Appendix B

CT.gov Registration Guidelines

Note: Any red **ERROR** must be addressed or changed; any blue **NOTE**: is only a suggestion. A red \* is a field that must be completed. Click on **Edit** to enter or change data.

Click on ***Save*** for all entries

|  |  |  |  |
| --- | --- | --- | --- |
| **Check if completed** | **Data field** | **Guidance** | **Comments** |
|  |  | Obtain password access | Contact an PRS Administrator: idale@peds.uab.edu; pjester@peds.uab.edu |
|  |  | Select ***New Record*** |  |
|  |  |  |  |
|  | Organization’s Unique Protocol ID | Suggest using the IRB / WIRB number but another number is acceptable | The IRB number will allow searching easier for the University |
|  | Brief Title | Shorten or abbreviation for the official title | Recommend selecting a brief title that will move the protocol to the beginning of the alphabet if recruitment is expected through CT.gov |
|  | Acronym | Optional |  |
|  | Record verification date | Month and year that record updated | These fields are updated each time the record is reviewed and updated |
|  | Recruitment status | Select one | This field is dynamic and changes throughout the study  |
|  | Study start date | Month and year | Date when enrollment began |
|  | Primary Completion Date | Month and year | Date last subject meets the primary endpoint |
|  | Study Completion Date | Month and year | Date of last subject visit |
|  | Responsible party | Select Principal Investigator |  |
|  | Investigator Name | Enter PIs name |  |
|  | Investigator Official Title | Enter ‘Principal Investigator’ |  |
|  | Collaborators | Enter funding agency  | If the name of your collaborator isn’t listed, enter a new one and then request CT.gov recognize the name |
|  | FDA Regulated intervention?` | If under an IND or IDE, select ‘yes’ , otherwise ‘no’ | Yes is if it is under an FDA regulated drug, device or biologic |
|  | Section 801 Clinical Trial? | *Yes* or *no*` | Select yes if this meets the definition of the FDAAA requirements for posting on CT.gov |
|  | Delayed response | Select ‘*No*’ unless otherwise known. | NOT a required field |
|  | IND/IDE protocol? | Yes or no | If yes, you will need information about the IND/IDE #, etc.. |
|  | Board Approval | Select appropriate status | This should be changed as status changes (pending, approved, etc.) |
|  | Board Name | *UAB IRB* or name of appropriate board |  |
|  | Board Affiliation | For UAB IRB, write in *University of Alabama at Birmingham* |  |
|  | Oversight Authority | Select from the list or request CT.gov ‘recognize’ the name | You may need to change a different wording. |
|  | Brief Description | Short paragraph | Write as if for the public: this could be a recruitment tool |
|  | Detailed Description | Several paragraphs |  |
|  | Condition of focus | List as many as you want |  |
|  | Key words | List as many as you want (optional) |  |
|  | Study design | Answer questions as appropriate for the study |  |
|  | Enrollment | Enter number expected to enroll |  |
|  | Type | Chose either anticipated or actual. | Actual will be selected at the completion of the study. |
|  | Arm Label: | Arm Label: what ever is appropriate | Can be as simple as Group 1 or Group 2 |
|  | Arm Description | Describe what will happen in each arm | It might be 1 drug or two drugs or several behavior methods |
|  | Intervention Type | Pick the most appropriate |  |
|  | Intervention name | For each intervention select a new ‘intervention’ |  |
|  | Intervention Description | Detail how the procedure will be done or how much and how drug will be administered |  |
|  | Outcome title | Write in a manner that it is measurable | Per the FDAAA law, only required to enter primary and secondary outcome measures. One measure cannot have more than 1 type of measure or address more than 1 time point. |
|  | Outcome Time Frame | Report in relation to baseline | ‘baseline to 6 months’ or ‘2 weeks after baseline surgery’ |
|  | Description | Provide enough detail so the reader can understand how the outcome measure was measured. Include scales if appropriate to the outcome measure |  |
|  | Safety Issue? | Check ‘yes’ if the outcome measures may identify a safety issue |  |
|  | Cross Reference | Select the appropriate intervention for each arm |  |
|  | Eligibility | Complete as appropriate; enter all inclusion and exclusion criteria |  |
|  | Overall contacts | Information from the PIs site | Enter whatever is appropriate |
|  | Add Locations | For multicenter trials – add all sites that are participating in the study. |  |
|  | References  | Enter either key references that support the protocol, and or enter references that report the results (not required) | NOTE: references that report the results will NOT substitute for entering the outcome measure resutlts |
|  | Approve | Must be completed by the PI or the PRS administrator per the PIs request |  |
|  | Release | Must be completed by the PI or the PRS administrator per the PIs request |  |
| After releasing and approving, an NCT number will be generated in 48 – 72 hours. If the number is not generated, CT.gov reviewers might generate Review Comments and a red flag will appear next to the record entry by the word Open |
|  | Open review comments and address all questions |  |  |
|  | Approve | Must be completed by the PI or the PRS administrator per the PIs request |  |
|  | Release | Must be completed by the PI or the PRS administrator per the PIs request |  |
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