A DIVE INTO ASPECTS OF CLINICALTRIALS.GOV PART II

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Outline

- **Responding to PRS review comments**
  - Major comments
  - Advisory issues
- **Writing outcome measures**
  - Title
  - Measure description
  - Time frame
- **Departing PI**
  - Checklist before leaving institution
- **Live demonstration of information entry - Results**
  - Tips and tricks

Review comments

- **Major comments**
  - Inconsistencies
  - Insufficient information
  - More than one parameter being listed
- **Advisory issues**
  - Optional to respond

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Arms and Interventions

Arms	Assigned Interventions
Active Comparator: Arm 1 mono-therapy: first-line monotherapy (sildenafil alone) - in pediatric subjects with PAH.	Drug: Mono-Therapy The subjects will be randomized to receive sildenafil alone and will undergo study procedures as outlined in section 1.3. There will not be a placebo group.
Active Comparator: Arm 2 duo-therapy: compare two treatment strategies - first-line combination therapy (sildenafil and bosentan)	Drug: Duo-Therapy The subjects will be randomized to receive combination up-front therapy sildenafil and bosentan and will undergo study procedures as outlined in section 1.3. There will not be a placebo group.

Comments [1]

Major Issues:

1) The Intervention Name does not appear to be sufficiently descriptive.

The Intervention Names are not specific. Please provide a trade and/or generic name for all drugs (e.g., "Ibuprofen", "Abilify®") and devices (e.g., "CPAP", "Heart Monitor") administered to participants. Names identifying a drug class should generally be included in the Intervention Description field.

Advisory Issues:

Provide brief, but informative Arm Titles. For example, "Aspirin" and "Placebo" are more informative than "1" and "2". Even if there is only one group, please use an informative Arm Title (e.g., "Aspirin").

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Arms and Interventions

Arms	Assigned Interventions
Active Comparator: Intervention group The Intervention group will receive a $50 voucher for ordering foods (ONLY omega-3 rich foods) weekly (4 times).	voucher for ordering foods (ONLY omega-3 rich foods) A $50 voucher will be provided weekly (4 times) for ordering only omega-3 rich foods. Groceries will be delivered to participants' home weekly.
Sham Comparator: Control group The Control group will receive a $50 voucher for ordering foods in general (any type of foods) weekly (4 times). Participants will NOT be limited to purchasing foods rich in omega-3.	voucher for ordering foods in general (any type of foods) A $50 voucher will be provided weekly (4 times) for ordering any type of food. Groceries will be delivered to participants' home weekly.

Comments [1]

Major Issues:

1) There appears to be information related to the payment of participants that is not permitted in the study record.

Please remove the specific compensation/reward information. Compensation information is not permitted in the study record.

[Time Frame: On transfer from the ICU or discharge from the hospital, whichever comes first]

Comments [4]

Major Issues:

1) The Time Frame does not appear to be specific and/or in the correct format.

The Time Frame provided is not specific. The Time Frame should indicate the specific time point(s) at which the outcome measure will be assessed and for which data will be reported. Examples:

- "1 year"
- "up to 24 weeks"
- "through study completion, an average of 1 year".

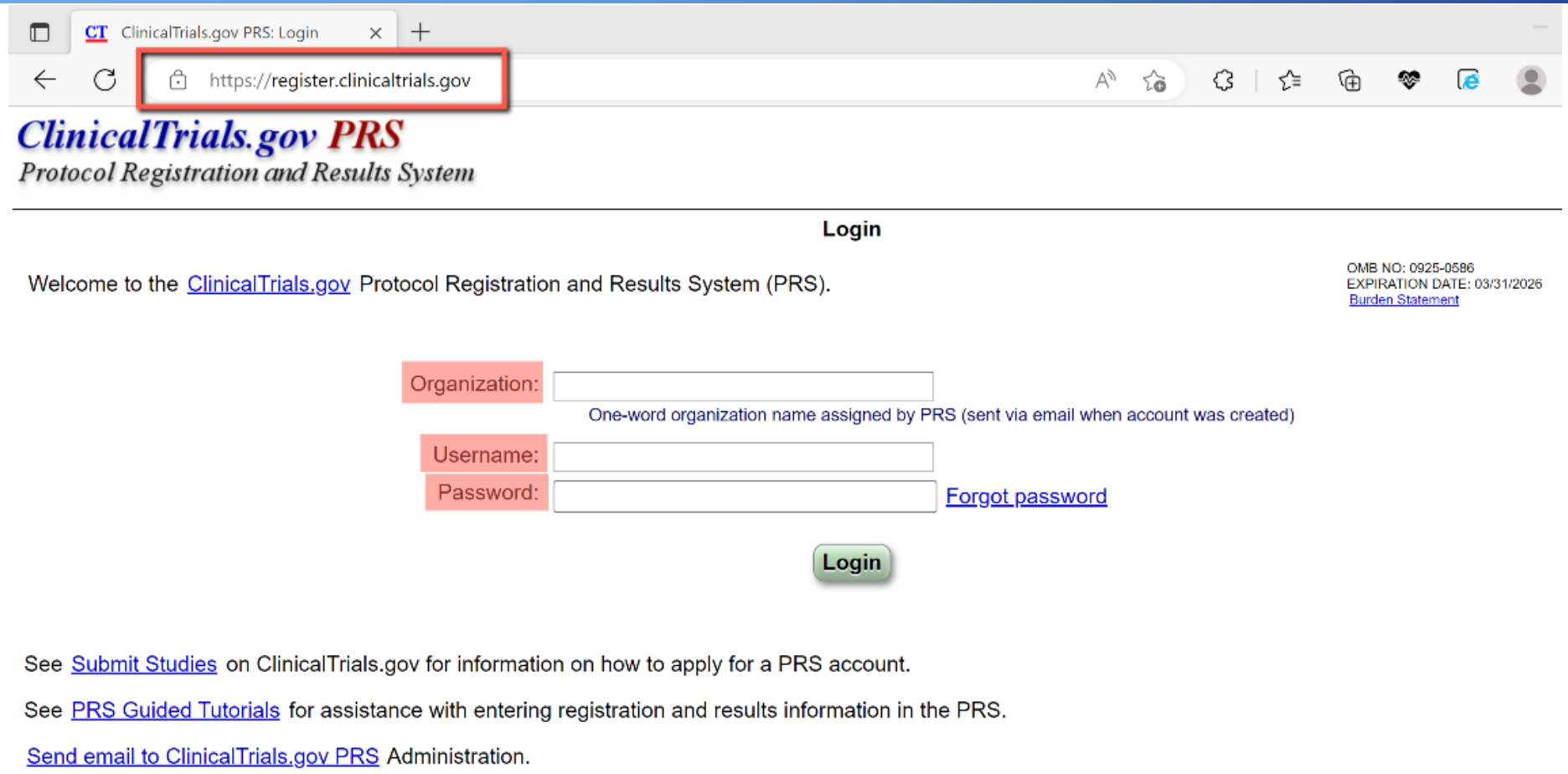
Outcome measures

- **Title**
  - Descriptive title – what is being measured
  - One parameter only or composite
- **Measure description**
  - Assessment tool
  - Unit of measure
- **Time frame**
  - When assessment is done
  - Duration of each participant assessment

Departing PI

- **PI Departure from institution**
  - Departure checklist
  - Transfer of record ownership
  - Update of PI/study official information

Live demo – Results Entry



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Questions?

Please visit our website for tutorials and more detailed information:
https://ictr.johnshopkins.edu/clinicaltrials-gov

See us on YouTube at "JohnsHopkinsCTgov"

Email us with any questions at
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