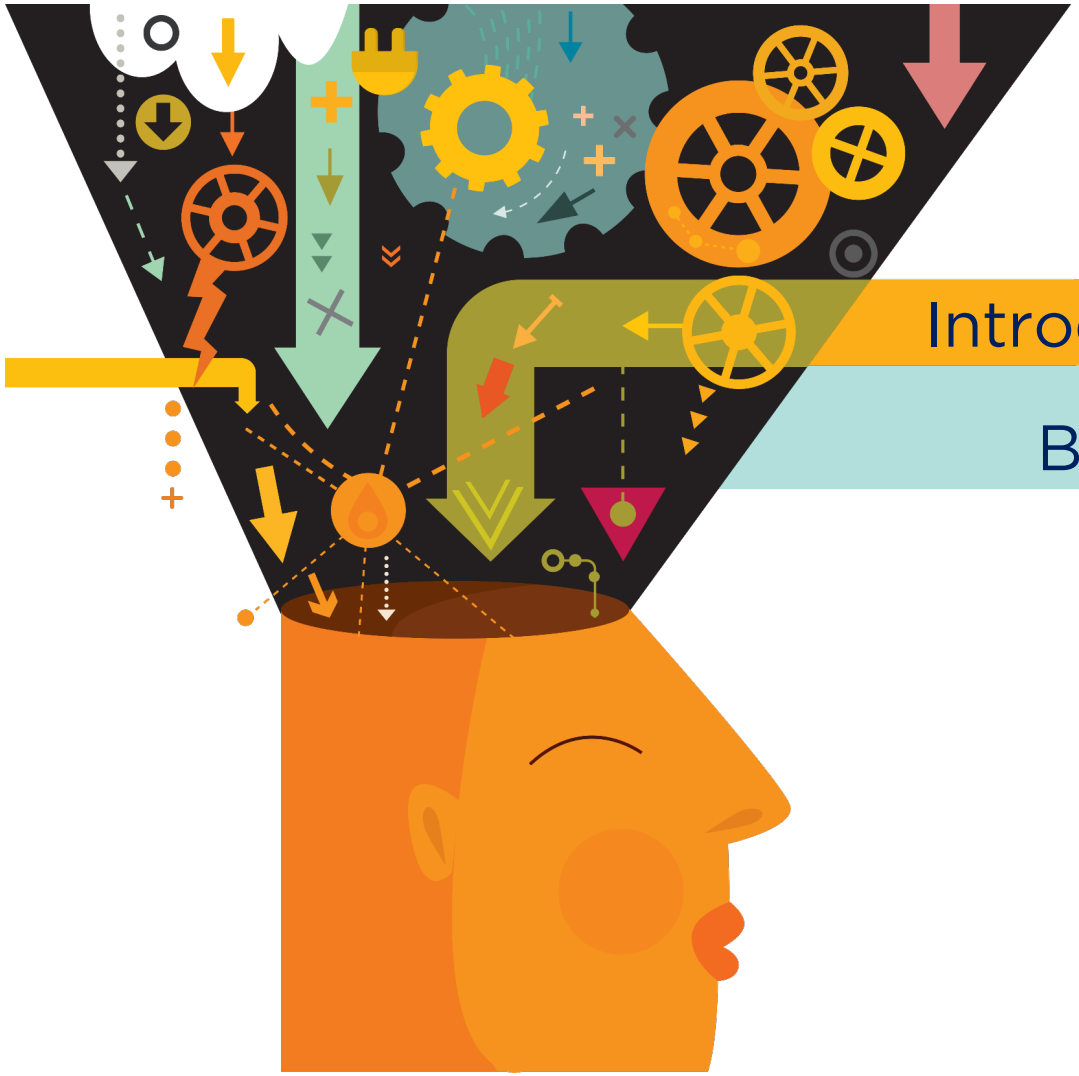


It's a rather interesting phenomenon. Every time I press this lever, that post-graduate student breathes a sigh of relief.

Data Management and Biostatistics



QUESTIONS?



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THANK YOU!