PM-306–Registration of Clinical Trials in ClinicalTrials.gov

1. PURPOSE:

To describe the creation of an account and registration of a clinical trial on ClinicalTrials.gov. This process involves two distinct steps:

Step 1 of 2: Creation of a ClinicalTrial.gov Account
Step 2 of 2: Registering a Clinical Trial

Please refer to SOP-307 – Results Reporting of Clinical Trials in ClinicalTrials.gov regarding the entry of clinical trial results with the ClinicalTrial.gov system.

2. SCOPE:

This SOP will provide instruction and promote consistency among all departments within UTRGV regarding the requirement of registering applicable clinical trials with ClinicalTrials.gov. The US Food and Drug Administration (FDA) is the government agency that requires registration of clinical trials. Section 801 of the Food and Drug Administration Amendments Act of 2007 (FDAAA 801 or US Public Law 110-85), passed on September 27, 2007, requires mandatory registration and results reporting for certain clinical trials of drugs, biologics, and devices of all applicable clinical trials initiated on or before September 27, 2007, and is ongoing as of December 27, 2007. The legislation coupled with the Final Rule for Clinical Trials Registration and Results Information Submission (42 CFR Part 11) creates the regulatory requirements and procedures for ClinicalTrials.gov.

The International Committee of Medical Journal Editor (ICMJE) member journal requires, as a condition of consideration for publication in their journals, registration in a public trial registry. The ICMJE does not advocate one particular registry, but its member journals require authors to register their trial in a registry that meets several criteria.

According to the Food and Drug Administration Act of 2007:

- Penalties may include civil monetary penalties up to a $10,000 fine for failing to submit or for submitting fraudulent information in ClinicalTrials.gov.
- After notification of non-compliance, the fine may go up to $10,000 per day until resolved.
- For federally funded grants, penalties may include withholding or recovery of grant funds.

2.1 Registration Requirements

2.1.1 FDA Regulated Research Requirements:

FDAAA required registration and results reporting of 'Applicable Trials'. An 'Applicable Trial' is defined as:

2.1.1.1 Interventional studies;
2.1.1.2 Studies involving drugs, biologics, or medical devices regulated by FDA;
2.1.1.3 Studies that require an IND or IDE;
2.1.1.4 Studies that one or more of the following applies:
2.1.1.4.1 At least one site in the US or its territories, or
2.1.1.4.2 The product is manufactured in and exported from the US or one of its territories.
2.1.1.5 Studies that are not Phase I (drug and biological products) or not Device Feasibility (device products)

- Clinical trials must be submitted for registration with ClinicalTrial.gov within 21 days after the enrollment of the first patient.
- For more information regarding 'Applicable Trials', see Elaboration of Definitions of Responsible Party and Applicable Clinical Trials. ClinicalTrials.gov also provided the Checklist and Elaboration for Evaluating Whether a Clinical Trial or Study is an Applicable Clinical Trial.
- While Phase I trials or device feasibility studies are not considered 'Applicable Trials' under the FDAAA regulations, they do need to be registered if the study will be published, use Medicare, or receive funding from the NIH, as described below.

2.2 ICMJE Requirements

The ICMJE requires and recommends that all medical journal editors require registration of clinical trials in a public trial registry at or before the time of first patient enrollment as a condition of consideration for publication. Editors requesting inclusion of their journal on the ICMJE website list of publications that follow ICMJE guidance should recognize that the listing implies enforcement by the journal of ICMJE's trial registration policy.

http://icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html

2.3 Medicare Requirements

Effective January 1, 2015, all Medicare qualifying trials, including some Phase I and device feasibility trials, are required to be registered into the ClinicalTrials.gov database. National Clinical Trial (NCT) numbers are required on clinical research related claims in order to receive payment. Patients should not be enrolled on a trial unless the NCT registration number is in place.

2.4 NIH Requirements

The National Institutes of Health (NIH) Policy on Dissemination of NIH-Funded Clinical Trials Information requires registration and results reporting, and applies to all clinical trials funded

by NIH, regardless of whether they are subject to the FDAAA 801 and the Final Rule effective January 18, 2017. The Policy is effective for competing applications and contract proposals submitted on or after January 18, 2017, and states that all NIH funded awardees and investigators conducting clinical trials will register and report the results of their clinical trials in ClinicalTrials.gov. Please refer to the following grants policy information from NIH's Office of Extramural Research to learn more about ensuring compliance with NIH's implementation of FDAAA 801: https://grants.nih.gov/policy/clinical-trials/reporting/index.htm

To help answer the question, "Does your human subjects research study meet the NIH Definition of a clinical trial?" please go to https://grants.nih.gov/ct-decision/index.htm.

3. RESPONSIBLE INDIVIDUALS:

3.1 FDA Regulated Research Requirements:

According to federal law, the 'Responsible Party' is responsible for registering and reporting results to ClinicalTrials.gov and is defined as:

3.1.1 The IND holder of the trial, or

3.1.2 For studies not conducted under an IND/IDE

3.1.2.1 The study sponsor or the grantee institution

3.1.2.2 Principal Investigator (PI) if there is no external funding agreement

3.1.3 Situations in which the Institution/PI is the Responsible Party

For trials being conducted under a funding agreement, grant (e.g., NIH awards) or department/internal funding, the funding recipient is considered the Responsible Party. Because the PI is in the best position to understand the research protocol study results and adverse events, the institution will designate the PI to assume the role of the Responsible Party.

In situations where UTRGV serves as the primary site for a clinical trial and the institution is determined to be the 'Responsible Party.' The Institution will designate this responsibility to the PI.

3.1.4 Situations in which Institution/PI is NOT the Responsible Party

For most industry sponsored trials, the sponsor will be the Responsible Party, and, as such, the institution and PI will NOT have to manage submissions to ClinicalTrials.gov. Similarly, for multi-center and academic center trials, only the lead site (overall PI) typically bears the responsibility for ClinicalTrials.gov reporting; site PIs typically do not have to do additional reporting.

3.1.5 What are the criteria for designating the PI as the "Responsible Party" for registering and reporting results?

According to federal law, the PI can serve as a Responsible Party if that individual:

3.1.5.1 Is responsible for conducting the trial.

3.1.5.2 Has access to and control over the data from the clinical trial.

3.1.5.3 Has the right to publish the results of the trial.

3.2 ICMJE Requirements

Anyone involved in the clinical trial could register the trial, in practice this responsibility usually falls with the individual submitting the publication to ICMJE journal, which is usually the Principal Investigator.

3.3 Medicare Requirements

In order to ensure proper research billing compliance, it is the responsibility of department research personnel to communicate the NCT number to their Research Finance Specialist (RFS) during administrative study start-up and prior to any patient enrollment on the trial. It is the responsibility of the RFS to associate the appropriate NCT number with study related claims and assure communication to the appropriate parties in revenue cycle management.

3.4 NIH Requirements

The trial's "Responsible Party" is responsible for two basic elements of compliance:

3.4.1 The registration of the Applicable Clinical Trials (ACTs) in ClinialTrials.gov, and

3.4.2 Reporting summary results information (including adverse events).

3.4.3 All NIH grantees, regardless of whether or not they are the "Responsible Party" under FDAAA are responsible for:

3.4.3.1 Certification that the responsible party has made all the required submissions to ClinicalTrials.gov for ACTs funded in whole or in part by the NIH. This certification is done in the grant application and progress report forms.

4. RELATED TERMS AND DEFINITIONS:

Applicable Clinical Trials (ACT)
International Committee of Medical Journal Editors (ICMJE)
Individual Participant Data (IPD)
National Clinical Trial (NCT) Number - another term for the ClinicalTrials.gov registry number unique to each record. The format for the ClinicalTrials.gov registry number is "NCT" follow by an 8-digit number (e.g., NCT00000419).
Protocol Registration and Results System (PRS)

Please reference the Standard Operating Procedures Glossary of Terms for complete definitions of terms in this SOP.

5. POLICY STATEMENT

All applicable clinical trials must be registered in ClinicalTrials.gov. All studies must be registered no later than 21 days after enrollment of the first participant. Failure to register applicable trials by an investigator could delay future research approvals.

The ICMJE clinical trial registration policy requires prospective registration (i.e., registration prior to first person enrolled) of all interventional clinical studies. Please see [Section] 7. REFERENCES for additional information.

6. PROCEDURES

6.1 Step 1: Creation of a ClinicalTrials.gov Account

UTRGV has an established organizational ClinicalTrials.gov account in the Protocol Registration and Results System (PRS). Contact the UTRGV PRS Administrator to assist with creating individual logins for the UTRGV account to register the applicable clinical trial in the system.

6.2 Step 2: Registering a Clinical Trial

Registration of a study will take approximately one (1) hour and it will be helpful to have the following:

- The protocol
- Informed Consent Document
- IRB approval date and IRB number (if available)

6.2.1 Login at https://register.clinicaltrials.gov/ with the information from your account registration using your username, password, and one-word organization name assigned by PRS (UTRGV).

6.2.2 Click on **"New Record"** in the Quicklinks dialogue box on the left or add a record in the "Records" drop down menu. A **"Create New Records"** page will be displayed.

Organization's Unique Protocol ID: use the assigned UTRGV IRB number. NOTE: If your study relies on an outside IRB, you may use the outside IRB number.
Brief Title: [DO NOT ENTER THE OFFICIAL STUDY TITLE NOR THE IRB NUMBER IN THIS FIELD]
Acronym (If Required): [CONDITIONAL, MAY BE LEFT BLANK]
Study Type: Select the appropriate type – (1) Interventional, (2) Observational, or (3) Expanded Access

6.2.3 Selection **"Continue"** to proceed followed by "Okay" in the next dialogue box.

6.2.4 An **"Edit Study Identification"** page will appear. Complete as follows: Organization's Unique Protocol ID: use the assigned UTRGV IRB number.

NOTE: If your study relies on an outside IRB, you may use the outside IRB number.
Brief Title: [DO NOT ENTER THE OFFICIAL STUDY TITLE NOR THE IRB NUMBER IN THIS FIELD]

Acronym (If Required): [CONDITIONAL, MAY BE LEFT BLANK]
Official Title: [ENTER STUDY'S FULL TITLE HERE]
Secondary IDs: [IF ANY, e.g., the grant number, funding agency number or other funding source number]

6.2.5 Select **"Continue"** to proceed.

6.2.6 An **"Edit Study Status"** page will appear. Complete as follows:
Record Verification Date: [ENTER MONTH AND YEAR]
Overall Recruitment Status: [CHOOSE FROM DROP DOWN MENU]
Study Start Date: [ENTER MONTH, DAY, YEAR, AND TYPE]
Primary Completion Date: [ENTER MONTH, DAY, YEAR, AND TYPE]
Study Completion Date: [ENTER MONTH, DAY, YEAR, AND TYPE]

6.2.7 Select **"Continue"** to proceed.

6.2.8 An **"Edit Sponsor/Collaborators"** page will appear. Complete as follows:
Responsible Party: [SELECT SPONSOR -INVESTIGATOR OR PRINCIPAL INVESTIGATOR]
Investigator Name (Username): [SELECT SPONSOR-INVESTIGATOR OR PRINCIPAL INVESTIGATOR]
Investigator Official Title: [INPUT THEIR TITLE]
Sponsor: [ENTER SPONSOR IF NOT PREPOPULATED BY THE SYSTEM]
Collaborators: [ENTER ORGANIZATION NAME OF ANY SUPPORTING, FUNDING, IMPLEMENTATION, DATA ANALYSIS, OR REPORTING ORGANIZATIONS]

6.2.9 Select **"Continue"** to proceed.

6.2.10 An **"Edit Oversight"** page will appear. Complete as follows:
U.S. FDA Regulated Drug: Enter "Yes" or "No" (A "Yes" is an IND regulated study).
U.S. FDA Regulated Device: Enter "Yes" or "No" (A "Yes" is an IDE regulated study).
U.S. FDA IND/IDE: Enter "Yes" or "No". Select "Yes" if either of the prior responses were "Yes".
Human Subjects Protection Review: Board Status: [ENTER THE APPROPRIATE RESPONSE (E.G., EXEMPT; EXPEDITED; SUBMITTED; PENDING; APPROVED, ETC)].
Data Monitoring Committee: Select "Yes" or "No".
FDA Regulated Intervention: Select "Yes" or "No".

6.2.11 Select **"Continue"** to proceed.

6.2.12 An **"Edit Study Description"** page will appear. Complete as follows:
NOTE: There are character limits with this section.

Brief Summary: [INPUT BRIEF SUMMATION OF THE STUDY].
Detailed Description: [INPUT A SPECIFIED OVERVIEW OF THE STUDY, NOT THE ENTIRE PROTOCOL.]

6.2.13 Select **"Continue"** to proceed.

6.2.14 An **"Edit Conditions"** page will appear. Complete as follows:
Conditions or Focus of Study: [SEARCH FOR TAGS RELATED TO THE DISEASE OR CONDITION INTO THE FIELD SPACE. THIS WILL QUERY THE DATABASE ON THE SITE FOR MATCHING TAGS.]
Keywords: [ENTER KEY TERMS HERE. THIS WILL HELP USERS FIND YOUR CLINICAL TRIAL.]

6.2.15 Select **"Continue"** to proceed.

6.2.16 An **"Edit [Observational/Interventional/Expanded Access] Study Design"** page will appear. Complete as follows:
Study Type: Select either:

A) Interventional,
B) Observational, or
C) Expanded Access.

Follow the guided prompts below (A-C) for the appropriate fit for your trial.

A) INTERVENTIONAL

a. PART I: STUDY DESIGN (Interventional Only)

Primary Purpose: Select, "Treatment, Prevention, Diagnostic, Supportive Care, Screening, Health Services Research, Basis Science, Device, Feasibility, or Other".
Study Phase: Select, "N/A, Early Phase I (Phase), Phase I, Phase 1/Phase 2, Phase 2, Phase 2/Phase 3, Phase 3, Phase 4".
Interventional Study Model: Select, "Single Group, Parallel, Crossover, Factorial, or Sequential".
Model Description: [NOT A REQUIRED FIELD, BEST FOR COMPLICATED DESIGN EXPLANATIONS.]
Number of Arms: [ENTER APPROPRIATE NUMBER PER TRIAL DESIGN.]
MASKING: Check one, "Participant, Care Provider, Investigator, Outcomes Assessor, or None (Open Label)."
Masking Description: [NOT A REQUIRED FIELD, BEST FOR COMPLICATED DESIGN EXPLANATION.]
Allocation: Select, "N/A, Randomized, or Non-Randomized."
Enrollment: [ENTER NUMBER OF SUBJECTS AND TYPE ANTICIPATED OR ACTUAL]

b. PART II: ARMS AND INTERVENTIONS (Interventional Only)

Arm Title: [ENTER DESCRIPTIVE TITLE FOR ARM].

Arm Type: Select from, “Experimental, Active Comparator, Placebo Comparator, Sham Comparator, No Intervention, or Other”.
Arm Description: Open field text box [DESCRIBE THE INTERVENTION(S) TO BE ADMINISTERED].
Interventions
Intervention Type: Select, “Drug, Device, Biologic/Vaccine, Procedure/Surgery, Radiation, Behavioral, Genetic, Dietary Supplement, Combination Product, Diagnostic Test, or Other.”
Intervention Name: [ENTER NAME OF INTERVENTION IN FIELD.]
Other Intervention Names: [ENTER ANY OTHER NAMES OF INTERVENTIONS.]
Intervention Description: [WRITE DESCRIPTIVE SUMARY OF THE INTERVENTION(S).]
Cross Reference: This field appears if there are more than 1 arm and/or more than 1 intervention.

c. PART III: OUTCOME MEASURES (Interventional Only)

Title: [ENTER TITLE FOR OUTCOME.]
Description: [WRITE A DESCRIPTION FOR THE OUTCOME TO BE MEASURED.]
Time Frame: [PICK AN ADEQUATE/APPROPRIATE TIME FRAME/]
NOTE: Additional Outcomes may be added, as needed.
Other Pre-Specified Outcomes
Title: [ENTER TITLE FOR OUTCOME.]
Description: [WRITE A DESCRIPTION FOR THE OUTCOME TO BE MEASURED.]
Time Frame: [PICK AN ADEQUATE/APPROPRIATE TIME FRAME.]
NOTE: Additional Outcomes may be added, as needed.

d. PART IV: ELIGIBILITY (Interventional Only)

Sex: Select, “Male”, “Female”, or “All”.
Gender Based: Select, “Yes” or “No”
Age Limits: [DETERMINE THE MINIMUM AND MAXIMUM VALUES.]
Accepts Healthy Volunteers: Select, “Yes” or “No”.
Eligibility Criteria: [ENTER THE INCLUSION CRITERIA AND THE EXCLUSION CRITERIA IN THE TEXT BOX].

e. PART V: CONTRACTS/LOCATIONS (Interventional Only)

Central Contact Person: [COMPLETE FIELDS: FIRST, MI, LAST NAME, AND DEGREE, PHONE & EXT, & EMAIL.]
Central Contact Backup: Not a required field.
Overall Study Officials: [COMPLETE FIELDS: FIRST MI, LAST NAME, AND DEGREE, ORGANIZATIONAL AFFILIATION, & OFFICIAL’S ROLE.]
Add Locations
Facility: [COMPLETE FIELDS: NAME, CITY, STATE/PROVINCE, ZIP/POSTAL CODE, AND COUNTRY.]

Site Recruitment Status: Select, "Not Yet Recruiting; Recruiting; Enrolled by Invitation; Active, Not Recruiting; Completed; Suspended; Terminated (Halted Prematurely); or Withdrawn (No Participants Enrolled)."
Facility Contact: [COMPLETE FIELDS: FIRST, MI, LAST NAME, AND DEGREE, PHONE & EXT, & EMAIL.]
Add Investigator: Add investigators as necessary.

f. PART VI: Individual Participant Data (IPD) SHARING (Interventional Only)

Plan to Share IPD: Select "Yes", "No", or "Undecided". [COMPLETE ACCORDING TO THE PREPOPULATED DROP DOWNS.]

g. PART VII: REFERENCES (Interventional Only)

Citations: Not required
Links: Not required.

B) OBSERVATIONAL

a. PART I: STUDY DESIGN (Observational Only)

NOTE: An optional patient registry button appears but is not a requirement.
Observational Study Model: Select either, "Cohort, Case-Control, Case-Only, Case-Crossover, Ecologic or Community, Family-Based, Other".
Time Perspective: Select either, "Retrospective, Prospective, Cross-Sectional, or Other".
Biospecimen Retention: Select either, "None Retained, Samples with DNA, or Samples without DNA".
Enrollment: [ENTER NUMBER OF SUBJECTS AND TYPE ANTICIPATED OR ACTUAL.]
Number of Groups/Cohorts: [ENTER THE CORRECT NUMBER PER THE TRIAL DESIGN.]

b. PART II: GROUPS AND INTERVENTIONS (Observational Only)

Group/Cohort Label: [ENTER LABEL FOR THE GROUP/COHORT.]
Group/Cohort Description: [COMPLETE WITH A BRIEF DESCRIPTION OF THE GROUP/COHORT.]
NOTE: Groups may be added as necessary.
Intervention Type: Select, "Drug, Device, Biological/Vaccine, Procedure/Surgery, Radiation, Behavioral, Genetic, Dietary Supplement, Combination Product, Diagnostic Test, or Other".
Intervention Name: [ENTER NAME FOR THE PLANNED INTERVENTION.]
Other Intervention Names: Complete as needed.
Intervention Description: [DESCRIBE THE PLANNED INTERVENTION.]
NOTE: Interventions may be added as necessary.
Cross-Reference:
NOTE: This field appears if there is more than one (1) arm and/or more than 1 intervention.

c. PART III: OUTCOME MEASURES (Observational Only)

Title: [ENTER TITLE FOR OUTCOME.]
Description: [WRITE A DESCRIPTION FOR THE OUTCOME TO BE MEASURED.]
Time Frame: [PICK AN ADEQUATE/APPROPRIATE TIME FRAME.]
NOTE: Additional Outcomes may be added, as needed.
Secondary Outcome Measures:
Title: [ENTER THE TITLE FOR THE OUTCOME.]
Description: [WRITE A DESCRIPTION FOR THE OUTCOME TO BE MEASURED.]
Time Frame: [PICK AN ADEQUATE/APPROPRIATE TIME FRAME.]
NOTE: Additional Outcomes may be added, as needed.
Other Pre-Specified Outcomes
Title: [ENTER TITLE FOR OUTCOME.]
Description: [WRITE A DESCRIPTION FOR THE OUTCOME TO BE MEASURED.]
Time Frame: [PICK AN ADEQUATE/APPROPRIATE TIME FRAME.]
NOTE: Additional Outcomes may be added, as needed.

d. PART IV: ELIGIBILIY (Observational Only)

Sex: Select "Male", "Female", or "All".
Gender Based: Select, "Yes" or "No".
Age Limits: [DETERMINE THE MINIMUM AND MAXIMUM VALUES.]
Accepts Healthy Volunteers: Select, "Yes" or "No".
Eligibility Criteria: [ENTER THE INLUSION CRITERIA AND THE EXCLUSION CRITERIA IN THE TEXT BOX.]

e. PART V: CONTACTS/LOCATIONS (Observational Only)

Central Contact Person: [COMPLETE FIELDS: FIRST, MI, LAST NAME, AND DEGREE, PHONE & EXT, & EMAIL.]
Central Contact Backup: Not a required field.
Overall Study Officials: [COMPLETE FIELDS: FIRST MI, LAST NAME, AND DEGREE, ORGANIZATIONAL AFFILIATION, & ROLE.]
Add Locations
Facility: [COMPLETE FIELDS: NAME, CITY, STATE/PROVINCE, ZIP/POSTAL CODE, AND COUNTRY.]
Site Recruitment Status: Select, "Not Yet Recruiting; Recruiting; Enrolled by Invitation; Active, Not Recruiting; Completed; Suspended; Terminated (Halted Prematurely); or Withdrawn (No Participants Enrolled)."
Facility Contact: [COMPLETE FIELDS: FIRST, MI, LAST NAME, AND DEGREE, PHONE & EXT, & EMAIL.]
Add Investigator: Add investigators as necessary.

f. PART VI: IPD SHARING (Observational Only)

Plan to Share IDP: Select, “Yes” or “No”, or “Undecided”. [COMPLETE ACCORDING TO THE PREPOPULATED DROP DOWNS.]

g. PART VII: REFERENCES (Observational Only)

Citations: Not required.
Links: Not required.

C) EXPANDED ACCESS

a. PART I: STUDY DESIGN (Expanded Access Only)

NOTE: An optional patient registry button appears but is not a requirement.
Type: Check the appropriate box(es): “Not Applicable, Individual Patients, Intermediate-Size Population, or Treatment IND/Protocol.”

b. PART II: INTERVENTIONS (Expanded Access Only)

Interventions/Exposures:
NOTE: Only applies when there are 2 or more groups and 1 or more interventions/exposures.
Intervention Type: Select, “Drug, Device, Biological/Vaccine, Procedure/Surgery, Radiation, Behavioral, Genetic, Dietary Supplement, Combination Product, Diagnostic Test, or Other”.
Intervention Name: [ENTER NAME FOR THE PLANNED INTERVENTION.]
Other Intervention Names: Complete as needed.
Intervention Description: [DESCRIBE THE PLANNED INTERVENTION.]
NOTE: Interventions may be added as necessary.
Cross-Reference
NOTE: This field appears if there are more than 1 arms and/or more than 1 intervention.

c. PART III: ELIGIBILITY (Expanded Access Only)

Sex: Select, “Male”, “Female”, or “All”.
Gender Based: Select, “Yes” or “No”.
Age Limits: [DETERMINE THE MINIMUM AND MAXIMUM VALUES.]
Accepts Healthy Volunteers: Select, “Yes” or “No”.
Eligibility Criteria: [ENTER THE INCLUSION CRITERIA AND THE EXCLUSION CRITERIA IN THE TEXT BOX.]

d. PART IV: CONTACTS/LOCATIONS (Expanded Access Only)

Central Contact Person: [COMPLETE FIELDS: FIRST, MI, LAST NAME, AND DEGREE, PHONE, & ETX, & EMAIL.]
Central Backup Contact: Not a required field.

Overall Study Officials: [COMPLETE FIELDS: FIRST, MI, LAST NAME, AND DEGREE, ORGANIZATIONAL AFFILIATION, & OFFICIAL'S ROLE.]
Add Locations
Facility: [COMPLETE FIELDS: NAME, CITY, STATE/PROVINCE, ZIP/POSTAL CODE, AND COUNTRY.]
Site Recruitment Status: Select, "Not Yet Recruiting; Recruiting; Enrolled by Invitation; Active; Not Recruiting; Completed; Suspended; Terminated (Halted Prematurely)' or Withdrawn (No Participants Enrolled)."
Facility Contact: [COMPLETE FIELDS: FIRST, MI, LAST NAME, AND DEGREE, PHONE & EXT, & EMAIL.]

e. PART V: REFERENCES (Expanded Access Only)

Citations: Not required.
Links: Not required.

6.2.17 Select **"Continue"** to proceed if all information is final. A second dialogue box will populate. To confirm completion, select "OK".

6.2.18 If there are any outstanding "ERROR(S)" these will be noted in red font and require correction or additional information to be addressed to complete the entry/registration of your trial in the ClinicalTrial.gov system. Once all outstanding "ERROR(S)" are addressed, the registration process includes review and approval.

6.2.19 Helpful Tips:

6.2.19.1.1 The system offers the option to save data if you do not have time to complete the entire process.

6.2.19.1.2 Be aware of fields marked with the following:

*FDAAA – Required to comply with US Public Law 10-85, Section 801

6.2.20 Once the registration of the study is released by the Responsible Party, it will be reviewed by personnel at ClinicalTrials.gov. Any comments are posted on the Responsible Party's account at ClinicalTrials.gov alongside an email. Corrections to trial registration can be made, as needed, and the trial can be released. If there are no review comments the trial is released to the public website within 2 business days with the assigned NCT #. This number should be kept on file in the study records, and the IRB application must be updated with the NCT # on or before the continuing review. The NCT # is required to be on the title page of the protocol, including a summary of amendments submitted when results are reported.

6.3 Updating Your Registered Study

Once a trial is registered, both FDA and ICMJE require that registrations be updated as follows:

6.3.1 FDA updating requirements:

6.3.1.1 Information must be updated at least once every 12 months.

6.3.1.2 If changes affect human subjects via a protocol amendment, the information must be updated within 30 days of the IRB's approval.

6.3.1.3 The registry must be updated within 30 days of any changes in recruitment status or completion of study.

6.3.1.4 Summary results (including adverse event information) need to be submitted not later than 1 year after the trial's primary completion date, with delays allowed in some circumstances.

6.3.1.5 The registry must be updated within 15 days of change in approval or clearance status of drugs and devices not previously approved by FDA.

6.3.2 ClinicalTrials.gov notifies the Responsible Party (or designee) account of which trials are due for updates.

6.3.3 ICMJE requires updating study information every 6 months.

6.3.4 For the most up-to-date information or to cross reference the requirements for ClinicalTrials.gov please visit https://clinicaltrials.gov/ct2/manage-recs/faq. Also see Clinical Research SOP PM-307 – Results Reporting of Clinical Trials in ClinicalTrials.gov.

7. REFERENCES

- ICMJE Obligation to Register Clinical Trials http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html
- NIH Guidance on Clinical Trials Registration in ClinicalTrials.gov – https://grants.nih.gov/clinicaltrials_fdaaa/
- ClinicalTrials.gov public website – https://clinicaltrials.gov
- ClinicalTrials.gov registration site – https://register.clinicaltrials.gov
- Registration at ClinicalTrials.gov: Fact Sheet – http://prsinfo.clinicaltrials.gov/
- Definitions of a Responsible Party and Applicable Clinical Trial – https://prsinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf
- Protocol Data Elements Definitions – https://prsinfo.clinicaltrials.gov/definitions.html
- ClinicalTrials.gov Training Materials – http://clinicaltrials.gov/ct2/manage-recs/present

- Learning Module 1: Clinical Trials.gov Overview and PL 110-85 Requirements – http://prsinfo.clinicaltrials.gov/WebinarSlidesBasicResults.pdf
- Frequently Asked Questions – https://clinicaltrials.gov/ct2/manage-recs/faq
- UTRGV SOP PM-307 Results Reporting of Clinical Trials in ClinicalTrials.gov
- 42 CFR 11 https://www.govinfo.gov/content/pkg/CFR-2019-title42-vol1/xml/CFR-2019-title42-vol1-part11.xml
- PRS User Guide – https://prsinfo.clinicaltrials.gov/prs-users-guide.html

8. FORMS OR ATTACHMENTS

None