Baylor College of Medicine

Office of Clinical Research

Submission to ClinicalTrials.gov

OCR-R-08-01

1. **PURPOSE:**

1.1. To describe the ClinicalTrials.gov registration process.

2. **SCOPE:**

2.1. This process applies to:

- Investigator-initiated studies that meet the criteria for an "Applicable Clinical Trial" and for which the Baylor College of Medicine (BCM) Principal Investigator (PI) is considered the "Responsible Party" per Section 801 of the Food and Drug Administration Amendments Act (FDAAA 801).

- All NIH-funded clinical trials regardless of study phase, type of intervention, or whether they are subject to the regulation per FDAAA 801. For additional information refer to NIH Policy on Dissemination of NIH-Funded Clinical Trial Information.

2.2. The International Committee of Medical Journal Editors (ICMJE) clinical trial registration policy requires prospective registration of all interventional clinical studies in a public registry such as ClinicalTrials.gov prior to the enrollment of the first participant. Registration is a condition of consideration for publication in ICMJE member journals.

3. **DEFINITIONS AND PROCEDURES:**

3.1. "Applicable Clinical Trial" is defined as follows:

- Trials of drugs and biologics. Controlled clinical investigations, other than phase 1 clinical investigations, of drugs or biological products subject to FDA regulation.

- Trials of devices.

    - Controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and
    - Pediatric post-market surveillance required by FDA.

Refer to flowchart for basic guidance on determining if a trial is considered an "applicable clinical trial" under FDAAA.

3.2. "Responsible Party" (RP) is defined as follows:

- The sponsor of the clinical trial or
- The principal investigator (PI) of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the PI:
    - Is responsible for conducting the trial
    - Has access to and control over the data from the clinical trial
    - Has the right to publish the results of the trial
    - Has the ability to meet all of FDAAA's requirements for the submission of clinical trial information
    - Is responsible for registration of the clinical study, maintaining the record, and posting study results to CT.gov.
- For BCM, the RP must be the PI of the protocol.

3.3. "Record Owner" (RO) is defined as follows:

- Designated by the RP to keep record up to date.
- PRS account holder who creates a study record in the ClinicalTrials.gov Protocol Registration System (PRS).
- Can maintain the record themselves or give one or more users access to a record to make changes.
- An administrator can change the RO after the record owner has been created.

3.4. Registration of Study in ClinicalTrials.gov

3.3.1. An investigator account is required to register a study in ClinicalTrials.gov. Accounts must be requested from the Office of Clinical Research (OCR).

3.3.2. The OCR will review the request to determine if the clinical trial requires CT.Gov registration and reporting.

3.3.3. Study registration is required no later than 21 calendar days after enrollment of the first participant. However, it is advised that the registration be completed prior to first patient enrollment to meet requirements of publishing with ICMJE.

3.3.4. The RP or RO enters clinical trial information in the PRS. Information should be simple and concise and readily understood by members of the public.

3.3.5. Instructions on how to enter study information in ClinicalTrials.gov can be found in the Guideline for Completion of a New Entry in Clinicaltrials.gov and at http://clinicaltrials.gov/ct2/manage-recs/how-register. Additional training is available through CITI "Protocol Registration and Results Summary Disclosure in ClinicalTrials.gov" course.

3.3.6. RP reviews posted study information for accuracy and completeness and releases the record in PRS for review.

3.3.7. RP or RO addresses reviewer comments from PRS reviewer.

3.5. Maintenance

3.4.1. RP is responsible for timely updates of study information in ClinicalTrials.gov. Annual updates are required for studies that are closed to new patient enrollment. Actively enrolling studies require updates every six months. This activity may be delegated to designee.

3.4.2. Instructions on how to update study information can be found at http://clinicaltrials.gov/ct2/manage-recs/how-edit

3.6. Study Results

3.5.1. The RP is responsible for submitting results.

3.5.2. If the study is an Applicable Clinical Trial, results are due within 12 months of the primary completion date (final data collection for primary end-point).

3.5.3. Instructions on how to submit results can be found at http://clinicaltrials.gov/ct2/manage-recs/how-report .

3.7. Study Close Out

3.6.1. The study is closed in ClinicalTrials.gov when all required clinical trial results information has been submitted as specified in 42 CFR 11.48 and corrections have been made or addressed in response to any electronic notice received from PRS reviewer.

3.8. Assurance & Compliance

3.7.1. BCM ClinicalTrials.gov registrations will be monitored by the OCR, with reporting reminders issued to Record Owners and PIs/Responsible Parties for maintaining timely updates to study records and results.

3.7.2. Study registrations that have been determined to be delinquent with any aspect of registration or results reporting will be forwarded to Research Compliance Services (RCS) for an assessment of non-compliance with applicable regulations and College policy.

3.9. Transfer of Record

3.7.1. On leaving BCM the RP will notify the OCR, and update their ClinicalTrial.gov record with their new contact information. If the departing investigator's funding is transferring to their new institution, the ClinicalTrials.gov RO is required to notify the administrator of ClinicalTrial.gov records at the new institution to request transfer of the clinical trial record to that institution.

4. MATERIALS AND REFERENCES

4.1. ClinicalTrials.gov

4.2. ClinicalTrials.Gov Protocol Registration System

4.3. Section 801 of the Food and Drug Administration Amendments Act (FDAAA 801)

4.4. Flowchart for basic guidance on determining if a trial is considered an "applicable clinical trial" under FDAAA

4.5. NIH Policy on Dissemination of NIH-Funded Clinical Trial Information

4.6. Clinical Trial Registration: A Statement from the International Committee of Medical Journal Editors (N Engl J Med 2004; 351:1250-1251)

4.7. Guideline for Completion of a New Entry in Clinicaltrials.gov

5. VERSION/REVISION HISTORY:

APPROVAL DATE	VERSION	OWNER	APPROVER	REVISION SUMMARY
6-12-17	01	OCR	ELC	

Guideline for Completion of a New Entry in Clinicaltrials.gov

Data Field	Guideline for Entry
Unique Protocol ID	• H#
Brief Title	• Short Name
Official Title	• Title from protocol
Study Type	• Interventional, Observational or Expanded Access
FDA Regulated Intervention	• Select "Yes" when study type is interventional or expanded access. Select "No" when study type is observational.
IND/IDE Protocol	• "Yes" if the study is conducted under an internally initiated IND/IDE. If the IND/IDE # is pending, answer "no" to this question. Once the IND/IDE # is available this will be changed to "yes" and the IND/IDE # is entered in the IND/IDE # field.
Secondary ID	• Short Title or Grant ID or Protocol Number
IND/IDE Info: Grantor	• IND/IDE info is only entered for internal IND/IDEs. Choices are CDER, CBER, or CDRH. The appropriate choice will be found on the IND acknowledgement letter.
IND/IDE #	• IND/IDE # number provided by the FDA
Serial #	• 1571 serial # the protocol was initially submitted on. If this protocol is the first protocol on the IND the serial # is 000. If an additional study added to an IND or IDE, use the serial number the FDA assigns when they received that particular additional study added.
Has Expanded Access	• This should be "No" unless the study is an "Expanded Access" study. • See definition at http://www.nlm.nih.gov/services/ctexpaccess.html . • Also refer to http://clinicaltrials.gov/ct2/manage-recs/how-register#Considerations .
Section 801 Protocol	• Select "yes" for all Phase II-IV device/drug/biologic studies. For all other studies, select "no."
Delayed Protocol Posting	• "This is "yes" only for applicable clinical trials that include a device not previously approved or cleared by the FDA for any use. For all other studies, select "No."
Responsible Party	• Select "principal investigator" or "sponsor investigator" as the type (must be Baylor PI of study).
Investigator Name	• Select the PI name from the list.
Investigator Official Title	• Official Baylor Title (i.e. Assistant Professor)
Investigator Affiliation	• Baylor College of Medicine
Sponsor	• Baylor College of Medicine
Collaborators	• Participating sites and other organizations (if any) providing support, including funding, design, implementation, data analysis and reporting.

Record Owner	• Assigned by Responsible Party. Select assigned Record Owner from Access List.
Review Board: Approval Status	• Select applicable IRB approval status.
Approval Number	• H #
Board Name	• Institutional Review Board for Human Subjects for Baylor College of Medicine and Affiliated Hospitals
Board Affiliation	• Baylor College of Medicine
Board Contact	• Enter the phone # (713-798-6970) and email address (irb@bcm.edu). The mail address is not required.
Data Monitoring Committee	• This should be "yes" if the study is reviewed by a data review committee or data safety monitoring board.
Oversight Authorities	• Enter the following: United States: Food and Drug Administration (insert only if research is FDA regulated) United States: Institutional Review Board
Brief Summary	• Use the background and purpose sections from the consent form. Remove all references to "you" and revise as appropriate.
Detailed Description	• Use the procedures section from the consent form but remove details that are not necessary (i.e., description of left over samples).
Record Verification	• Date record was reviewed and verified as accurate. This should be updated each time the record is revised and when verifying the record even if no changes have been made.
Overall Status	• Choose one of the following and update as the status changes: ○ Not yet recruiting: participants are not yet being recruited ○ Recruiting: participants are currently being recruited ○ Enrolling by invitation: participants are being (or will be) selected from a predetermined population ○ Active, not recruiting: study is ongoing (i.e., patients are being treated or examined), but participants are not currently being recruited or enrolled ○ Completed: the study has concluded normally; participants are no longer being examined or treated (i.e., last patient's last visit has occurred) ○ Suspended: recruiting or enrolling participants has halted prematurely but potentially will resume ○ Terminated: recruiting or enrolling participants has halted prematurely and will not resume; participants are no longer being examined or treated ○ Withdrawn: study halted prematurely, prior to enrollment of first participant
Study Start Date	• Date enrollment to the protocol begins.

Primary Completion Date	• The date the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome.

Study Completion Date	• Final date data was collected for the study.
Study Design: Primary Purpose	• Should always be "treatment" but double check that it isn't one of the other options.
Study Phase	• Use the information in CTMS. Also check in the title of the protocol and the statistics section of the protocol.
Intervention Model	• Usually this will be Single Group.
Number of Arms	• Number of intervention groups. Enter 1 for single arm study. Will only be more than 1 if groups/treatments are being analyzed separately.
Masking	• Usually this will be Open Label. Other choices as listed. If blinding is involved, masked roles must be indicated.
Allocation	• Choose N/A for single arm studies. Other choices as listed.
Study Endpoint Classification	• Type of primary outcome or endpoint that the protocol is designed to evaluate. Examples: choose safety for phase I studies, safety/efficacy for phase I/II studies.
Enrollment	• Enter the expected number of patients that will be treated on the study.
Outcome Measures	• Enter the primary and secondary outcomes for the protocol. Only enter outcomes that are covered in the statistical section. The title should describe what exactly is being measured (i.e. for toxicity outcome, adverse events are being measured/assessed). The timeframe should be when that outcome is being assessed (i.e. for a dose escalation study the timeframe for the safety assessment is how long the patient is assessed for DLT, usually 6 weeks).
Conditions	• Enter the primary disease or condition being studied.
Keywords	• Enter the disease/indication and each drug.
Arms	• Specify the arms corresponding to the number of arms specified in Study Design. The following will need to be entered for each arm (even if there is only one arm): o Arm label – the short name used to identify the arm. Should be descriptive yet concise. o Arm type – usually experimental but the other choices are Active comparator, Placebo comparator, Sham comparator, no intervention or other o Arm description - brief description of the arm. This may not be necessary if the associated intervention description contains sufficient information to describe the arm.
Interventions	• Enter an intervention for each drug/treatment being given. Do not list supportive care or premedication.
Eligibility Criteria	• Enter the inclusion and exclusion criteria from the protocol.
Gender	• Enter as appropriate
Minimum and maximum age	• Leave blank if there is no min and/or max age.

Accepts healthy volunteers	• Obtain from BRAIN Summary Section E2.
Central Contact	• PI
Central Contact Backup	• Primary Study Coordinator
Study Officials/Investigators	• PI
Locations	• Add the locations where subjects will be recruited/ enrolled. Facility contact should be the Site PI. Do not list co-investigators. Recruitment status should also be indicated for those sites.