True 2.0
Training Views

September 18, 2013
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.

User Name: 
Password: 
Login

After signing into this site, you are bound by the terms and conditions set forth when you received your account.
Page for Sandy West

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.

Clinical Trials Requiring Action or Nearing Activation

<table>
<thead>
<tr>
<th>Filter by</th>
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<th>Clear</th>
<th>Advanced</th>
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Budgets Requiring Action

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Documents Requiring Action

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Page for Sandy West

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.

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.
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

Notes and Instructions:

Seeking Funding from Industry:
Use this option for USC Investigator-Initiated studies that need a preliminary budget. When selecting the sponsor, use "Unfunded or Seeking Funding" unless you know the sponsor with which you will be contracting in the future.

Other: With some exceptions, HRA does not contract for government or foundation funded studies. This includes cancer research consortiums, NIH, DOD and studies that will require department or division funding. HRA does provide budgets, MCAs, ROFs and IRB Consistency Checklists for these types of studies if they include patient care tests and procedures.
2.1 * Select the type of submission.
- Request to begin contracting
- Request for a preliminary budget
- Request for negotiation of a CDA
  Clear

2.2 * What type of industry-funded research will be conducted?
- Industry-Initiated
  - USC Investigator-Initiated
  - USC will be a subsite to a Non-USC Investigator-Initiated study
  - USC will be a sub-site to an industry-initiated study
- Service Agreement
  Clear

Notes and Instructions:

Ready to Begin Contracting: You will be required to upload a draft contract, protocol, and sponsor's proposed budget for this submission type.

Requesting Preliminary Budget: You will be required to upload a protocol. Once you have accepted the preliminary budget, the submission will be awaiting Resubmission until you are ready to begin contracting. At that time, change the type of submission on this page, upload the required documents, and use the activity Submit to HRA to begin contracting.

Requesting Negotiation of a CDA: Upload the CDA document. When the CDA is executed, you will receive an email. When the study is ready for contracting, change the submission type on this page.
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

Notes and Instructions:

**Seeking Funding from Industry:**
Use this option for USC Investigator-Initiated studies that need a preliminary budget. When selecting the sponsor, use "Unfunded or Seeking Funding" unless you know the sponsor with which you will be contracting in the future.

**Other:** With some exceptions, HRA does not contract for government or foundation funded studies. This includes cancer research consortia, NIH, DOD and studies that will require department or division funding. HRA does provide budgets, MCAs, ROFs and IRB Consistency Checklists for these types of studies if they include patient care tests and procedures.
1.21 The only type of submission allowed for studies seeking funding is a request for a preliminary budget. If you do not feel this is correct, choose a different funding source on the previous page.

- Request for a preliminary budget
- Clear

For what type of industry funded research are you seeking funding?

- USC Investigator Initiated
- USC will be a sub-site to a Non-USC Investigator Initiated study
- USC will be a sub-site to an industry-initiated study
- Clear

Notes and Instructions:

Requesting Preliminary Budget:
You will be required to upload a protocol. Once you have accepted the preliminary budget, the submission will be Awaiting Resubmission until you are ready to begin contracting. At that time, change the type of submission on this page, upload the required documents and use the activity Submit to HRA to begin contracting.
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

iSTAR Submissions: If the study has been submitted to iSTAR, be sure to link this submission with iSTAR on the Study Information page.

We recommend submitting to TRUE 2.0 as soon as your study is submitted to iSTAR so that the time required to complete the budget, MCA and consistency checklist do not delay the approval of your study.

Exception Letters: HRA does not normally contract for non-industry studies. You may request approval from the Dean’s office for HRA to complete the contract. Unless there is a standing exception letter (see below), it is required that a signed HRA Clinical Agreement Exception Letter be uploaded.

Buffet Foundation and DIRC: There is a standing approval for HRA to complete these contracts so it is not necessary to upload an exception letter.
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):

Industry-initiated Contract for Training 2

2.03 Study Full Title:

Put in the entire study title from protocol

2.04 Sponsor’s Protocol Number:

YR454545

2.05 Protocol Version:

November 2011

2.06 * Choose the Study Type from the listing below:

- Drug
- Device
- Drug and Device
- Procedure only
- Data Collection only
- Tissue/Blood Collection only
- Registry Study
- Service Vendor

Notes and Instructions

iSTAR LINK: You must know the IRB number and PI name to find the study for the link.

Study Type: If both drugs and devices are involved in this study, be sure to select Drug and Device. If all required drug and device info is not entered, your submission may be returned for additional information.
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):

Add

<table>
<thead>
<tr>
<th>IND Number</th>
<th>Drug Name</th>
<th>FDA Status</th>
</tr>
</thead>
</table>

There are no items to display

2.02 * Select the Phase from the list below:

- Phase 0
- Phase I
- Phase II
- Phase III
- Phase III/IV
- Phase IV
- Other
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
- Clear

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.

<table>
<thead>
<tr>
<th>2.01</th>
<th>Drug Information (Create one entry for each drug or placebo)</th>
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<tbody>
<tr>
<td></td>
<td>Add</td>
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<tr>
<td></td>
<td>IND Number</td>
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<td>Delete</td>
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<table>
<thead>
<tr>
<th>2.02</th>
<th>Select the Phase from the list below:</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Phase III</td>
</tr>
</tbody>
</table>

Save | Exit | Hide/Show Errors | Print... | Jump To: - 2.01 Drug Information -
Device Information

Please create an entry for each device that will be used in this study.

2.02 Device Information

Please create an entry for each device that will be used in this study

Add

<table>
<thead>
<tr>
<th>Generic and Brand Name of Device</th>
<th>Regulatory Category</th>
<th>IDE Number</th>
<th>Price</th>
</tr>
</thead>
</table>

There are no items to display

University Hospital Norris Value Analysis Requirement

If this study will be conducted at University or Norris Hospital, all devices used in the study must be approved by the Value Analysis Research Committee (VAC).

You will need to complete and upload a VAC form for each device. The VAC form may be found at on your My Home page.

HRA will review and submit the form to VAC.
2.02a * Generic and Brand Name of Device:

2.02b * Indicate the category of regulation for this device:
   - The device is exempt from IDE regulations
   - The device has a humanitarian device exemption
   - The device qualifies for an abbreviated IDE - non-significant risk devices
   - The device requires an IDE - significant risk devices
     Clear

2.02c * IDE Number:

2.02d * If the study has an IDE, indicate whether the FDA has assigned the device Type A or Type B status:
   - Type A
   - Type B
   - Unknown
     Clear

2.02e * Is the device being used on-label?
   - Yes  - No  Clear
**Device Information**

Please create an entry for each device that will be used in this study.

2.02 Device Information

Please create an entry for each device that will be used in this study

<table>
<thead>
<tr>
<th>Add</th>
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<th>Regulatory Category</th>
<th>IDE Number</th>
<th>Price</th>
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<tbody>
<tr>
<td></td>
<td>Miracula Eluding Stent</td>
<td>Significant Risk Devices</td>
<td>23456</td>
<td></td>
</tr>
</tbody>
</table>

**University Hospital/Norris Value Analysis Requirement**

If this study will be conducted at University or Norris Hospital, all devices used in the study must be approved by the Value Analysis Research Committee (VAC).

You will need to complete and upload a VAC form for each device. The VAC form may be found at on your My Home page.

HRA will review and submit the form to VAC.
Study Enrollment and Budgeting Considerations

2.11 * What is the maximum number of participants you plan to recruit at USC?  
24

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

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

2.13 Enter the password for the Sponsor’s Budget, if needed.
12345

2.14 Enter the password for the Protocol, if needed.
54321

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

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

2.17 If the study involves cycles, how many cycles will the average patient undergo (i.e. average time to disease progression)?  
6

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):

- [None]  Add

  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:

- Add

<table>
<thead>
<tr>
<th>Sponsor Name</th>
<th>Sponsor Type</th>
<th>Contact Name</th>
<th>Title</th>
<th>Contact Phone</th>
<th>Fax Contact</th>
<th>Email</th>
<th>Address1</th>
<th>Address2</th>
<th>City</th>
<th>State</th>
<th>Zip</th>
</tr>
</thead>
</table>

There are no items to display

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

- Add

<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>
</tr>
</thead>
</table>

There are no items to display

Notes and Instructions

Definition of Sponsor: For this purpose, the sponsor is the funding source for the study.

Primary Sponsor: Press Add to select a sponsor from the current list of active sponsors. You must also enter the sponsor's contact information. If you are seeking unfunding for an unknown sponsor, select "Unknown or Seeking Funding" as the Primary Sponsor.

New Sponsors: If you cannot find the sponsor on the listing, use the add button here to manually enter the sponsor's information and contact. HRA will create a new sponsor from your information, so please be accurate.

Other Sponsors: Select the other sponsoring organizations here. Include co-sponsors, CROs, facilitator companies and any other sponsor that may need to be contacted.
Please provide the following information:

3.01 Primary Sponsor and Contact Information
   [None] Add
   FirstName LastName
   If you could not find the person, please provide:
   Add
   Sponsor Name Sponsor Contact
   There are no items to display.

3.02 Enter Co-Sponsors, CRG Members
   Add
   Sponsor Name
   There are no items to display.

Enter contact person information for this sponsor:

- Title:
- FirstName:
- LastName:
- Phone:
- Fax:
- Email:
- Address1:
- Address2:
- City:
- St:
- Zip:

Notes:
Please provide the following information:

3.01 Primary Sponsor and Contact Information

First Name: Last Name: GLAXOSMITHKLINE

Enter contact person information for this sponsor:

Title:
First Name:
Last Name:
Phone:
Fax:
Email:
Address 1:
Address 2:
City:
St:
Zip:
Notes:

3.02 Enter Co-Sponsors, CBOs, and Other:

Add

There are no items to display.
Please provide the following information about the sponsors of this study:

3.01 Primary Sponsor and Contact Information

GLAXOSMITHKLINE

First Name Last Name

If you cannot find the information, add it: Add

3.02 Enter Co-Sponsors, CROs, and Sponsors

Add

Sponsor Name
There are no items to display.
Please provide the following information about the sponsors of this study:

3.01 Primary Sponsor and Co-Sponsor
   - Sponsor Name: GSK
   - Sponsor Type: CRO
   - Contact Person Information:
     - Title:
     - FirstName:
     - LastName:
     - Phone:
     - Email:
     - Fax:
     - Address1:
     - Address2:
     - City:
     - St:
     - Zip:

3.02 Enter Co-Sponsors, CROs
Please tell us who will be working on this study:

4.01 Use the Add button to select each member of the study staff. Be sure to enter all the necessary information for each member. Note that this must be done carefully.

Add

First Name
There are no items to display.

Add Personnel_Role - Windows Internet Explorer

Add Personnel_Role

* Person: moore

* Person Role:

Primary Contact:

- Moore Kimberly OBSTETRICS & GYNECOLOGY
- Moore Mary MEDICAL ONCOLOGY

* Required

OK OK and Add Another Cancel
**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.

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<tr>
<td>Update</td>
<td>Sandy</td>
<td>West</td>
<td>Study Coordinator</td>
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</tr>
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**Notes and Instructions:**

- **Required Persons:** A person must be selected for the roles of Principal Investigator and Primary Study Contact. The PI may be designated to fulfill both roles, if desired. Many important study emails are sent to the Primary Contact.
- If the PI or Primary Contact is not a TRUE 2.0 user, an account must be created before a study can be submitted.
Study Site(s) and Organizations:

5.01: Check if the study will require utilization of these services

- Clinical Reference Lab
- Clinical Trials Unit (CTU)
- Day Hospital Research
- IDS Pharmacy for LAC+USC Research
- Keck Ambulatory Clinics
- Keck Inpatient Hospital
- Pathology and Lab Services

5.02: Please check all other sites to be used during this study:

- 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 5P21 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 University Hospital
- USC Westside Prostate Cancer Center

5.03: Support Organizations Involved in this study:

- CISO  The Clinical Investigations Support Office (CISO) at the USC Norris Comprehensive Cancer Center.
- CRU  Division of Cardiovascular Medicine Clinical Research Unit
## Clinical Trial Attachments: Industry-Initiated Contract for Training 2 -- FP00000970

### 1.0
- **Protocol Password:** 54321
- **Budget Password:** 12345

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**Activities Component Unavailable**
### Clinical Trial Attachments: Industry-Initiated Contract for Training 2  --  FP00000970

**1.0**
- Protocol Password: 54321
- Budget Password: 12345

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<td></td>
<td>Activities Component Unavailable</td>
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</tbody>
</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

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.
**Industry-Initiated Contract for Training 2 -- FP00000970**

<table>
<thead>
<tr>
<th>Principal Investigator:</th>
<th>Date Accepted:</th>
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<tbody>
<tr>
<td>Mary Moore</td>
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<td>MEDICAL ONCOLOGY</td>
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<table>
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<tr>
<th>Primary Contact:</th>
<th>Participants:</th>
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<tbody>
<tr>
<td>Sandy West</td>
<td>24</td>
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<tr>
<td>Amy Cienfuegos</td>
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<table>
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**Contract and Other Document Reviews**

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<td>11/13/2011 9:40 AM</td>
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<td>Clinical Trial Agreement</td>
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</tbody>
</table>

**Budget Groupings**

No data to display.
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.

Clinical Trials Requiring Action or Nearing Activation

- **Industry-Initiated Contract for Training 2**
  - Date Modified: 11/13/2011 9:40 AM
  - State: Presubmission
  - PI Name: Moore
  - Submission Type: Industry Initiated Trial
  - Request Type: Contract

Budgets Requiring Action

- No data to display.

Documents Requiring Action

- No data to display.
Logged in History
Industry-Initiated Contract for Training 2 -- FP00000970

Submitted to HRA
West, Sandy
11/13/2011 9:46 AM PST

This contract is very similar to the one we did three months ago for GSK.
Email from Sponsor
A Study Has Been Returned to Presubmission

hratue2@health-research.org

To: TRUE2 HRA

Subject: A study has been returned to Presubmission
From: Amy Cienfuegos
To: Sandy West
Regarding: FP0000970 - Industry-Initiated Contract for Training 2
Status: Returned to Presubmission
Description: The study above has been returned to Presubmission. Click on the study ID to connect to TRUE 2.0 and make the necessary changes to your submission.
Comments: Noticed that the protocol is missing page 7. Please upload a new version.

Warning: This is a private message for TRUE 2.0 users only. If the reader of this message is not the intended recipient you are hereby notified that any dissemination, distribution or copying of this information is STRICTLY PROHIBITED.
Page for Sandy West

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.

Clinical Trials Requiring Action or Nearing Activation

<table>
<thead>
<tr>
<th>Name</th>
<th>Date Modified</th>
<th>State</th>
<th>PI Name</th>
<th>Submission Type</th>
<th>Request Type</th>
</tr>
</thead>
</table>

Budgets Requiring Action

No data to display.

Documents Requiring Action

No data to display.
**Industry-Initiated Contract for Training 2 -- FP00000970**

| **Principal Investigator:** | Mary Moore  
**Medical Oncology** |
|------------------------------|---------------------|
| **Primary Contact:** | Sandy West  
**Amy Cienfuegos** |
| **IRB # and Status:** | CIC # |
| **Sponsors:** | GLAXOSMITHKLINE  
QUINTILES INC  
CRO |
| **Submission Type:** | Industry-Initiated |
| **Contract Status:** |  |
| **Budget Status:** | Budget Begun |

**Contract and Other Document Reviews**

<table>
<thead>
<tr>
<th>Name</th>
<th>SmartForm</th>
<th>Date Modified</th>
<th>State</th>
<th>Type of Document</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Trial Agreement</td>
<td></td>
<td>11/13/2011 9:40 AM</td>
<td>Draft Contract Uploaded</td>
<td>Clinical Trial Agreement</td>
</tr>
</tbody>
</table>

**Activities**

- Go to Attachments Page
- Activities to Move Forward:  
  - Submit to HRA  
  - Request CDA Assistance

**Email Activities**

- Log a Comment (with email option)

**General Activities**

- Link IRB Study From iSTAR
- Withdraw or Close
Clinical Trial Attachments: Industry-Initiated Contract for Training 2 -- FP00000970

<table>
<thead>
<tr>
<th>Type</th>
<th>Title &amp; Description</th>
<th>Upload a file</th>
<th>My Activities</th>
<th>Version</th>
<th>Last Modified</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Trial Agreement</td>
<td>Clinical Trial Agreement</td>
<td></td>
<td></td>
<td>0.01</td>
<td>11/13/2011</td>
<td>Draft Contract Uploaded</td>
</tr>
<tr>
<td>Protocol</td>
<td>Protocol</td>
<td></td>
<td></td>
<td>0.01</td>
<td>11/13/2011</td>
<td>Uploaded</td>
</tr>
<tr>
<td>Sponsor Budget - Initial Offer</td>
<td>Sponsor Budget - Initial Offer</td>
<td></td>
<td></td>
<td>0.01</td>
<td>11/13/2011</td>
<td>Uploaded</td>
</tr>
</tbody>
</table>
Clinical Trial Attachments: Industry-Initiated Contract for Training 2 -- FP00000070

1.0
Protocol Password: 54321
Budget Password: 12345

2.0
Protocol

Notify Contract Administrator and Budget Specialist that there is a new version of Document Uploaded

Comment:
Revised Version

OK  Cancel
Clinical Trial Attachments: Industry-Initiated Contract for Training 2 -- FP00000970

1.0 Protocol Password: 54321
   Budget Password: 12345

<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>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Trial Agreement</td>
<td>Clinical Trial Agreement</td>
<td>Browse... Upload</td>
<td>MyActivities</td>
<td>0.01</td>
<td>11/13/2011 9:40 AM</td>
<td>Draft.Contract Uploaded</td>
</tr>
<tr>
<td>Protocol</td>
<td>Protocol</td>
<td>Browse... Upload</td>
<td>MyActivities</td>
<td>0.02</td>
<td>11/13/2011 9:53 AM</td>
<td>Uploaded</td>
</tr>
</tbody>
</table>

Resource History for Protocol

- Title: Protocol
- File: Protocol.doc
- Owner: Sandy West
- Author: Sandy West
- Content Type: Protocol.doc
- Version: 0.02
- Description: Revised Version
- History:
  - Date: 11/13/11 9:53 AM, Version: 0.02, Person: Sandy West, Action: Updated File, Notes: Revised Version, Uploaded File: Protocol.doc
  - Date: 11/13/11 9:40 AM, Version: 0.01, Person: Sandy West, Action: File Created, Notes: Protocol.doc

OK
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.
**Industry-Initiated Contract for Training 2**  --  **FP00000970**

<table>
<thead>
<tr>
<th>Activity</th>
<th>Author</th>
<th>Activity Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Requested Internal Budget Development</td>
<td>Deack, Denise</td>
<td>11/13/2011 10:01 AM PST</td>
</tr>
<tr>
<td>See attached plan for use of the CTU</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CTU Plan sent by SC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assigned or Reassigned HRA Contract Associate</td>
<td>Cienfuegos, Amy</td>
<td>11/13/2011 0:58 AM PST</td>
</tr>
<tr>
<td>Accepted study submission and documents</td>
<td>Cienfuegos, Amy</td>
<td>11/13/2011 9:57 AM PST</td>
</tr>
<tr>
<td>Protocol is fine now, Thanks.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Submitted to HRA</td>
<td>West, Sandy</td>
<td>11/13/2011 9:56 AM PST</td>
</tr>
<tr>
<td>Returned to Presubmission</td>
<td>Cienfuegos, Amy</td>
<td>11/13/2011 9:49 AM PST</td>
</tr>
<tr>
<td>Noticed that the protocol is missing page 7. Please upload a new version.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Submitted to HRA</td>
<td>West, Sandy</td>
<td>11/13/2011 9:46 AM PST</td>
</tr>
<tr>
<td>This contract is very similar to the one we did three months ago for GSK</td>
<td>Email from Sponsor</td>
<td></td>
</tr>
</tbody>
</table>
**Industry-Initiated Contract for Training 2 -- FP00000970**

### Summary

<table>
<thead>
<tr>
<th><strong>Principal Investigator:</strong></th>
<th>Mary Moore</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary Contact:</strong></td>
<td>Sandy West</td>
</tr>
<tr>
<td><strong>Owner/HRA Contact:</strong></td>
<td>Dennis Deak</td>
</tr>
<tr>
<td><strong>IRB # and Status:</strong></td>
<td>CIC #</td>
</tr>
<tr>
<td><strong>Sponsors:</strong></td>
<td>GLAXOSMITHKLINE</td>
</tr>
<tr>
<td></td>
<td>QUINTILES INC</td>
</tr>
<tr>
<td><strong>Submission Type:</strong></td>
<td>Clinical Trials.gov</td>
</tr>
<tr>
<td><strong>Contract Status:</strong></td>
<td>Industry-Initiated</td>
</tr>
<tr>
<td><strong>Budget Status:</strong></td>
<td>Budget Begun</td>
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</tbody>
</table>

### Contract and Other Document Reviews

<table>
<thead>
<tr>
<th><strong>Name</strong></th>
<th><strong>SmartForm</strong></th>
<th><strong>Date Modified</strong></th>
<th><strong>State</strong></th>
<th><strong>Type of Document</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Trial Agreement</td>
<td></td>
<td>11/13/2011 1:57 AM</td>
<td>Awaiting CTM Contract Reeliner</td>
<td>Clinical Trial Agreement</td>
</tr>
<tr>
<td>Moore_GLAXOSMITHKLINE_FPP970</td>
<td>SmartForm</td>
<td>11/13/2011 10:01 AM</td>
<td>Awaiting Internal Budget Development</td>
<td></td>
</tr>
</tbody>
</table>
Page for Sandy West

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.
Log a Comment (with email option)

Comments:
For Vivian: We have revised our CTU order. They are attached.

Email This Comment To the Persons Selected:
First Name: Vivian
Last Name: Ludan

Attachments (Logged in History. Check below to send with email to persons selected, if any):
- Revised CTU Plan (0.01)

Check to include the attachment(s) in Email to persons selected above, if any:
<table>
<thead>
<tr>
<th>Activity</th>
<th>Author</th>
<th>Activity Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comments Logged</td>
<td>West, Sandy</td>
<td>11/13/2011 10:09 AM PST</td>
</tr>
<tr>
<td>For Vivian: We have revised our CTU order. They are attached.</td>
<td>Deack, Denise</td>
<td>11/13/2011 10:01 AM PST</td>
</tr>
<tr>
<td>Revised CTU Plan</td>
<td>Clientuegos, Amy</td>
<td>11/13/2011 9:58 AM PST</td>
</tr>
<tr>
<td>Requested Internal Budget Development</td>
<td>Clientuegos, Amy</td>
<td>11/13/2011 9:57 AM PST</td>
</tr>
<tr>
<td>Attached plan for use of the CTU</td>
<td>Clientuegos, Amy</td>
<td>11/13/2011 9:49 AM PST</td>
</tr>
<tr>
<td>CTU Plan sent by SC</td>
<td>West, Sandy</td>
<td>11/13/2011 9:46 AM PST</td>
</tr>
<tr>
<td>Protocol is fine now, Thanks.</td>
<td>West, Sandy</td>
<td>11/13/2011 9:46 AM PST</td>
</tr>
<tr>
<td>Submitted to HRA</td>
<td>West, Sandy</td>
<td>11/13/2011 9:46 AM PST</td>
</tr>
<tr>
<td>Returned to Presubmission</td>
<td>Clientuegos, Amy</td>
<td>11/13/2011 9:45 AM PST</td>
</tr>
<tr>
<td>Noticed that the protocol is missing page 7. Please upload a new version.</td>
<td>Clientuegos, Amy</td>
<td>11/13/2011 9:45 AM PST</td>
</tr>
<tr>
<td>Submitted to HRA</td>
<td>West, Sandy</td>
<td>11/13/2011 9:44 AM PST</td>
</tr>
<tr>
<td>Email from Sponsor</td>
<td>Clientuegos, Amy</td>
<td>11/13/2011 9:44 AM PST</td>
</tr>
</tbody>
</table>
Your Budgets in Progress Awaiting CTABB Action

<table>
<thead>
<tr>
<th>Name</th>
<th>SmartForm</th>
<th>Date Modified</th>
<th>State</th>
<th>Clinical Trial Name</th>
<th>HRA Project</th>
<th>IRB No</th>
<th>IRB Status</th>
<th>Budget Requested</th>
<th>Budget Began</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moore_GLAXOSMITHKLINE_FP967</td>
<td>Execute Activity</td>
<td>11/12/2011 4:35 PM</td>
<td>Awaiting Internal Budget Development</td>
<td>Industry-Initiated Contract for Training</td>
<td>399999</td>
<td></td>
<td></td>
<td>Pending</td>
<td>11/14/2011</td>
<td>Inbox Comment, Comment, Inbox Comment, Comment</td>
</tr>
</tbody>
</table>

Budgets On Hold

No data to display.

New Budget Requests Not Yet Begun

<table>
<thead>
<tr>
<th>Name</th>
<th>SmartForm</th>
<th>Date Modified</th>
<th>State</th>
<th>Clinical Trial Name</th>
<th>HRA Project</th>
<th>IRB No</th>
<th>IRB Status</th>
<th>Budget Requested</th>
<th>Budget Began</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moore_GLAXOSMITHKLINE_FP970</td>
<td>Execute Activity</td>
<td>11/13/2011 10:01 AM</td>
<td>Awaiting Internal Budget Development</td>
<td>Industry-Initiated Contract for Training 2</td>
<td>383839</td>
<td></td>
<td></td>
<td>11/13/2011</td>
<td></td>
<td>Per SC, this budget should be very similar to the one for project 383838. See the attachment for a CTU plan</td>
</tr>
</tbody>
</table>

1 of 1 results
Request for TRUE 2.0 Budget and MCA Approval

donotreply@usc.edu

To: TRUE2 HRA

Attachments:
- [ ] Download all attachments
- [ ] Budget Template for Review (13 KB)
- [ ] MCA for PI to Sign (13 KB)

TRUE 2.0 Notification

Subject: A budget is ready for your approval
From: Vivian Ludyan - hsrcru2@health-research.org
To: Mary Moore
Regarding: BU000000443 - Moore_GLAXOSMITHKLINE_FP970
FP00000970 - Industry-Initiated Contract for Training 2
HRA Project: 393939 CIC:

Description: The budget template and MCA documents for the study shown above are attached. The PI must sign the MCA and return it before HRA can negotiate the budget with the sponsor. Please email it to me at the address above. Sandy, please look at the staff time for visit 6. The visit seems a little more complicated than average. Is the time allotted sufficient?

Thank you,
Vivian Ludyan

Sunday, November 13, 2011 10:15
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.

**Clinical Trials Requiring Action or Hearing Activation**

No data to display.

**Budgets Requiring Action**

<table>
<thead>
<tr>
<th>Name</th>
<th>Date Modified</th>
<th>State</th>
<th>Clinical Trial Name</th>
<th>PI Name</th>
</tr>
</thead>
</table>
### Budget Current State

**Awaiting PI Budget Approval**

#### Summary

**Sponsor:** GLAXOSMITHKLINE  
**PI Name:** Mary Moore  
**Department/Division:** MEDICAL ONCOLOGY  
**Current Owner/Reviewer:** Vivian Ludan  
**CTAB Budget Specialist:** Vivian Ludan  
**Budget Negotiator:**  
**Study ID:** FP0000970  
**Study Name:** Industry-Initiated Contract for Training 2  
**Target Enrollment:** 24  
**HRA Contract Associate:** Denise Deack  
**Primary Study Contact:** Sandy West

#### Clinical Trial Arms

**No data to display**

#### Budget External Review Status

<table>
<thead>
<tr>
<th>Email</th>
<th>Approver</th>
<th>Organization</th>
<th>Requested</th>
<th>Responded</th>
<th>Approved</th>
<th>Notes</th>
</tr>
</thead>
</table>

There are no items to display
A Contract Has Been Routed to the PI for Signature.

donotreply@usc.edu

To: TRUE2 HRA

Subject: A Contract Has Been Routed to the PI for Signature

To: Sandy West

From: Amy Cienfuegos

Regarding: Clinical Trial Agreement - Clinical Trial Agreement

Description: The contract for the study shown above has been routed to the PI for signature.

Ed is driving over to your office with the contract for Dr. Moore to sign. Please return it at your earliest convenience.
<table>
<thead>
<tr>
<th>Select</th>
<th>ID</th>
<th>Title</th>
<th>PI First Name</th>
<th>PI Last Name</th>
<th>Status</th>
<th>Approval Date</th>
<th>Expiration Date</th>
<th>State Entry Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>HS-11-00018</td>
<td>test collab</td>
<td>Darcy</td>
<td>Spicer</td>
<td>Divisional Review</td>
<td></td>
<td></td>
<td>Fri Apr 22 15:19:49 PDT 2011</td>
</tr>
</tbody>
</table>

1 results for ctp_studies/AJAXLookupByIDAndPI where id="HS.11.00018" AND where lastname="Spicer" in 40345ms from istardavl.usc.edu/Stardev
**Industry-Initiated Contract for Training 2 -- FP0000970**

**Principal Investigator:** Mary Moore  
**Medical Oncology**  
**Date Accepted:** 11/13/2011

**Primary Contact:** Sandy West  
**Secondary Contact:** Denise Deack

**IRB # and Status:** HS-11-00018  
**Divisional Review**

**Sponsors:**  
- GLAXOSMITHKLINE
- QUINLIES INC
- CRO

**Submission Type:** Industry-Initiated  
**Clinical Trials.gov**  
**Clinical Project #:** 393939

**Contact Status:** Budget Began  
**Date:** 11/15/2011

**Contract and Other Document Reviews**

<table>
<thead>
<tr>
<th>Name</th>
<th>SmartForm</th>
<th>Date Modified</th>
<th>State</th>
<th>Type of Document</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Trial Agreement</td>
<td>[Edit]</td>
<td>11/13/2011 10:31 AM</td>
<td>Executed</td>
<td>Clinical Trial Agreement</td>
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</table>

**Budget Groupings**

<table>
<thead>
<tr>
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<th>Date Modified</th>
<th>State</th>
<th>Total Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moore_GLAXOSMITHKLINE_FP0970</td>
<td>[Edit]</td>
<td>11/13/2011 10:26 AM</td>
<td>Finalized</td>
<td>$0.00</td>
</tr>
</tbody>
</table>
A Study Has Been Activated

donotreply@usc.edu

To: TRUE 2 HRA

Subject: A Study Has Been Activated

To: Mary Moore

From: Denise Deack

Regarding: FP000000078 - Industry-Initiated Contract for Training 2

Description: The study shown above has been activated in TRUE 2.0.

Comments:

Warning: This is a private message for TRUE 2.0 users only. If the reader of this message is not the intended recipient you are hereby notified that any dissemination, distribution or copying of this information is STRICTLY PROHIBITED.

Health Research Association
1640 Marvelo St, 7th Floor
Los Angeles, CA 90033
Phone: (323)222-4091
Fax: (323)542-0947
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.
## Industry-Initiated Contract for Training 2 -- FP00000970

### Final Documents

<table>
<thead>
<tr>
<th>Name</th>
<th>Type</th>
<th>Date Modified</th>
<th>Owner</th>
<th>State</th>
</tr>
</thead>
</table>

### All Documents Uploaded for This Submission

<table>
<thead>
<tr>
<th>Name</th>
<th>Type</th>
<th>Date Modified</th>
<th>Owner</th>
<th>State</th>
</tr>
</thead>
<tbody>
<tr>
<td>[File] Clinical Trial Agreement</td>
<td>Clinical Trial Agreement</td>
<td>11/13/2011 9:40 AM</td>
<td>Denise Deack</td>
<td>Executed</td>
</tr>
</tbody>
</table>
Notify of Amendment

Comment
Received new protocol from sponsor. May require an amendment

Attachment

<table>
<thead>
<tr>
<th>Add</th>
<th>Document</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>New Protocol Dated November 12, 2011 (0.01)</td>
<td></td>
</tr>
</tbody>
</table>

OK  Cancel
Questions?