How To Register A Protocol

ClinicalTrials.gov

Shared by UABMC on 4/11/17
“Final Rule for the FDAAA 801 on Clinical Trial Reporting”

• For all “Applicable Clinical Trials”
• Studies need to be registered no later than 21 days after enrollment of the first patient.
Applicable Clinical Trials

Include:

• **Trials of drugs and biologics** – All controlled clinical investigations, other than phase 1 (all Interventional Studies that meet established criteria).
  – One or more sites, IND, involves a drug, biologic, or device

• **Trials of devices** – Controlled trials with **health outcomes** of devices, other than small feasibility studies and 2) pediatric post-market surveillance required by the FDA
Applicable Clinical Trials

Exclusions:

• Trials that do not include drugs, biologics, or devices (such as behavioral interventions)
• Phase 1 drug trials, including studies in which investigational drugs are used as research tools
• Non-interventional (observational) clinical research (such as cohort or case-control studies)
• Small clinical trials to determine the feasibility of a device, where the primary outcome measure relates to feasibility and not to health outcomes
Final Rule For NIH Policy on Clinical Trial Reporting

• All NIH-funded clinical trials will be expected to register and submit results information to ClinicalTrials.gov.
• This policy applies to all NIH-funded clinical trials regardless of study phase, type of intervention, or whether they are subject to the regulation. (For example, NIH-funded phase 1 clinical trials of an FDA-regulated product are covered by this policy as are clinical trials studying interventions not regulated by the FDA, such as behavioral interventions.)
• As such, the policy encompasses all NIH-funded clinical trials, including applicable clinical trials subject to the regulation.
• Policy applies: all NIH-funded awardees and investigators in whole or part, including phase I
<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
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</thead>
<tbody>
<tr>
<td>Organization's Unique Protocol ID</td>
<td>F00123456</td>
</tr>
<tr>
<td>Brief Title</td>
<td>Efficacy of Drug X vs Drug Y in Non-Small Lung Cell Lung Cancer</td>
</tr>
<tr>
<td>Acronym (if any)</td>
<td>NSCLC</td>
</tr>
<tr>
<td>Study Type</td>
<td>Interventional (or clinical trial) — participants assigned to intervention(s) based on a protocol</td>
</tr>
<tr>
<td></td>
<td>Observational — participants not assigned to intervention(s) based on a protocol, typically in context of routine care</td>
</tr>
<tr>
<td></td>
<td>Expanded Access — availability of an experimental drug or device outside of a clinical trial protocol</td>
</tr>
</tbody>
</table>

* Required

§ Required if Study Start Date is on or after January 18, 2017

[*] Conditionally required (see Definitions)
Agenda of Information

The following web pages allow data entry for each protocol module:

- Study Identification
- Study Status
- Sponsor/Collaborators
- Oversight
- Description
- Conditions
- Study Design
- Interventions
- Eligibility
- Contacts/Locations
- References

On each page, select Continue to save data entered and proceed to the next page.

On any page, select Quit to stop entering data. Data entered on previous pages will be retained. To complete data entry later, open the record from the home page.
**Official Title**

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
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</thead>
<tbody>
<tr>
<td>Organization's Unique Protocol ID</td>
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<tr>
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</tr>
<tr>
<td>[*] Acronym:</td>
<td>NSCLC</td>
</tr>
<tr>
<td></td>
<td>If specified, will be included at end of Brief Title in parentheses.</td>
</tr>
<tr>
<td>* Official Title:</td>
<td>Evaluating the Efficacy and Safety of a New Novel Drug Combination Against the Standard Treatment for Non-Small Cell Lung Cancer</td>
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<td></td>
<td>❗️ WARNING: Official Title has not been entered.</td>
</tr>
<tr>
<td>[*] Secondary IDs:</td>
<td></td>
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</table>

* Required

* § Required if Study Start Date is on or after January 18, 2017

[*] Conditionally required (see Definitions)
### ClinicalTrials.gov PRS

**Protocol Registration and Results System**

#### Quick Links
- New Record
- Admin Quick Reference
- Problem Resolution Guide

#### Record List

<table>
<thead>
<tr>
<th>Protocol ID</th>
<th>ClinicalTrials.gov ID</th>
<th>Brief Title</th>
<th>Record Status</th>
<th>Last Update</th>
<th>Record Owner</th>
<th>Responsible Party</th>
<th>Problems</th>
</tr>
</thead>
<tbody>
<tr>
<td>Open</td>
<td>F160920009</td>
<td>The Topic Trial: Study to Determine the Safety and Efficacy of Ivecotin</td>
<td>In Progress</td>
<td>03/07/2017 12:01</td>
<td>ewestfala</td>
<td>Mark Dransfield, MD</td>
<td><a href="mailto:mdtransfield@ubomc.edu">mdtransfield@ubomc.edu</a></td>
</tr>
<tr>
<td>Open</td>
<td>X141114004</td>
<td>Evaluating the Efficacy and Compatibility of Elinconamizole 10% Solution (Jublia) for the Treatment of Toenail Onychomycosis in Patients Wearing Toenail Polish Compared to Those Without Polish</td>
<td>In Progress</td>
<td>01/12/2017 14:08</td>
<td>cwan9</td>
<td>Boni Elowsk, MD</td>
<td><a href="mailto:belowski@uab.edu">belowski@uab.edu</a></td>
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<tr>
<td>Open</td>
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<td>Efficacy of Drug X/Y vs Drug Y in Non-Small Cell Lung Cancer (NSCLC)</td>
<td>In Progress</td>
<td>03/10/2017 17:08</td>
<td>dhmckenz</td>
<td>[Sponsor]</td>
<td></td>
</tr>
</tbody>
</table>
Study Dates & Recruitment Completed

* Record Verification Date:
  Month: March ▼ Year: 2017

* Overall Recruitment Status:
  Recruiting ▼

  Before selecting Suspended, Terminated or Withdrawn see the Overall Recruitment Status definition.

Tip: Day is not required for Anticipated dates.

* § Study Start Date:
  Month: April ▼ Day: 1 Year: 2017 Type: Actual ▼

  Beginning of participant enrollment.

* Primary Completion Date:
  Month: December ▼ Day: 31 Year: 2017 Type: Anticipated ▼

  Final data collection date for primary outcome measure.

* § Study Completion Date:
  Month: December ▼ Day: 31 Year: 2017 Type: Anticipated ▼

  Final data collection date for study.

* Required

* § Required if Study Start Date is on or after January 18, 2017

[▶] Conditionally required (see Definitions)
Sponsor/Collaborators

* Responsible Party:

Select Sponsor unless the Principal Investigator has been designated as Responsible Party or the Principal Investigator is the Sponsor.

* Sponsor:

University of Alabama at Birmingham

Primary organization conducting study and associated data analysis (not necessarily a funding source).

Collaborators:

Enter only the organization name.

* Required

* § Required if Study Start Date is on or after January 18, 2017

[*] Conditionally required (see Definitions)
## Sponsor/Collaborators

**Completed**

### Investigator Information

- **Investigator Name [Username]**: Elaine C. Moreland [emoreland]
- **Investigator Official Title**: Primary Investigator
- **Investigator Affiliation**: University of Alabama at Birmingham

### Sponsor

- **Sponsor**: University of Alabama at Birmingham
  
  Primary organization conducting study and associated data analysis (not necessarily a funding source).

### Collaborators

- **World Health Organization (WHO)**

---

*Required

* § Required if Study Start Date is on or after January 18, 2017

* ** Conditionally required (see Definitions)
Oversight

<table>
<thead>
<tr>
<th>Question</th>
<th>Selection</th>
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</thead>
<tbody>
<tr>
<td>^ § U.S. FDA-regulated Drug:</td>
<td>-Select--</td>
</tr>
<tr>
<td>Studying one or more U.S. FDA-regulated drug or biologic products?</td>
<td>-Select--</td>
</tr>
<tr>
<td>* § U.S. FDA-regulated Device:</td>
<td>-Select--</td>
</tr>
<tr>
<td>Studying one or more U.S. FDA-regulated device products?</td>
<td>-Select--</td>
</tr>
<tr>
<td>* U.S. FDA IND/IDE Study:</td>
<td>-Select--</td>
</tr>
<tr>
<td>(Not public) Studying drug/device product with U.S. FDA Investigational New Drug (IND) Application or Investigational Device Exemption (IDE)?</td>
<td>-Select--</td>
</tr>
<tr>
<td>* Human Subjects Protection Review:</td>
<td>-Select--</td>
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<tr>
<td>Data Monitoring Committee:</td>
<td>-Select--</td>
</tr>
<tr>
<td>Plan to Share IPD:</td>
<td>-Select--</td>
</tr>
<tr>
<td>Indicate if there is a plan to make individual participant data (IPD) available to other researchers.</td>
<td>-Select--</td>
</tr>
<tr>
<td>FDA Regulated Intervention:</td>
<td>-Select--</td>
</tr>
</tbody>
</table>

^ Required
* § Required if Study Start Date is on or after January 18, 2017
** Conditionally required (see Definitions)
Oversight Completed

<table>
<thead>
<tr>
<th>Field</th>
<th>Selection</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>U.S. FDA-regulated Drug</td>
<td>Yes</td>
<td>Studying one or more U.S. FDA-regulated drug or biologic products?</td>
</tr>
<tr>
<td>U.S. FDA-regulated Device</td>
<td>No</td>
<td>Studying one or more U.S. FDA-regulated device products?</td>
</tr>
<tr>
<td>U.S. FDA IND/IDE Study (Not public)</td>
<td>No</td>
<td>Studying drug/device product with U.S. FDA Investigational New Drug (IND) Application or Investigational Device Exemption (IDE)?</td>
</tr>
<tr>
<td>Product Exported from U.S.</td>
<td>No</td>
<td>Studying a drug or device product that is manufactured in and exported from the U.S.?</td>
</tr>
<tr>
<td>Human Subjects Protection Review</td>
<td></td>
<td>The following information is required if the study meets each of these criteria: not required to be registered under 42 CFR Part 11, not funded in whole or in part by the U.S. government, and is not conducted under an IND or IDE. [This information is not made public.]</td>
</tr>
<tr>
<td>Approval Number</td>
<td>F00123458</td>
<td></td>
</tr>
<tr>
<td>Board Name</td>
<td>Institutional Review Board for Human Use</td>
<td></td>
</tr>
<tr>
<td>Board Affiliation</td>
<td>University of Alabama at Birmingham</td>
<td></td>
</tr>
<tr>
<td>Board Contact</td>
<td>Phone: 205-732-1134 Extension:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Email: <a href="mailto:irb@uab.edu">irb@uab.edu</a></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Address: Administration Building, Room 470 701 South 20th Street Birmingham, AL 35294-0104</td>
<td></td>
</tr>
<tr>
<td>Data Monitoring Committee</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Plan to Share IPD</td>
<td>Undecided</td>
<td>Indicate if there is a plan to make individual participant data (IPD) available to other researchers.</td>
</tr>
<tr>
<td>Plan Description</td>
<td></td>
<td>Describe the IPD sharing plan, including what IPD are to be shared with other researchers, when it will be available, and how it may be obtained.</td>
</tr>
<tr>
<td>FDA Regulated Intervention</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>
Study Description Completed

Brief Summary:
This study is being done to determine the overall progression-free survival (PFS) in patients with advanced or metastatic (Stage IIIb - pleural effusion/IV), non-squamous histology NSCLC treated with standard chemotherapy treatment vs combination chemotherapy.

Detailed Description:
Subjects will be treated with chemotherapy with Drug X and Drug Y weekly for 3 out of 4 weeks. Treatment with chemotherapy will be expressed as a 4-week cycle. Tumor response to treatment will be evaluated every 8 weeks.

Treatment with chemotherapy will continue for a total of 6 cycles unless there is evidence of disease progression, intolerable toxicity, or withdrawal of consent. Maintenance therapy will then continue until disease progression, intolerable toxicity or withdrawal of consent.

Potential biologic parameters to monitor anti-tumor activity of metronomic chemotherapy will be evaluated in 10 subjects. These biomarkers include: sequential determination of blood levels of VEGF, VEGFR2, thrombospondin-1, E-selectin, ICAM-1, and circulating endothelial cells and endothelial precursor cells.

Avoid duplicating information that will be entered elsewhere, such as Eligibility Criteria or Outcome Measures.

* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)
Conditions

Edit Conditions

^ Conditions or Focus of Study:

Search MeSH, the National Library of Medicine's Medical Subject Headings, for valid condition terms.
If there are no conditions under study, enter brief description of focus of study instead.

Keywords:

^ Required
§ Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)
Conditions Complete

* Conditions or Focus of Study: Carcinoma, Non-Small-Cell Lung

  Search MeSH, the National Library of Medicine’s Medical Subject Headings, for valid condition terms.

  + Add Condition

Keywords:

- Non-Small Cell Lung
- NSCLC
- Drug X
- Drug Y

Continue  Back  Quit

* Required
* § Required if Study Start Date is on or after January 18, 2017
* [*] Conditionally required (see Definitions)
**Interventional Study Design**

- **Study Type:** Interventional
- **Primary Purpose:** [Select]
- **Study Phase:** [Select]
- **Interventional Study Model:** [Select]
- **Number of Arms:** [ ]
- **Masking:**
  - [ ] Participant
  - [ ] Care Provider
  - [ ] Investigator
  - [ ] Outcomes Assessor
  - [ ] No Masking

- **Masking Description:** [ ]
- **Allocation:** [Select]
- **Enrollment:**
  - **Number of Subjects:** [ ]
  - **Type:** [Select]

* Required
* Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)
**Interventional Study Design Completed**

<table>
<thead>
<tr>
<th><strong>^ Study Type:</strong></th>
<th>Interventional</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>^ § Primary Purpose:</strong></td>
<td>Treatment</td>
</tr>
<tr>
<td><strong>^ § Study Phase:</strong></td>
<td>Phase 2/Phase 3</td>
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<tr>
<td><strong>^ § Interventional Study Model:</strong></td>
<td>Parallel</td>
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<tr>
<td><strong>Model Description:</strong></td>
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<tr>
<td><strong>^ § Number of Arms:</strong></td>
<td>2</td>
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<tr>
<td><strong>^ § Masking:</strong></td>
<td>No Masking</td>
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<tr>
<td>Masking Description:</td>
<td>Open-label</td>
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<tr>
<td><strong>^ § Allocation:</strong></td>
<td>Randomized</td>
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<tr>
<td><strong>^ § Enrollment:</strong></td>
<td>Number of Subjects: 50</td>
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</table>

*Required if Study Start Date is on or after January 18, 2017

*Conditionally required (see Definitions)
Arms

* Required
* § Required if Study Start Date is on or after January 18, 2017
[•] Conditionally required (see Definitions)
Arms Defined

**Arms:**

- **Arm Title:** Docetaxel & Bevacizumab
  
  Formerly Arm Label. Brief, descriptive label to be used as row or column heading in tables.

- **Arm Type:** Experimental
  
  [ ] Arm Description:
  
  Describe treatment for Drug X (Docetaxel) & Drug Y (Bevacizumab)

- **Arm Title:** Docetaxel
  
  * Arm Type: Active Comparator
    
    [ ] Arm Description:
    
    Describe treatment for (Docetaxel)

- **Save**  
  
  * Required
  
  * § Required if Study Start Date is on or after January 18, 2017
  
  [*] Conditionally required (see Definitions)
Interventions

- Intervention Type: --Select--
- Intervention Name:
- Other Names: (if any)
- Intervention Description:

For a drug, use generic name if established. Use the same name as in the associated Arm/Group Description(s).

Include brand names, serial numbers and code names to improve search results on the ClinicalTrials.gov web site.

Do not repeat information already included in arm/group descriptions.

* Required
* § Required if Study Start Date is on or after January 16, 2017
[*] Conditionally required (see Definitions)
## Intervention Defined

<table>
<thead>
<tr>
<th>Arms: Experimental: Docetaxel &amp; Bevacizumab</th>
<th>Active Comparator: Docetaxel</th>
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<tr>
<td>Interventions:</td>
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</tr>
<tr>
<td>* Intervention Type:</td>
<td>Drug</td>
</tr>
<tr>
<td>* Intervention Name:</td>
<td>Docetaxel &amp; Bevacizumab</td>
</tr>
<tr>
<td>[*] Other Names (if any)</td>
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<tr>
<td>* § Intervention Description:</td>
<td>A novel new combination treatment...</td>
</tr>
<tr>
<td></td>
<td>Do not repeat information already included in arm/group descriptions.</td>
</tr>
</tbody>
</table>

| * Intervention Type:                       | Drug                          |
| * Intervention Name:                       | Docetaxel                     |
| [*] Other Names (if any)                   | Taxotere (Docetaxel)          |
| * § Intervention Description:              | Standard Treatment...         |

**Help**  **Definitions**
Arms & Interventions

Arms
- Experimental: Docetaxel & Bevacizumab
  Describe treatment for Drug X (Docetaxel) & Drug Y (Bevacizumab)

- Active Comparator: Docetaxel
  Describe treatment for (Docetaxel)

Interventions
- Intervention: Drug: Docetaxel & Bevacizumab
  Other Names:
  Avastin (Bevacizumab)
  Taxotere (Docetaxel)
  A novel new combination treatment...

- Intervention: Drug: Docetaxel
  Other Names:
  Taxotere (Docetaxel)
  Standard Treatment...

Cross-Reference

<table>
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<th>Interventions</th>
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<td>Experimental: Docetaxel &amp; Bevacizumab</td>
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<tr>
<td>Describe treatment for Drug X (Docetaxel) &amp; Drug Y (Bevacizumab)</td>
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</tr>
<tr>
<td>Drug: Docetaxel &amp; Bevacizumab</td>
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<tr>
<td>Drug: Docetaxel</td>
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<tr>
<td>Active Comparator: Docetaxel</td>
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<tr>
<td>Describe treatment for (Docetaxel)</td>
<td>✔</td>
</tr>
</tbody>
</table>

✔ Intervention is administered to patients in this Arm.
Outcome Measures

* Primary Outcome Measure:

- **Title:**
- **Description:**
- **Time Frame:**

[*] Secondary Outcome Measures:
(if any)

* Other Pre-specified Outcomes:

* Required

* § Required if Study Start Date is on or after January 18, 2017

[*] Conditionally required (see Definitions)
# Outcome Measures

## Edit Outcome Measures

<table>
<thead>
<tr>
<th>Outcome 1</th>
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<tbody>
<tr>
<td><strong>Title:</strong> Progression Free Survival</td>
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<tr>
<td><strong>Description:</strong> Describe exactly how you plan to measure your primary outcome</td>
</tr>
<tr>
<td><strong>Time Frame:</strong> Baseline through 12 months</td>
</tr>
</tbody>
</table>

- [Add Primary Outcome](#)

<table>
<thead>
<tr>
<th>Outcome 2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title:</strong> Overall Survival</td>
</tr>
<tr>
<td><strong>Description:</strong> Describe exactly how you plan to measure your secondary outcome</td>
</tr>
<tr>
<td><strong>Time Frame:</strong> Baseline through 12 months</td>
</tr>
</tbody>
</table>

- [Copy Outcome](#)
- [Delete Outcome](#)

- [Add Secondary Outcome](#)
# Eligibility

**Edit Eligibility**

**Sex:**
- All

* Biological sex of eligible participants.

**Gender Based:**
- No

If applicable, indicate if participant eligibility is based on self-representation of gender identity.

**Age Limits:**
- Minimum: 35 Years
- Maximum: 65 Years

**Accepts Healthy Volunteers:**
- Yes

**Eligibility Criteria:**
- Inclusion Criteria:
  - 
- Exclusion Criteria:
  - 

---

Special Characters
Overall Contacts

Central Contact Person:
Central Contact Backup:
Overall Study Officials:

Copy locations... from a master list, extracted from this organization's records.
## Overall Contacts

### Edit Overall Contacts

<table>
<thead>
<tr>
<th>Help</th>
<th>Definitions</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Central Contact Person:</th>
<th>First Name:</th>
<th>MI:</th>
<th>Last Name:</th>
<th>Degree:</th>
</tr>
</thead>
<tbody>
<tr>
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<td>Email:</td>
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</table>

<table>
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<tr>
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<th>Last Name:</th>
<th>Degree:</th>
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<tbody>
<tr>
<td>Phone:</td>
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<td></td>
<td>Email:</td>
<td></td>
</tr>
</tbody>
</table>

Either Central Contact or Facility Contacts are required.
The individual's official title may be substituted for Last Name (leave First Name, MI and Degree blank).

<table>
<thead>
<tr>
<th>Overall Study Officials:</th>
<th>+ Add Study Official</th>
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</thead>
</table>


## Edit Location

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td><strong>Facility:</strong> Name must be provided to identify the location.</td>
</tr>
<tr>
<td>City</td>
<td><strong>Facility:</strong> City information should be included.</td>
</tr>
<tr>
<td>State/Province: Alabama</td>
<td><strong>Facility:</strong> State and province information should be entered.</td>
</tr>
<tr>
<td>ZIP/Postal Code</td>
<td><strong>Facility:</strong> ZIP code for physical location should be supplied.</td>
</tr>
<tr>
<td>Country: United States</td>
<td><strong>Facility:</strong> Country information should be included.</td>
</tr>
<tr>
<td>Site Recruitment Status</td>
<td><strong>Facility:</strong> Recruitment status for this individual location must be set.</td>
</tr>
<tr>
<td>Facility Contact</td>
<td><strong>Facility Contact:</strong> First Name, MI, Last Name, Phone, Email, Degree.</td>
</tr>
<tr>
<td>Facility Contact Backup</td>
<td><strong>Facility Contact Backup:</strong> First Name, MI, Last Name, Phone, Email, Degree.</td>
</tr>
</tbody>
</table>

*Either Central Contact or Facility Contacts are required.*

The individual's official title may be substituted for Last Name (leave First Name, MI and Degree blank).

**Investigators:**

- **Add Investigator**
References

Citations
Definition: Citations to publications related to the protocol: background and/or results. Provide either the PubMed Unique Identifier (PMID) of an article or enter the full bibliographic citation.

PubMed Identifier
Definition: PMID for the citation in MEDLINE

Citation
Definition: bibliographic reference in NLM’s MEDLINE format
Limit: 2000 characters.

Results Reference
Definition: Indicate if the reference provided reports on results from this clinical study.

Links
Definition: A Web site directly relevant to the protocol may be entered, if desired. Do not include sites whose primary goal is to advertise or sell commercial products or services. Links to educational, research, government, and other non-profit Web pages are acceptable. All submitted links are subject to review by ClinicalTrials.gov.

URL
Definition: complete URL, including http:// or https://
Limit: 3999 characters.

Description
Definition: title or brief description of the linked page.
Limit: 254 characters.
Available Study Data/Documents
Definition: Study data sets and documents that are being shared. Provide the following information for each:

**Type**
Definition: The type of data set or document being shared.
- Individual Participant Data Set
- Study Protocol
- Statistical Analysis Plan
- Informed Consent Form
- Clinical Study Report
- Analytic Code
- Other (specify)

**URL**
Definition: The Web address used to request or access the data set or document.
Limit: 3999 characters.

**Identifier**
Definition: The unique identifier used by a data repository for the data set or document.
Limit: 30 characters.

**Comments**
Definition: Additional information including the name of the data repository or other location where the data set or document is available. Provide any additional explanations about the data set or document and instructions for obtaining access, particularly if a URL is not provided.
Limit: 1000 characters.