Things Researchers wished they knew about ClinicalTrials.gov before they started registration

1. Not all clinical trials have to be registered. In general, you only need to register studies that are classified as Applicable Clinical Trials (ACTs), receive federal funding, or will be published.
2. To determine if study is an Applicable Clinical Trial (ACT), use the checklist at: https://prsinfo.clinicaltrials.gov/AKT_Checklist.pdf.
3. The PRS staff is ready and willing to help you with any question or concern. You can request a conference call with the PRS staff for help with submitting results data.

Study Record

4. In the Study Identification section, enter the IRB# as the Unique Protocol ID and enter the grant number as the Secondary ID.
5. Do not use personal pronouns in the study record.
6. In the Study Description, the “Brief Summary” should be written in simple terms for the lay public to understand. The optional “Detailed Description” is for the technical community and can be much more detailed.
7. When using acronyms, be sure to spell out the name on the first entry.
8. Phase 1 studies determine safety, toxicity of drugs and are usually done on small number of participants. "Phase 1" not used for studies on approved drugs.
9. Feasibility studies determine if a device prototype works as the designer intended. The outcome measures for feasibility studies relates to functionality of the device prototype rather than to health outcomes. Studies evaluating devices already approved and on the market are NOT feasibility studies.
10. List any funding agency and collaborating institution in the Sponsor/Collaborators section.
11. The Eligibility Criteria list does not have to match exactly what is in the protocol. Just provide enough information for the public to be able to determine if they qualify. In general, you can simply tailor the list to what is on the informed consent form.
12. To meet ICMJE requirements, the official title of the study record must match protocol title, the Study Officials field in Contacts/locations must be completed, and the IPD Sharing Plan must be YES or No.
13. The "Plan to Share IPD" data element is intended to communicate whether there is a plan to make de-identified individual participant data (IPD) collected in this study available to researchers OUTSIDE the primary study group and institution. If sharing, the description should say what will be shared, when the data will be available (i.e. for 5 years after study is published), and how the data may be obtained. ClinicalTrials.gov does not accept the actual IPD data; if you wish to share data, it should be housed on an external site or database. You can provide a link to the online site or contact information for the database. ICMJE requires a YES or NO answer for this data element at the initial registration. The answer can be changed later with an explanation.

Protocol Tips

14. The Arm Title or Group/Cohort Label should be brief and descriptive (i.e. “Aspirin” and “Placebo” are more descriptive than “Arm 1” and “Arm 2”)
15. The **Outcome Measures** must be measurable quantities. Outcome measures are not objectives/goal; they do not begin with the word “To”. Describe the metric used to measure the outcome measure.

16. Primary and Secondary **Outcome Measures** should be clearly listed in the protocol. If protocol does not distinguish primary and secondary from tertiary, you will have to list all outcome measures found in the protocol.

17. **DO NOT upload protocol/SAP** before the study is completed. You may have to revised these documents throughout the study and the final version is what should be uploaded, so it is best to wait until results are being reported to load documents.

18. The Informed Consent Form must contain the ClinicalTrials.gov disclosure statement