Clinical Research Shared Service Standard Operating Procedure

SOP 306-CPC  Web-Based Accrual Data Submission Procedures

Approval signature: ____________________________
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Purpose:
This Standard Operating Procedure (SOP) was compiled as a user's reference for the use of the Center's OnCore System web interface. The Data Submission pages were developed as a priority item in order to make the submission of prevention studies data as easy as possible, over a secure and encrypted connection as required by HIPAA regulations. The following paragraphs and images were developed as a quick reference for the use of the Accrual Data Submission web pages(s) only.

References:
NIH Requirements for Comprehensive Cancer Centers-Standard Cancer Center Information Summaries (NCI Summary 4 Guidelines 06/06):

Authors:
Revised by SOPRC.

Target Audience or Responsibilities:
University of Arizona Cancer Center members, staff, faculty, collaborators and/or employees responsible for data collected in research projects involving human subjects whose enrollment is not directly managed by the Clinical Research Shared Service.

Definition of Terms:
OnCore: Database used to store protocol and patient data at the University of Arizona Cancer Center.

Safety Issues:
The National Cancer Institute requires that accrual data be reported for all research protocols involving human subjects. This web-based interface was designed to facilitate compliance with this mandate.
Process Steps for submitting accrual data via the web site:

1) Logging into CRISWeb:
   - Enter the following website address in the ‘address’ line in Microsoft Internet Explorer or similar web browsing software: https://ua.azcc.arizona.edu/upload
   - If you need an account, please contact mjohnson@azcc.arizona and ask for a user account to be able to upload files into OnCore.
   - You will not be able to overwrite, change, or read the content of any data files that have been submitted to the web site.

2) Main Page:
   Once the user has successfully logged in to the web server, the Main Menu will appear in the browser window. There are two steps to submitting a data file.

   STEP #1 requires that the user select the study for which the user is submitting data from a drop down box.

   Click on the drop down box and select the protocol number corresponding to the data you are submitting.

   **Step 1:**

   Choose Protocol # 00-0426-01
   
   If your protocol number is not in the dropdown box, please fill out a protocol submission form and submit to the Clinical Trials Office. Thank you!
   
   - If the protocol number for this study does not appear, please submit a protocol submission form by clicking here in Step 1 or send an email to: oncore@azcc.arizona.edu or phone 520-626-8018.

   When you click here, and open the document, make any changes, and save it to your local hard drive.
• When you get the pop-up window, click Save.

File Download

Do you want to open or save this file?

Name: ProtocolSubmissionForm.doc
Type: Microsoft Word Document, 209KB
From: www.azcc.arizona.edu

Open Save Cancel

✓ Always ask before opening this type of file

While files from the internet can be useful, some files can potentially harm your computer. If you do not trust the source, do not open or save this file. What's the risk?

• When you get the next pop-up window, click Open.

Download complete

Download Complete

ProtocolSubmissionForm.doc from www.azcc.arizona.edu

Downloaded: 209KB in 1 sec
Download to: C:/Dev/ProtocolSubmissionForm.doc
Transfer rate: 209KB/Sec

Close this dialog box when download completes

Open Open Folder Close

• This will open the document in MS Word. Fill out the form and email it to oncore@azcc.arizona.edu.
• By submitting this form, it will notify the CTO to add the study.
• Return to STEP #1 at least 24 hours later to see if the study has been added to the drop down menu. If the study has not been added, please send an email to oncore@azcc.arizona.edu.
STEP #2

Once the protocol number for which you are submitting data has been selected, proceed to STEP #2. There are two parts to STEP #2: a) contact information; and b) file information.

a) Contact Information:
Enter first and last name in the “Submitted by” window. Type email address, telephone number and the principal investigator of the study in the Email, Phone and PI boxes, respectively.

<table>
<thead>
<tr>
<th>Step 2:</th>
<th>Fill the form out below:</th>
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<tbody>
<tr>
<td><strong>Contact Information</strong></td>
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<tr>
<td>Submitted by</td>
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<td>Email</td>
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<td>HSC</td>
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<td>Comments</td>
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b) File Information:
- To attach the data file, click on Browse.”

File Information (click on the Browse button to locate file you wish to upload)

[Upload]
- Using the Windows "browse to" file dialog box, find the desired data file and click "open". The filename will appear in the text box to the left of the Browse button. The web site will only accept uploads of .txt file type. Choose the file that contains accrual data as required in SOP 302-CPC and SOP 303-CPC.

![Choose file dialog box](image)

- Click the "Upload" button to upload the file to the web server.
- You will receive an email indicating successful upload or corrections that may be needed.
- Should you have any problems uploading, please do not hesitate to contact oncore@azcc.arizona.edu