TRUE 2.0
Clinical Trials Submission and Management

This is an electronic gateway for the submission, review, approval and tracking of clinical trials and related budgets for research at USC.

After signing into this site, you are bound by the terms and conditions set forth when you received your account.
Create Clinical Trial submissions using Smart Forms that will guide you through the process and submit them to Health Research Association for contracting and budgeting assistance.
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Clinical Trials Requiring Action or Nearing Activation

No data to display.

Budgets Requiring Action

No data to display.

Documents Requiring Action

No data to display.
Non–Industry MCA Submission
1.1 What is the funding source for the study you are submitting?

- Industry Funding
- Seeking Funding from Industry
- Other (includes NIH, DOD, foundations, other government funding, department or division funding)

Clear
1.02 What type of non-industry submission are you making?
- Study has been or will be submitted to iSTAR and requires a budget, Medicare coverage analysis and consistency checklist only
- Requesting preliminary budget review for a funding proposal
- Requesting HRA to complete a contract under an HRA Clinical Agreement Exception Letter

Clear

1.03 If the study has been submitted to the IRB through iSTAR, does it currently have a pending contingency for an HRA consistency checklist?
- Yes
- No

Clear
Please provide the following information about the study:

2.01 If this study has already been submitted to the IRB, use the [Search for iSTAR Submission] button to enter the IRB number and PI Name to link this submission with the iSTAR submission. This link can be created whenever the iSTAR submission is begun.

ISTAR Name:
IRB Number:

Search for iSTAR Submission

2.02 * Brief Study Title (Will be used on lists and reports):
Non-Industry Submission Test Study

2.03 Study Full Title:

2.04 Sponsor's Protocol Number:

2.05 Protocol Version:

2.06 * Choose the Study Type from the listing below:
Drug
Enter Drug Details

2.01a  * Drug Name:

2.01b  The FDA Investigational New Drug (IND) Status of the drug or biological.

An IND is a request for authorization from the Food and Drug Administration to administer an investigational drug or biological product to humans.

The drug has an IND as evidenced by:
- Sponsor Protocol Imprinted with IND number
- Communication from the Sponsor or FDA with the number
- An IND application will be submitted for the drug.
- The drug is believed to be exempt from the IND regulations.

2.01c  * IND Number (if not known yet, or if drug is exempt, enter 'NA'):

Will the Principal Investigator hold the IND?
- Yes
- No

2.01d  Check all applicable pharmacies where the drug will be stored or dispensed.
- USC Ambulatory Pharmacy Service (IDS)
- Norris Pharmacy
- University Hospital Pharmacy
- LAC Pharmacy
- Other:

2.01e  How will the drug be purchased?
- Bill to HRA
- Bill to insurance
- Provided by Sponsor
- Clear

2.01f  What is the FDA status of the investigational item or service?
- Investigational
- Approved
- Clear

2.01g  If FDA Approved, is the investigational item or service being used off-label?
- Yes
- No
- Clear
Drug Information

Please enter information for each drug involved in this study, including investigational and non-investigational drugs and placebos.

2.01  * Drug Information (Create one entry for each drug or placebo):

<table>
<thead>
<tr>
<th></th>
<th>IND Number</th>
<th>Drug Name</th>
<th>FDA Status</th>
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</thead>
<tbody>
<tr>
<td>Add</td>
<td>NA</td>
<td>Drug 1</td>
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</table>

2.02  * Select the Phase from the list below:

- Phase 1
Study Enrollment and Budgeting Considerations

2.11 What is the maximum number of participants you plan to recruit at USC?
20

2.12 Do you foresee that this study will use the 3T MRI?
☐ Yes  ☐ No  ☐ Clear

If yes, please indicate which visits will require the 3T MRI.

2.13 Enter the password for the Sponsor’s Budget, if needed.

2.14 Enter the password for the Protocol, if needed.

2.15 Will the data analysis be done at USC?
☐ Yes  ☐ No  ☐ Clear

2.16 Will the statistical analysis be done at USC?
☐ Yes  ☐ No  ☐ Clear

2.17 If the study involves cycles, how many cycles will the average patient undergo (i.e. average time to disease progression)?

2.18 Please describe any other special budgeting considerations for this study.
# Please provide the following information about the sponsors of this study:

## 3.01 Primary Sponsor and Contact Person

Press Add to select from the active sponsor listing:

<table>
<thead>
<tr>
<th>Sponsor Name</th>
<th>Sponsor Type</th>
<th>Contact Name</th>
<th>Title</th>
<th>Contact Phone</th>
<th>Fax</th>
<th>Contact Email</th>
<th>Address1</th>
<th>Address2</th>
<th>City</th>
<th>State</th>
<th>Zip</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABBOTT CARDIOVASCULAR</td>
<td>Update</td>
<td>Delete</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

First Name Last Name Phone Email

If you could not find the sponsor from the active sponsor listing, please enter the information regarding the sponsor here:

## 3.02 Enter Co-Sponsors, CROs and other sponsoring organizations and companies here:

<table>
<thead>
<tr>
<th>Sponsor Name</th>
<th>Sponsor Type</th>
<th>First Name</th>
<th>Last Name</th>
<th>Email</th>
<th>Phone</th>
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<tbody>
<tr>
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There are no items to display
Please tell us who will be working on this study:

4.01 Use the Add button to select each member of the study staff. See the Notes and Instructions for details on entering the study staff, as this must be done carefully.

<table>
<thead>
<tr>
<th>Add</th>
<th>First Name</th>
<th>Last Name</th>
<th>Role</th>
<th>Primary Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Update</td>
<td>Rebecca</td>
<td>Simms</td>
<td>Principal Investigator</td>
<td>yes</td>
</tr>
</tbody>
</table>
Study Site(s) and Organizations:

5.01: Check if the study will require utilization of these services:
- Clinical Trials Unit (CTU)
- Investigational Drug Service (IDS) Pharmacy
- Keck Hospital Pharmacy
- Norris Hospital Clinical Pharmacy
- Pathology and Lab Services

5.02: Please check all other sites to be used during this study:
- USC University Hospital
- Cardiovascular Thoracic Institute (CVTI)
- Doheny Eye Institute and Hospital
- Doheny Image Reading Center
- El Monte Comprehensive Health Center
- H. Claude Hudson Comprehensive Center
- LAC+USC SP21 Building
- LAC+USC Medical Center
- LAC+USC Outpatient Clinics
- Other Location (e.g., subject's home, community)
- Roybal Comprehensive Health Center
- USC Ambulatory Health Center
- USC Healthcare Consultation Center I or II
- USC Medical School
- USC Norris Comprehensive Cancer Center
- USC Westside Prostate Cancer Center

5.03: Support Organizations Involved in this study:
- CISO
- Clinical Reference Lab
- CRU

The Clinical Investigations Support Office (CISO) at the USC Norris Comprehensive Cancer Center.
Division of Cardiovascular Medicine Clinical Research Unit
Clinical Trial Attachments: Non-Industry Submission Test Study  -- FP00001552

1.0 Protocol Password:
Budget Password:

<table>
<thead>
<tr>
<th>File Type</th>
<th>Title &amp; Description</th>
<th>Upload a file</th>
<th>My Activities</th>
<th>Version</th>
<th>Last Modified</th>
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<tr>
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<td>Generate</td>
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</table>
Congratulations...

You have reached the end of the submission Smart Forms.

To Submit a Study use the activity 'Submit to HRA':

To avoid errors, please use View Smart Forms Progress to confirm that all required fields have been entered.

The following documents must be uploaded:

- All submissions
- The protocol
- Informed Consent Form
- All industry-initiated submissions
- The Clinical Trial Agreement (draft contract) or Master Agreement Workorder
- The Sponsor's initial budget offer

To Request a Preliminary Budget use the activity 'Request Preliminary Budget':

Only the protocol must be uploaded. This type of request is allowed automatically for investigator-initiated studies that are seeking funding and studies in departments and divisions that require preliminary budgets for committee review. Other requests for preliminary budgets are subject to approval. Offer a justification on the activity form and you will be informed if the request is accepted.
### Non-Industry Submission Test Study - FP01001552

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
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<tbody>
<tr>
<td>Principal Investigator</td>
<td>Rebecca Simms</td>
</tr>
<tr>
<td>Primary Contact</td>
<td>Rebecca Simms</td>
</tr>
<tr>
<td>IRB # and Status</td>
<td>CIC #</td>
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<td>Sponsors</td>
<td>ABBOTT CARDIOVASCULAR.</td>
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<td>MCA Status</td>
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<td>Budget</td>
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<td>Trial Arms</td>
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