1. PURPOSE:
This Standard Operating Procedure (SOP) describes the creation of an account and registration of a clinical trial on ClinicalTrials.gov.

This process involves 2 distinct steps:
   Step 1 of 2: Creation of a ClinicalTrials.gov Account
   Step 2 of 2: Registering a Clinical Trial

Please refer to “SOP-406: Results Reporting of Clinical Trials in ClinicalTrials.gov” regarding the entry of clinical trials results within the ClinicalTrials.gov system.

2. SCOPE:
This SOP will provide instruction and promote consistency among all departments within University Hospitals Cleveland Medical Center regarding the requirement of registering applicable clinical trials with ClinicalTrials.gov. The U.S. 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. This legislation coupled with the Final Rule for Clinical Trials Registration and Results Information Submission creates the regulatory requirements and procedures for ClinicalTrials.gov.

The International Committee of Medical Journal Editors (ICMJE) member journals require, as a condition of consideration for publication in their journals, registration in a public trials 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 Amendments Act of 2007:
- Penalties may include civil monetary penalties up to $10,000 fine for failing to submit or for submitting fraudulent information to ClinicalTrials.gov.
- After notification of noncompliance, the fine may go up to $10,000 per day until resolved.
- For federally funded grants, penalties may include the withholding or recovery of grant funds.

REGISTRATION REQUIREMENTS:
Ultimately all interventional studies need to be registered.

(1) FDA Regulated Research Requirements:

Developed by the UH Clinical Research Center SOP Committee
FDAAA requires registration of ‘Applicable Trials’. An ‘Applicable Trial’ is defined as:
- Interventional studies;
- Studies involving drugs, biologics, or medical devices regulated by FDA;
- Studies that require an IND or IDE;
- Studies that one or more of the following applies:
  - at least one site in the US or one of its territories, or
  - the product is manufactured in and exported from the US or one of its territories.

Clinical trials must be submitted for registration with ClinicalTrials.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

(2) ICMJE Requirements:
ICMJE requires registration of any human research project that prospectively assigns human subjects to intervention or comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome.

(3) Medicare Requirements:
Effective January 1, 2015, all Medicare qualifying trials, including some Phase 1 and device feasibility trials, are required to be registered into the ClinicalTrials.gov database. 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. See http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM8401.pdf

(4) NIH Requirements:
The National Institutes of Health (NIH) Policy on Dissemination of NIH-Funded Clinical Trial Information 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.

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:
   (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:

- The IND/IDE holder of the trial, or
- For studies not conducted under an IND/IDE
  - The study sponsor or the grantee institution,
  - Principal Investigator, if there is no external funding agreement

**Situations in which 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 best position to understand the research protocol study results and adverse events, the institution will designate the Principal Investigator to assume the role of the Responsible Party.

In situations where UH 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 Principal Investigator.

**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 responsibility for ClinicalTrials.gov reporting; site PIs typically do not have to do additional reporting.

**What are the criteria for designating the Principal Investigator as the “Responsible Party” for registering and reporting results?**

According to federal law, the Principal Investigator can serve as a Responsible Party if that individual

- 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

**(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 the ICMJE journal, which is usually the Principal Investigator.

**(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 this communication to the appropriate parties in revenue cycle management.

(4) NIH Requirements:
The trial’s “responsible party” is responsible for two basic elements of compliance:
- The registration of the ACTs in ClinicalTrials.gov, and
- The reporting of summary results information (including adverse events)

All NIH grantees, regardless of whether or not they are the “responsible party” under FDAAA are responsible for:
- Certification in the grant application and progress report forms that the responsible party has made all required submissions to ClinicalTrials.gov for ACTs funded in whole or in part by the NIH.

4. DEFINITIONS:
Please see “[Section] 7. REFERENCES;” for complete definitions of any additional terms not listed below.

CCCC: Case Comprehensive Cancer Center

NCT Number: 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” followed by an 8-digit number (e.g., NCT00000419).

PRS (Protocol Registration and Results System): A quality control and reviewing body to ensure all aspects of a clinical trial are entered according to federal regulations.

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. In addition, 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:

Step 1: Creation of a ClinicalTrials.gov Account

6.1 Establish an Individual Account with ClinicalTrials.gov Protocol Registration System (PRS). See Appendix A: Creation of a ClinicalTrials.gov Account for a walkthrough of account registration or follow the listed steps below.

NOTE: Cancer studies have their own account, should be registered as Case Comprehensive Cancer Center (CCCC) rather than University Hospitals Cleveland Medical Center, and there is a centralized registration coordinator who acts as the responsible party designee. Contact your Department Administrator for more information on registering cancer studies. Proceed to Step 2 of 2: Registering a Clinical Trial.

6.1.2 Accept terms and conditions.
6.1.3 Enter “Sponsor Information” as follows:
   Registering IND/IDE Study?: Yes or No
   Type of Organization: Nonprofit Organization
   Country: United States
   Organization Name: University Hospitals Cleveland Medical Center
   Organization Address: 11100 Euclid Avenue
   Cleveland, OH 44106
   Organization Abbreviations and Acronyms: UHCMC
   Parent Organizations (if any): [LEAVE BLANK]
   Organization Contact: Grace McComsey, MD
   Organization Phone: (216) 844-5568
   Organization Email: Grace.McComsey@UHhospitals.org
   Organization Website (optional): [LEAVE BLANK]
   Funding Organization: [ENTER INDUSTRY SPONSOR OR FUNDER HERE]
6.1.4 Enter “Investigator Information” as follows:
   Investigator Name: [ENTER FULL NAME]
   Affiliation (If Not the Sponsor): [ENTER SEPARATE INSTITUTIONAL AFFILIATION IF APPLICABLE, IF NOT LEAVE BLANK]
   Investigator Phone: [ENTER PHONE LINE]
   Investigator Email: [ENTER EMAIL ADDRESS]
6.1.5 Enter “Regulatory Information” as follows:
   NOTE: See 6.1.3 above. If the “Registering IND/IDE Study?” response was “Yes”, the Regulatory Authority should be listed as the “U.S. Food & Drug Administration”. See Appendix A for reference to FDA Regulatory Authority Addresses. If the “Registering
IND/IDE Study?” response was “No”, the Regulatory Authority should be listed as “University Hospitals Cleveland Medical Center Institutional Review Board”.
Regulatory Authority: University Hospitals Cleveland Medical Center Institutional Review Board
Regulatory Authority Address: 11100 Euclid Avenue
Cleveland, OH 44106

6.1.6 Ensure complete and accurate information and click “Submit Application”.
6.1.7 An account creation verification email will be sent to you within 2 – 5 business days.

Step 2: Registering a Clinical Trial

6.2. Registration of a study will take approximately 1 hour and it will be helpful to have the following:
- The protocol
- Informed consent document
- IRB approval date and number (if available)

6.2.2. 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 (UHCMC)

6.2.3. 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 UHCMC IRB number.
NOTE: If your study is an IND/IDE-regulated study (as indicated in 6.1.3), generate your own unique and identifiable ID for the protocol.

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

6.2.4. Select “Continue” to proceed followed by “Okay” in the next dialogue box.

6.2.5. An “Edit Study Identification” page will appear. Complete as follows:

Organization’s Unique Protocol ID: use the assigned UHCMC IRB number.
NOTE: If your study is an IND/IDE-regulated study (as indicated in 7.1.3), generate your own unique and identifiable ID for the protocol.

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]
6.2.6. Select “Continue” to proceed.

6.2.7. 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]

6.2.8. Select “Continue” to proceed.

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

6.2.10. Select “Continue” to proceed.

6.2.11. An “Edit Oversight” page will appear. Complete as follows:
- U.S. FDA Regulated Drug: Enter “Yes” or “No”. Note: A “Yes” is an IND regulated study.
- U.S. FDA Regulated Device: Enter “Yes” or “No”. Note: 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; SUBMITTED, PENDING; SUBMITTED, APPROVED; ETC.)]
- Data Monitoring Committee: Select “Yes” or “No”.
- FDA Regulated Intervention: Select “Yes” or “No”.

6.2.12. Select “Continue” to proceed.

6.2.13. 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.]


6.2.15. 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.]

6.2.16. Select “Continue” to proceed.

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, Basic Science, Device Feasibility, or Other”.
      Study Phase: Select, “N/A, Early Phase 1 (Phase 0), Phase 1, 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 EXPLANATIONS.]
      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)
      Arms
      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, Biological/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 SUMMARY 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)

Primary Outcome Measure

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 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: CONTACTS/LOCATIONS (Interventional Only)

Contacts
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: IPD SHARING (Interventional Only)
Plan to Share IPD: Select “Yes”, “No”, or “Undecided”. [COMPLETE ACCORDING TO THE PREPOPULATED DROP DOWNS.]

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)
Groups
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
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: OUTCOME MEASURES (Observational Only)

Primary Outcome Measure
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 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 (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 INCLUSION 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, & 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: IPD SHARING (Observational Only)

Plan to Share IPD: Select “Yes”, “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 & 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.

e. PART V: REFERENCES (Expanded Access Only)

Citations: Not required.

Links: Not required.

6.2.18. Select “Continue” to proceed if all information is final. A second dialogue box will populate. To confirm completion, select “OK”.

6.2.19. 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 ClinicalTrials.gov system. Once all outstanding “ERROR(S)” are addressed, the registration process includes review and approval.

6.3. Helpful Tips:
6.3.2. The system offers the option to save data if you do not have time to complete the entire process

6.3.3. Be aware of fields marked with the following:

<table>
<thead>
<tr>
<th></th>
<th>Required by ClinicalTrials.gov</th>
</tr>
</thead>
<tbody>
<tr>
<td>*</td>
<td>FDAAA Required to comply with US Public Law 110-85, Section 801</td>
</tr>
</tbody>
</table>

6.4. 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 re-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.

### Updating Your Registered Study

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

**FDA** updating requirements:
- Information must be updated at least once every 12 months
- If changes affect human subjects via a protocol amendment, the information must be updated within 30 days of the IRB’s approval
- The registry must be updated within 30 days of any changes in recruitment status or completion of study*
- The registry must be updated within 15 days of change in approval or clearance status of drugs and devices not previously approved by FDA

*Once a study is closed to accrual, the Responsible Party or designee will then monitor the patient status (on treatment, off treatment, off study), to determine the PCD. This date can be entered in ClinicalTrials.gov as “anticipated” and updated as the study moves forward. Once the date is set as “actual” then the Responsible Party has one year from that date to enter results.

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

**ICMJE** requires updating study information every 6 months.

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](https://clinicaltrials.gov/ct2/manage-recs/faq)
* Once a study is closed to accrual, the Responsible Party or designee will then monitor the patient status (on treatment, off treatment, off study), to determine the completion of the study. This date can be entered in ClinicalTrials.gov as “anticipated” and updated as the study moves forward. Once the date is set as “actual” then the sponsor has one year from that date to enter results. Please see “SOP Number: SC-406 Results Reporting of Clinical Trials in ClinicalTrials.gov”.

7. REFERENCES:

- ClinicalTrials.gov public website - [http://clinicaltrials.gov](http://clinicaltrials.gov)
- ClinicalTrials.gov registration site - [https://register.clinicaltrials.gov](https://register.clinicaltrials.gov)
- Protocol Data Element Definitions - [http://prsinfo.clinicaltrials.gov/definitions.html](http://prsinfo.clinicaltrials.gov/definitions.html)
- Learning Module 1: ClinicalTrials.gov Overview and PL 110-85 Requirements - [http://prsinfo.clinicaltrials.gov/WebinarSlidesBasicResults.pdf](http://prsinfo.clinicaltrials.gov/WebinarSlidesBasicResults.pdf)
- UHCMC Research SOP Number: SC-406 Results Reporting of Clinical Trials in ClinicalTrials.gov

8. FORMS OR ATTACHMENTS:

Appendix A: Creation of a ClinicalTrials.gov Account
Appendix B: Registering a Clinical Trial
STANDARD OPERATING PROCEDURE (SOP) FOR CLINICAL RESEARCH

Title: Registration of Clinical Trials in ClinicalTrials.gov

SOP NUMBER: SC-401

Last Revised: 07/2018
Prior Version: 05/2017

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APPROVALS

Approved by Dr. Grace McComsey, Associate Chief Scientific Officer, University Hospitals Health System, Director, UH Clinical Research Center– August 7, 2018
Appendix A: Creation of a ClinicalTrials.gov Account

Step 1 of 2: Creation of a ClinicalTrials.gov Account
A step-by-step walkthrough to facilitate account registration process:

Home Screen:
Ensure you are applying for a “PRS Individual Account” using the URL noted above.
There are four sections to this page: Acceptance of Terms, Sponsor Information, Investigator Information, and Regulatory Information

START ACCOUNT REGISTRATION
Acceptance of Term: Accept the conditions.

We updated the design of this site on December 18, 2017. Learn more.
ClinicalTrials.gov

Apply for a PRS Individual Account

Each entity submitting data to ClinicalTrials.gov must adhere to the following terms and conditions, which are intended to ensure the accuracy, currency, and validity of the data:
- Only data for studies that are in conformance with applicable human subjects or ethics review regulations (or equivalent) and applicable regulations of the national (or regional) health authority (or equivalent) may be submitted.
- Notice of changes in recruitment status must be provided as soon as possible, but no later than 30 days after such changes. All other submitted data must be reviewed, verified, and updated as necessary and no less than every 12 months.
- The submitting organization, or individual designated as the Responsible Party, is responsible for the completeness and accuracy of the data submitted to ClinicalTrials.gov.
- Study data must be submitted in English.
- Multiple groups within a single entity (e.g., company, university, government agency) must share a single Protocol Registration and Results System (PRS) organization account.
- Previous versions of study data will be available to the public, although the default view will be the most recent version.

(Acceptance Required) □ Accept □ Do Not Accept
Appendix A: Creation of a ClinicalTrials.gov Account

Sponsor Information: Complete the following section with the EXACT same information as seen in the image below.

![Sponsor Information form]

- Registering IND/IDE Studies: Yes
- Type of Organization: Nonprofit Organization
- Country: United States
- Organization Name: University Hospitals Cleveland Medical Center
- Organization Address: 11100 Euclid Avenue, Cleveland, OH 44106
- Organization Acronyms: UHCMC
- Organization Contact: Grace McComsey, MD
- Organization Phone: 216-445-6668
- Organization Email: grace.mccomsey@uhhospitals.org
- Organization Website (optional):
- Funding Organization:
Appendix A: Creation of a ClinicalTrials.gov Account

**Investigator Information & Regulatory Information:*** Input the investigator for the clinical trial in this section. Note: the email inserted here will receive correspondence from the ClinicalTrials.gov automated messaging system at the end of the registration process.

<table>
<thead>
<tr>
<th>Investigator Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Investigator Name:</strong> Jenna (Stump) Arlow</td>
</tr>
<tr>
<td><strong>Affiliation (if not the sponsor):</strong></td>
</tr>
<tr>
<td><strong>Investigator Phone:</strong> 2162860754</td>
</tr>
<tr>
<td><strong>Investigator Email:</strong> <a href="mailto:jenna.stump@uhhospitals.org">jenna.stump@uhhospitals.org</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Regulatory Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Regulatory Authority:</strong> University Hospitals Cleveland Medical Center Institutional Review Board</td>
</tr>
<tr>
<td><strong>Regulatory Authority Address:</strong> 11100 Euclid Avenue Cleveland, OH 44106</td>
</tr>
</tbody>
</table>

To the best of my knowledge, the above information is true and correct. Questions about this form and the PRS may be sent to register@ClinicalTrials.gov.

There are 2 options for the Regulatory Authority. It is either:

**OPTION 1** - U.S. Food and Drug Administration, or
**OPTION 2** - University Hospitals Cleveland Medical Center Institutional Review Board.

**OPTION 1** - For all IND/IDE-regulated studies (also commonly referred to as FDA-regulated studies), please use one of the three Centers below:

<table>
<thead>
<tr>
<th>Regulatory Authority</th>
<th>U.S. Food and Drug Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory Authority Address</td>
<td>Center for Devices and Radiological Health (CDRH) 10903 New Hampshire Avenue Silver Spring, MD 20993-0002</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Regulatory Authority</th>
<th>U.S. Food and Drug Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory Authority Address</td>
<td>Center for Drug Evaluation and Research (CDER) 5901-B Ammendale Rd. Beltsville, MD 20705-1266</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Regulatory Authority</th>
<th>U.S. Food and Drug Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory Authority Address</td>
<td>Center for Biologics Evaluation and Research (CBER)</td>
</tr>
</tbody>
</table>
Appendix A: Creation of a ClinicalTrials.gov Account

10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

OPTION 2 - For all other studies (e.g., non-significant risk studies), please use:

Regulatory Authority: University Hospitals Cleveland Medical Center Institutional Review Board
Regulatory Authority Address: 11100 Euclid Avenue
Cleveland, OH 44106

After clicking “Submit Application” button the following screen will appear.

Note: An account creation can take up to 5 business days, but generally an email will be generated within 2 business days.

END OF ACCOUNT REGISTRATION
Appendix A: Creation of a ClinicalTrials.gov Account

You will receive an email from register@clinicaltrials.gov. Again, this may take up to 5 business days but is generally within a 2 business day window. Please check your spam/junk email folders to ensure the email message is not filtered away from your inbox.

-----Original Message-----
From: ClinicalTrials.gov Registration [mailto:register@clinicaltrials.gov]
Sent: Wednesday, March 21, 2018 9:56 AM
To: Stump, Jenna <Jenna.Stump@UHhospitals.org>
Subject: ClinicalTrials.gov PRS Account Created

A PRS user account has been created for you.

The PRS URL is https://register.clinicaltrials.gov. To login, you will need the following information:

Organization: UHClevelandMC
User Name: 
Password: 

Please login and change your password as soon as possible. Also verify that the following information is correct.

Full Name: Jenna (Stump) Arlow
E-Mail: jenna.stump@uhhospitals.org

If you have questions about the system or have trouble logging in, please contact your organization's PRS administrator.

To log in, select the link within the email: https://register.clinicaltrials.gov. Enter the assigned username and password and select “Login”.

Welcome to the ClinicalTrials.gov Protocol Registration and Results System.

Login

NOTICE: The PRS will be offline for a software upgrade Thursday, beginning at 8:30 AM EDT (12:30 UTC). Expected downtime is 1 hour.

Organization: UHClevelandMC
Username: JAdlow
Password: *********

Login

See Submit Studies on ClinicalTrials.gov for information on how to apply for an account, how to register your study, and how to submit results.
Step 2 of 2: Registration of a Clinical Trial in ClinicalTrials.gov
A step-by-step walkthrough to facilitate registration of a clinical trial in ClinicalTrials.gov: https://register.clinicaltrials.gov

START REGISTERING A CLINICAL TRIAL

Click on the “New Record” in the Quicklinks dialogue box on the left or add a record in the “Records” Drop Down menu.

The image below is the “Create New Record” page.
Appendix B: Registering a Clinical Trial

To avoid duplicate or invalid registration of your study, check the following before proceeding with registration:

1. Studies may only be registered by the Responsible Party. The Responsible Party for a clinical study is the Sponsor, Sponsor-Investigator, or Sponsor-designated Principal Investigator who meets specific requirements:
   - When a study is subject to U.S. Food and Drug Administration regulations and conducted under an Investigational New Drug application (IND) or investigational device exemption (IDE), the IND or IDE holder is considered the Sponsor or Sponsor-Investigator.
   - When a study is not conducted under an IND or IDE, the entity or single person who initiates the study, by preparing and/or planning the study, and who has authority and control over the study, is considered the Sponsor or Sponsor-Investigator.

2. Use the PRS account of the Sponsor or Sponsor-Investigator to register the study. If the Sponsor has designated the Principal Investigator to be the Responsible Party for a study, that study must be registered using the PRS account of the Sponsor.

3. Multi-site studies are NOT registered by individual sites. If this is a multi-site study, it must be registered only once, by the Responsible Party (IND/IDE holder or the person or organization who initiates the study and who has authority and control over the study) or its designated Principal Investigator (PI).

4. Coordinate with all collaborators before registering. If the study has multiple collaborators, contact the other organizations to confirm that the study has not already been registered and to notify them that your organization (or designates PI) as Responsible Party, is registering the study.

5. Refer to the ClinicalTrials.gov Review of Protocol Submissions document for a description of items evaluated by ClinicalTrials.gov after protocol information is submitted.
Appendix B: Registering a Clinical Trial

The “Organization’s Unique Protocol ID” should be the IRB# assigned to your study. If your study is an IND/IDE-regulated study, please generate a unique and identifiable ID for the study. Enter a “Brief Title” (not the full official study title and no IRB# yet) and identify your “Study Type” (Interventional, Observational, or Expanded Access).

NOTE: The response of “Study Type” will change the required information within the ClinicalTrials.gov system.

See Section “Interventional Study”.
See Section “Observational Study”.
See Section “Expanded Access”.

Select “Continue” to proceed followed by “OK” for the dialogue box below.
Appendix B: Registering a Clinical Trial

Now enter your study’s “Official Title” in the corresponding section—different than the “Brief Title” above it. Select “Continue” when ready.
Appendix B: Registering a Clinical Trial

Enter the “Record Verification Date” and “Overall Recruitment Status”. For the three dates required below, you must complete the Month, Date, Year, AND Type. Omission of one of these will yield an error.

The Investigator Name [Username] field is an exhaustive list of investigators at our institution. Scroll until the name of the appropriate investigator is found and select their name. Enter their official title also just below the drop-down. Add other collaborators, or “Continue” on.
Appendix B: Registering a Clinical Trial

Fill out the oversight information using the prompts provided. Should you have any questions about these sections, double check with the appropriate personnel that the information is correct.

Include a “Brief Summary” of the study followed by a “Detailed Description”. There are character limits so be sure to be concise yet sufficient with this information.
Appendix B: Registering a Clinical Trial

Add condition(s) or focus of the study. Keywords can be entered as well. The goal would be to navigate to your specific study as a member of the public. Be specific!

Complete the following prompts based on your study design. Note: the prompts may be different based on the study type which was selected earlier (A) Interventional (B) Observational, and C) Expanded Access.

A) Interventional

Explain the Study Design for your study. Add Arms and types of masking as required. Don’t
Appendix B: Registering a Clinical Trial

forget to describe them if you have multiples! Enter # of subjects for Enrollment. Select Enrollment Type.

Describe Arm Title, Type, and Description. Add additional Arms if necessary.

Enter Intervention Type, Name, and Descriptions. Add additional Interventions if necessary.
Enter Outcome Measures information for Primary and Secondary study outcomes. Enter Title, Description, and Time Frame. Add Outcomes as necessary.
Enter study Eligibility information including, Sex, Gender, Age Limits, Accepts Healthy Volunteers, and Eligibility Criteria. Eligibility Criteria should be Inclusion and Exclusion Criteria as described in the protocol.

Enter the study Contacts, including Central Contact Person, Central Contact Backup, and Overall Study Officials.
Enter Location(s) of the study’s conduct with recruitment status and site contact information. Enter Investigators at the specific locations.

Enter Yes or No if there is a Plan to Share Individual Participant Data (IPD) available to other researchers. If yes, enter a Description of the IPD.
Enter References, including Citations and Links and IPD Information as necessary.

NOTE: If “A) Intervventional” is complete, skip section “B) Observational” and section “C) Expanded Access” and proceed to the section “Finish Data Entry”.

**B) Observational**
Appendix B: Registering a Clinical Trial

Explain the groups/cohorts for your study. Add groups/cohorts as required. Don’t forget to describe them if you have multiples!

The groups will require information about the intervention or exposure. Identify and describe these accordingly.

Identify the primary and secondary outcome measures with a planned time frame also.
Along with the study population, identify the parameters for eligibility within the study.
Enter study Eligibility information, including, Sex, Gender, Age Limits, Accepts Healthy Volunteers, and Eligibility Criteria. Eligibility Criteria should be Inclusion and Exclusion Criteria as described in the protocol.
Appendix B: Registering a Clinical Trial

![Image of Edit Overall Contacts form with fields filled in]

- **Central Contact Person:**
  - First Name: Jenna
  - Last Name: Stump Arlow
  - Degree: MS
  - Phone: 2162660754
  - Email: jenna.stump@uohospitals.org

- **Central Contact Backup:**
  - First Name: 
  - Last Name: 
  - Degree: 
  - Phone: 
  - Email: 

- **Overall Study Officials:**
  - First Name: Jenna
  - Last Name: Stump Arlow
  - Degree: MS
  - Organizational Affiliation: University Hospitals Cleveland Medical Center
  - Official's Role: Study Principal Investigator

* Required
* § Required if Study Start Date is on or after January 18, 2017
* [*] Conditionally required (see Definitions)
Appendix B: Registering a Clinical Trial

Enter Location(s) of the study’s conduct with recruitment status and site contact information. Enter Investigators at the specific locations.

Enter the study Contacts, including Central Contact Person, Central Contact Backup, and Overall Study Officials.

Enter Yes or No if there is a Plan to Share Individual Participant Data (IPD) available to other researchers. If yes, enter a Description of the IPD.
Appendix B: Registering a Clinical Trial

Enter References, including Citations and Links and IPD Information as necessary.

NOTE: If “B) Observational” is complete, skip section “C) Expanded Access” and proceed to the section “Finish Data Entry”.

C) Expanded Access

Add information about the intervention or exposure. Identify and describe these accordingly.
Along with the study population, identify the parameters for eligibility within the study.
Appendix B: Registering a Clinical Trial

Enter study Eligibility information, including, Sex, Gender, Age Limits, Accepts Healthy Volunteers, and Eligibility Criteria. Eligibility Criteria should be Inclusion and Exclusion Criteria as described in the protocol.
Appendix B: Registering a Clinical Trial

Enter the study Contacts, including Central Contact Person, Central Contact Backup, and Overall Study Officials.
Appendix B: Registering a Clinical Trial

Enter Location(s) of the study’s conduct with recruitment status and site contact information. Enter Investigators at the specific locations.

Enter References, including Citations and Links and IPD Information as necessary.
Appendix B: Registering a Clinical Trial

**Finish Data Entry**

After completing either the Interventional, Observational, or Expanded Access tracks, proceed to finish your data entry.

If final press “Continue” then dialogue box below will populate confirming completion.

| You have finished data entry for the Protocol Section. Review any Errors, Warnings or Notes and make changes as needed. Select Preview to see a rough approximation of how the record will appear on ClinicalTrials.gov. Select the “Record Summary” link in the top left corner of the page to see next steps for finishing the record submission process. OK |

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 ClinicalTrials.gov system. Once all outstanding “ERROR(S)” are addressed, the registration process includes review and approval.
Appendix B: Registering a Clinical Trial

After clicking “OK” an overview page will allow for quick review of the entry prior to approval.

![Overview page of ClinicalTrials.gov](image-url)
Appendix B: Registering a Clinical Trial

This record summary contains a status bar at the top of the page. Specifically, it identifies the process by stages:

1. “In Progress”
2. “Entry Completed”
3. “Approved”
4. “Released”
5. “PRS Review”
6. “Public”

You can see we are on Step 1 “In Progress”. Once the data entry has been completed, select the “Entry Complete” button.

In the “Protocol Section”, the completed modules are shown to give you an overview of your progress for the entry.
Appendix B: Registering a Clinical Trial

Now you should proceed to Step 2 “Entry Completed”. It is time to allow the responsible party to review and approve the information and data entered in the system. Please ensure this is an active and dynamic review process and not simply a step to be completed. After all, the Sponsor/Investigator is responsible for the information submitted.

After the responsible party concurs with the entered data, the responsible party (Sponsor/Investigator) should select “Approve”.

After approval, we proceed to Step 3 “Approved”. This step allows us to “Release” the entered clinical trial information to the ClinicalTrials.gov PRS.

Upon “Release” the clinical trial information entered into the system is routed and reviewed by the ClinicalTrials.gov system. At this point, Form FDA 3674 can be completed for IND/IDE-regulated studies.
Here is the protocol registration steps spelled out and identifies the parties which are responsible for each of the aforementioned steps.

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
<th>Performed by</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Enter all required information in the Protocol Section of the record.</td>
<td>Record Owner</td>
</tr>
<tr>
<td>2.</td>
<td>Select <strong>Entry Complete</strong> on the Record page.</td>
<td>Record Owner</td>
</tr>
<tr>
<td>3.</td>
<td>Review the record for accuracy and completeness, assessing whether any corrections need to be made.</td>
<td>Jenna (Stump) Arlow</td>
</tr>
<tr>
<td>4.</td>
<td>Select <strong>Approve</strong> on the Record page.</td>
<td>Jenna (Stump) Arlow</td>
</tr>
<tr>
<td>5.</td>
<td>Select <strong>Release</strong>... on the Record page to submit the record to ClinicalTrials.gov.</td>
<td>Jenna (Stump) Arlow</td>
</tr>
<tr>
<td>6.</td>
<td>Perform final review and processing of the record.</td>
<td>ClinicalTrials.gov PRS</td>
</tr>
</tbody>
</table>

Records are made available to the public through the ClinicalTrials.gov web site within 2 to 5 days of Release, following successful PRS Review. The ClinicalTrials.gov Identifier (NCT number) is assigned as part of that process.

**Tips:**
- Record Owner steps may also be performed by any User who is on the record's Access List or by any UHClevelandMC Administrator.
- Resolve all Errors and Warnings, if any.
- For active studies, update Verification Date when updating or reviewing a record, even if no other changes are made.

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**END OF REGISTERING A CLINICAL TRIAL**

This is the main page once you enter the site. Now that you’ve completed the registration process. You can view the study information and open your study here.