Work Instruction
Study Registration
Velos - eResearch 9.2

Version: 2.0, 4/29/2015
<table>
<thead>
<tr>
<th>Version/Amendment #:</th>
<th>Version Date:</th>
<th>Description:</th>
<th>Completed By:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Version 0.1</td>
<td>04/03/2014</td>
<td>Initial Draft Document</td>
<td>Jason R. Bates, MBA</td>
</tr>
<tr>
<td>Version 0.2</td>
<td>05/05/2014</td>
<td>Updates to Initial Draft, creation of Study Registration Process</td>
<td>Jason R. Bates, MBA</td>
</tr>
<tr>
<td>Version 0.3</td>
<td>07/28/2014</td>
<td>Update: Changed to Velos application version 9.2</td>
<td>Jason R. Bates, MBA</td>
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<tr>
<td>Version 0.4</td>
<td>09/09/2014</td>
<td>Updates for Suggested Additions</td>
<td>Jason R. Bates, MBA</td>
</tr>
<tr>
<td>Version 0.5</td>
<td>09/25/2014</td>
<td>Updated to new format</td>
<td>Lissa Persson</td>
</tr>
<tr>
<td>Version 1.0</td>
<td>11/18/2014</td>
<td>Finalize Document</td>
<td>Pamela Sabrsula</td>
</tr>
<tr>
<td>Version 1.1</td>
<td>02/17/2015</td>
<td>CTRC Review</td>
<td>Kim Markosfeld</td>
</tr>
<tr>
<td>Version 1.2</td>
<td>03/09/2015</td>
<td>Reviewing and accepting changes</td>
<td>Lissa Persson</td>
</tr>
<tr>
<td>Version 2.0</td>
<td>04/29/2015</td>
<td>Finalize Document</td>
<td>Pamela Sabrsula</td>
</tr>
</tbody>
</table>

Documentation of Change History:

Version 0.1, 04/03/2014: Initial Draft Document “Velos – eResearch Workflow Process,”

Version 0.2, 05/05/2014: Update to Initial Draft. Document has been converted from a complete workflow process to a single process, “Velos – eResearch Workflow Process, Study Registration.” Additional process workflows will follow for all processes.

Version 0.3, 07/28/2014: Velos application version updated to 9.2. Additional revisions based on information provided, information highlighted for review.

Version 0.4, 09/09/2014: Addition of requested sections with regards to Purpose, Responsibilities, Entry or Prerequisite and Exit criteria.

Version 1.0, 11/18/2014: Finalize document

Version 1.1, 02/17/2015: Updated with Cancer Center specific instruction

Version 1.2, 03/09/2015: Reviewing and accepting changes

Version 2.0, 04/29/2015: Finalize document
Work Instruction Study Registration

PURPOSE:
The purpose of this work instruction is to walk users through the process of creating and registering a new study within Velos eResearch.

RESPONSIBILITY:
It is the responsibility of the designated Study Entry team to create the initial study record within eResearch.

These responsibilities are defined in Appendix: A – Roles and Responsibilities.

ENTRY/PREREQUISITE CRITERIA:
Prior to performing the tasks described in this work instruction, the following must be completed:

- Principal Investigator has initiated or agreed to conduct the Study Protocol
- The Study Entry Team has received, or has access to, all documents necessary for completion of this task

REFERENCE DOCUMENTS
The most current version of the following documents may be used as reference points throughout these work instructions, as applicable:

- Research Common Application – Step 1 Intent to Conduct Research
- Research Common Application – Step 2 Institutional
- Research Common Application – Step 2 UTHSCSA Continuation IRB Application
- Study Protocol document
- Clinical Trial Agreement and Budget, or other Funding Agreement
- Other forms or documents, as applicable

<table>
<thead>
<tr>
<th>Role/Function</th>
<th>Description of Action</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study Entry Team</strong></td>
<td>1. Log into eResearch</td>
</tr>
<tr>
<td></td>
<td>2. Click the <strong>MANAGE</strong> button from the toolbar menu and select <strong>SEARCH</strong> under the <strong>STUDIES</strong></td>
</tr>
<tr>
<td></td>
<td>3. Click on the <strong>Advanced Search</strong> hyperlink</td>
</tr>
<tr>
<td></td>
<td>4. Enter any of the specific study-related information to search for study</td>
</tr>
<tr>
<td></td>
<td>▪ Note: <strong>More Study Details</strong> field can be used to search for identifiers such as the HSC-IRB #, Sponsor Protocol number, or Study Short Title</td>
</tr>
<tr>
<td></td>
<td>5. Click the <strong>SEARCH</strong> button.</td>
</tr>
<tr>
<td></td>
<td>6. If the Study was found:</td>
</tr>
<tr>
<td></td>
<td>▪ a. Review information to ensure it is correct</td>
</tr>
<tr>
<td></td>
<td>▪ b. Make corrections as needed</td>
</tr>
<tr>
<td></td>
<td>▪ c. Enter <strong>e-Signature</strong> and click <strong>SUBMIT</strong> to ensure data is SAVED</td>
</tr>
<tr>
<td></td>
<td>7. If the Study was NOT found, please proceed to next section below</td>
</tr>
</tbody>
</table>
**Register a New Study**

1. Click the **MANAGE** button from the toolbar menu and select **NEW** under the **STUDIES** option.

2. **Complete Study Summary tab:**
   The Study Summary tab is the first step in adding a new study into Velos – eResearch. Mandatory fields are marked with an asterisk (*), and must be completed prior to submitting the Study.

**Complete the Study Information**

1. **Study Entered By** (REQUIRED)
   a. MODIFY the default name by clicking on the **Select user** link and selecting the “PI’s Point of contact”. For a non-cancer study, this is specified in the “Research Common Application Step 1” document.
   
   ![PI's Point of Contact](image)

   b. **(CANCER ONLY)** – Once the summary tab data has been completed and saved, if the user entering the study is also the Regulatory Contact, click on the **Study Team tab** and change role from “Data Manager” to “Regulatory Contact”. Add the individual who is the actual “Data Manager” designated by the research team lead.

   | **NOTE:** This field will default to name of the individual entering the Study into eResearch. The individual in this section will automatically be added to the “Study Team” tab and given the role of “Data Manager”.

2. **Principal Investigator** (REQUIRED) – Click the **Select user** link to select the name of the “Principal Investigator”.

   | **NOTE:** The individual in this section will automatically be added to the “Study Team” tab and given the role of “Principal Investigator”.

3. **If Other** (OPTIONAL) – This field does not require data entry.

4. **Study Contact** (OPTIONAL) – This field does not require data entry.

5. **MARK the CHECKBOXES** as applicable to the study.
   a. **Principal Investigator was a major author/initiator of this study?** – Check this box if study is Investigator Initiated and was written by the Principal Investigator.

   b. **CTRP Reportable** – This field **MUST** be checked for **ALL Cancer Studies**.
Complete the Study Information (cont.)

**NOTE:** When this box is checked it will trigger the “NCI Trial Identifier” for completion. If the Study includes an IND or IDE, then IND/IDE Information below must also be completed.

c. **FDA Regulated Study** – This is only applicable to Investigator Initiated Studies where the Principal Investigator (or institution) holds the IND/IDE for investigational drug, device or biologic. By checking this box, users are required to provide a reason for change when patient data is updated or deleted.

d. **IND/IDE Information Available?** – When this field is checked the following information will appear for entry. Complete as requested. The CTRP Reportable function will also use this information for reporting.

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Study Entry Team

Complete the Study Definition

1. **Study Number** (READ-ONLY FIELD) – This is a system generated number. eResearch will populate this field after study information has been saved to the system using the following convention: CTMS YY-NNNN (i.e. CTMS 13-0023).

2. **Title** (REQUIRED) – ENTER this information as it is specified in the “Protocol Title Page” or “Protocol Summary Page,” sections of the “Study Protocol” document.

3. **Objective** (REQUIRED) – ENTER this information as specified in the “Primary Objective” of “Study Objectives” section of the “Study Protocol” document.

4. **Summary** (REQUIRED) –
   a. For Non-cancer studies, ENTER this information as it is specified in the “Summary” section of the “Study Protocol” document.
   b. For Cancer studies, ENTER a layperson description to include the following:
      i. Purpose of the study
      ii. Eligibility/Ineligibility criteria for candidates
      iii. Additional information, as needed

5. **NCI Trial Identifier** – ENTER the Identifier provided by the National Cancer Institute if applicable (Cancer only).

6. **NCT Number** – ENTER the National Clinical Trials number, as applicable. This number is obtained by registering the study on ClinicalTrials.gov.
<table>
<thead>
<tr>
<th>Study Entry Team</th>
<th><strong>Complete the Study Details</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>7. Do you want information in this section to be available to the public? Y/N</strong> –</td>
<td>**1. **Agent/Device (NOT REQUIRED) – ENTER the agent or device being investigated by the Study. Enter the information as specified in the “Study Protocol” document.</td>
</tr>
<tr>
<td>a. For Non-cancer: Defaults to No, as use for this has yet to be determined.</td>
<td>2. Division (REQUIRED) – SELECT the appropriate Health Science Center – Department. <strong>NOTE:</strong> SELECT “Cancer Center” for ALL cancer-related trials</td>
</tr>
<tr>
<td>b. For Cancer, this option is listed for each section. This allows the selected Information to be aggregated when broadcasting the study and can be viewed in the summary for Public Broadcast report. Public refers to the users for the Account. SELECT “Yes” for all the sections to be included in the Public Summary.</td>
<td>3. Therapeutic Area/CDST (REQUIRED) – SELECT the most appropriate area from the drop-down menu. <strong>NOTE:</strong> The options available in the drop down menu will change dependent on the “Division” selected. Please select most appropriate.</td>
</tr>
<tr>
<td><strong>2. Division (REQUIRED) – SELECT the appropriate Health Science Center – Department.</strong> <strong>NOTE:</strong> SELECT “Cancer Center” for ALL cancer-related trials</td>
<td>4. Disease Site (REQUIRED) –</td>
</tr>
<tr>
<td>a. Non-cancer – SELECT the “N/A” option.</td>
<td>a. Non-cancer – SELECT the “N/A” option.</td>
</tr>
<tr>
<td>b. Cancer only – Select the disease site relevant to the study, if there is more than 1 disease site targeted by the study, select “Multiple Sites”</td>
<td>b. Cancer only – Select the disease site relevant to the study, if there is more than 1 disease site targeted by the study, select “Multiple Sites”</td>
</tr>
<tr>
<td>5. Specific Sites (NOT REQUIRED) – This field has been deactivated, and will not be used. <strong>Do not select any information in the Specific Disease Site fields.</strong></td>
<td>5. Specific Sites (NOT REQUIRED) – This field has been deactivated, and will not be used. <strong>Do not select any information in the Specific Disease Site fields.</strong></td>
</tr>
<tr>
<td><strong>6. National Sample Size (REQUIRED) – ENTER the information as specified in the “Study Protocol” document.</strong> <strong>NOTE:</strong> The Local Sample Size will be entered once the Study Summary page has been completed and submitted.</td>
<td>6. National Sample Size (REQUIRED) – ENTER the information as specified in the “Study Protocol” document. <strong>NOTE:</strong> The Local Sample Size will be entered once the Study Summary page has been completed and submitted.</td>
</tr>
<tr>
<td><strong>7. Study Duration (REQUIRED) – ENTER the Study Duration specified in the “Study Protocol” document or as listed on clinicaltrials.gov.</strong></td>
<td>7. Study Duration (REQUIRED) – ENTER the Study Duration specified in the “Study Protocol” document or as listed on clinicaltrials.gov.</td>
</tr>
<tr>
<td><strong>8. Estimated Begin Date (REQUIRED) –</strong></td>
<td>a. Non-Cancer only - ENTER the date as provided from the Principal Investigator. This date is determined by either the Sponsor, or by the PI for Investigator Initiated</td>
</tr>
</tbody>
</table>
Complete the Study Details (cont.)

b. **Cancer only** - For Industry sponsored and cooperative group studies, the estimated begin date would be 90 days from receipt of protocol package to Site Initiation Visit; and 120 days for Investigator Initiated studies.

9. **Do you want information in this section to be available to the public? Y/N**
   
a. For **Non-cancer** – default to **No**

b. For **Cancer** - **SELECT “Yes”** for the information to be included in the Public Broadcast.

Study Entry Team

Complete the Study Design

1. **Phase** (REQUIRED) – SELECT the phase specified in the Study Protocol.

   ![Refer](#) REFER: To the Phases in the Definitions section of this work instruction for further details.

2. **Study Source** (REQUIRED) – SELECT the applicable Study Source. Options available for selection are as follows:
   
a. **Externally Peer Reviewed** – R01s, SPORES, U01s, U10s, P01s, CPRIT or other trial mechanisms supported by the NIH or supported by other peer-reviewed funding organizations.

b. **Industrial** – Sponsor or Industry driven Studies, controlled by an external entity, such as a pharmaceutical company or research organization.

c. **Institutional** – Clinical Research Studies authored or co-authored by UTHSCSA Investigators. The Investigator or Institution holds the intellectual product or property rights for the Study. The Investigator has the primary responsibility for the conceptualization, design, management, implementation and reporting of results and findings for the Study.

d. **National** – NCI National Clinical Trials Network (NCTN) and other NIH-supported National Trial Networks and Cooperative Groups.

   ![Refer](#) REFER: Appendix C References for further details.

3. **Study Scope** (REQUIRED) – SELECT the study scope specified in the Study Protocol. Options available for selection are as follows:

   a. **Multi-Center Study** – Research conducted at more than one location

b. **Multi National Study** – Research conducted at more than one location and in more than one country

c. **Single Center Study** – Research conducted at one location

4. **Clinical Research Category** (REQUIRED) – SELECT the clinical research category specified in the Study Protocol, or select the category that most closely describes the category of research the protocol aligns with. Options available for selection are as follows:

   a. **Ancillary/Correlative** – trials that are secondary to another trial, or a type of trial that tests for a relationship between a condition and a potential causal factor of the condition.
i. **Ancillary**: studies are stimulated by, but are not a required part of, a main clinical trial/study, and that utilize patient or other resources of the main trial/study to generate information relevant to it. Ancillary studies must be linked to an active clinical research study and should include only patients accrued to that clinical research study. Only studies that can be linked to individual patient or participant data should be reported.

ii. **Correlative**: laboratory based studies using specimens to assess cancer risk, clinical outcomes, response to therapies, etc. Only studies that can be linked to individual patient or participant data should be reported.

b. **Interventional** – A clinical study in which participants are assigned to receive one or more interventions (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study protocol. Participants may receive diagnostic, therapeutic, behavioral or other types of interventions. The assignment of the intervention may or may not be random. The participants are followed and biomedical and/or health outcomes are assessed.

REFER: To Types of Interventional Studies in the Definitions section of this work instruction for further details.

c. **Observational** – Studies in human beings in which biomedical and/or health outcomes are assessed in pre-defined groups of individuals. Subjects in the study may receive diagnostic, therapeutic, or other interventions, but the investigator does not assign specific interventions to the subjects of the study.

REFER: To Examples of Observational Studies in the Definitions section of this work instruction for further details.

5. **Study Linked to** (NOT REQUIRED) – CLICK on the Select link to select any studies that may be related to this Study.

   a. Examples of studies that may be related are Concurrent Studies, Sister Studies, Companion Studies, Correlative Studies, Extension Studies, Legacy Studies, etc.

6. **Blinding** (NOT REQUIRED) – SELECT the blinding specified in the Study Protocol. Options available for selection are as follows:

   a. **Double** – A Study in which both the Subject and the Investigator are unaware of the treatment assignments. The Investigator only learns about the treatment assignments of the participants after all data has been recorded, collected and analyzed.

   b. **None** – There is no blind for the Study.
Complete the Study Design (cont.)

<p>| | |</p>
<table>
<thead>
<tr>
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</tr>
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<tbody>
<tr>
<td>c. <strong>Single</strong> – The Subject does not know the treatment assignment but the Investigator does.</td>
<td></td>
</tr>
<tr>
<td>d. <strong>Triple</strong> – A Study in which the Subject, the Investigator and the people that who organize and analyze the Study data are unaware of the treatment assignments. Treatment assignments are revealed after all data has been recorded, collected and analyzed.</td>
<td></td>
</tr>
</tbody>
</table>

7. **Randomization** (NOT REQUIRED) – SELECT the randomization specified in the Study Protocol. Options available for selection are as follows:
   a. **Randomized** – A Study in which Subjects are assigned to the different Study groups by chance.
   b. **Non-Randomized** – A Study in which Subjects are not assigned to the different Study groups by chance.

8. **Do you want information in this section to be available to the public? Y/N**
   a. For Non-cancer – default to No
   b. For Cancer - SELECT “Yes” for the information to be included in the Public Broadcast.

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Study Entry Team

**Complete the Sponsor Information**

<p>| | |</p>
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>1. <strong>Sponsor Name</strong> (REQUIRED) – CLICK on the Select Sponsor link to select the Sponsor of this study.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>a. <strong>EMAIL:</strong> If Sponsor is NOT on the list, email <a href="mailto:ctms-support@uthscsa.edu">ctms-support@uthscsa.edu</a> to request an update/addition to the Sponsor list. Include the full contract Sponsor name in the request.</td>
</tr>
<tr>
<td></td>
<td>b. ENTER the sponsor name in the If Other field until notified by CTMS Support that Sponsor has been added to the list.</td>
</tr>
<tr>
<td></td>
<td>c. Once notified that Sponsor added to list, UPDATE the Sponsor field and delete the reference from If Other</td>
</tr>
</tbody>
</table>

**NOTE:** If there is more than one Sponsor for a study, enter the additional sponsors on the “Additional Sponsor Tracking” form, located under the FORMS tab.

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<tbody>
<tr>
<td>2. <strong>Sponsor ID</strong> (NOT REQUIRED) – This field is yet to be defined and is not required.</td>
<td></td>
</tr>
</tbody>
</table>

<p>| | |</p>
<table>
<thead>
<tr>
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<th></th>
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</thead>
<tbody>
<tr>
<td>3. <strong>Contact</strong> (OPTIONAL) – ENTER the primary Sponsor related contact. The primary Sponsor contact can be any of the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>a. The Site Monitor</td>
</tr>
<tr>
<td></td>
<td>b. Project Manager</td>
</tr>
<tr>
<td></td>
<td>c. Lead Medical Monitor</td>
</tr>
<tr>
<td></td>
<td>d. Legal Sponsor Contact</td>
</tr>
</tbody>
</table>

**NOTE:** The Contact specified in this field is also specified in the “Sponsor Contacts Form” located under the FORMS tab.
<table>
<thead>
<tr>
<th><strong>Complete the Sponsor Information (cont.)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>4. <strong>Other Information</strong> (OPTIONAL) – This field is optional. The “Sponsor Contacts Form” located under the “Forms” tab can be used to capture additional sponsor information.</td>
</tr>
<tr>
<td>5. <strong>☐ NIH Grant Information</strong> – This applies to NIH Externally Peer Reviewed Studies. Mark this checkbox to record funding information for an NIH Grant. The following fields become available:</td>
</tr>
</tbody>
</table>

![NIH Grant Information](image)

- a. **Funding Mechanism** (REQUIRED) – The NIH provided activity code, which is used to differentiate supported research related programs. (3-digit Alpha numeric combination)
  - REFER: Appendix C References for further details.

- b. **Institute Code** (REQUIRED) – The NIH provided acronym, which represents the two-letter code for the NIH Institute or Center. (2-digit Alpha combination)
  - REFER: Appendix C References for further details.

- c. **Serial Number** (REQUIRED) – The NIH provided unique identifier, the “Serial Number” is composed of the following:
  - i. **Type Code**: Indicates an application is new, a renewal, a noncompeting application or other type.
  - ii. **Activity Code**: Lists the type of grant that has been applied for
  - iii. **Institute Code**: The NIH provided acronym, which represent the two-letter code for the NIH Institute or Center.
  - iv. **Serial Number**: Unique five or six digit number assigned by the NIH Center for Scientific Review (CSR).
  - v. **Support Year**: The year the grant application was submitted
  - vi. **Suffix Code**: (optional) Code used for supplements, amendments or fellowship institutional allowances.

- d. **NCI Division/Program Code** (REQUIRED) – The NCI provided acronym, which represent the NCI Institute or Center.

6. **Do you want information in this section to be available to the public? Y/N**
   Default to No for all studies as it is not necessary information for patient recruitment opportunities.
### Define Keywords and Save

1. **Keywords** *(REQUIRED)* – ENTER keywords that will facilitate searching for the Study, Study Population, investigational article used in the study, etc.
   a. Specific keywords for the study should be used as well as common and general words.
   b. Separate keywords with a comma, i.e. insulin resistant, IND 12, xxx, study drug name, Diabetes, Diabetes Mellitus, Diabetes Type 2.

2. ENTER e-SIGNATURE and click the **SUBMIT** button to SAVE the Study Summary information.

### Complete More Study Details

**NOTE:** This section is not available until primary Study Summary information is **SAVED**.

1. In the **Study Definition** section, CLICK on the More Study Details icon.
2. ENTER the following information on the More Study Detail form, if it is applicable to the study:
   a. **Short Title** – An abbreviated title intended to be used across organizations to refer to the study in a standard way (may be sponsor provided).
   b. **IRB Number** – the HSCSA IRB Number. (Do not enter a central IRB number as this is maintained within the OIRB information).
   c. **Sponsor Protocol Number** – The sponsor’s standard reference number for the study.
   d. **PGID** – The OSP’s project or grant ID that is associated with the study.
   e. **Research Account Number** - The research account number created in EPIC, if required.
   f. **CMS Qualifying Trial?** – This is the result of the coverage analysis. This provides quick reference to studies meeting requirements of a qualified trial under the Medicare Clinical Trial Policy.
   g. **CTRC Number** *(CANCER STUDIES ONLY)* – Legacy CTRC# of the study. Current studies use auto generated CTMS number from eResearch.
   h. **Protocol ID** *(READ ONLY FIELD/CANCER STUDIES ONLY)* – This field is populated from the “New Protocol Submission Form” when the Study Source is “National Cooperative Group” or “Other Externally Peer-reviewed”.
   i. **Program Code** *(Cancer only)* – Select the program code representing the program in which the Primary Investigator’s study falls under. The following options are available:
      i. 1 (CDP) - Cancer Development and Progression
      ii. 2 (EDT) - Experimental and Developmental Therapeutics
      iii. 3 (CPPS) - Cancer Prevention and Population Science
         ☐ EMAIL CancerResearch@uthscsa.edu If you are unsure of the program code.
   j. **Affiliate Information** – The following sections allow for up to 3 affiliates and the Affiliate’s unique trial identifier to be tracked within eResearch.
      i. Affiliate 1
      ii. Affiliate 1 – Project ID
      iii. Affiliate 2
**Work Instruction Study Registration**

| **Complete More Study Details (cont.)** | iv. Affiliate 2 – Project ID  
v. Affiliate 3  
vi. Affiliate 3 – Project ID |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>3. ENTER your e-SIGNATURE and click the SUBMIT button to SAVE the information and close the More Study Details form window.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Study Entry Team</strong></th>
<th>In the Study Details section, click on the Local Sample Size link and ENTER the Local Sample Size or Enrollment Target for “UTHSCSA”.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Return to Complete Local Sample Size</strong></td>
<td><strong>NOTE:</strong> Any other organizations listed should be left blank as the system is not configured to utilize this feature in this manner.</td>
</tr>
<tr>
<td>2. ENTER your e-SIGNATURE and click the SUBMIT button to SAVE the information and close the Local Sample Size form.</td>
<td></td>
</tr>
</tbody>
</table>

**Exit Criteria:**  
Upon completion of this work instruction, the Study Summary Page should be complete with a study record created for the study entered.

**Appendix A: ROLES & RESPONSIBILITIES**

<table>
<thead>
<tr>
<th><strong>RACI Chart</strong></th>
<th><strong>Study Entry Team</strong></th>
<th><strong>Research Team</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>STUDY REGISTRATION</strong></td>
<td><strong>Principal Investigator</strong></td>
<td><strong>Research Team</strong></td>
</tr>
<tr>
<td>Complete Study Summary tab</td>
<td>R = Responsible party</td>
<td></td>
</tr>
<tr>
<td>- Study Information</td>
<td>R, A</td>
<td>C</td>
</tr>
<tr>
<td>- Study Definition</td>
<td>R, A</td>
<td>C</td>
</tr>
<tr>
<td>- Study Details</td>
<td>R, A</td>
<td>C</td>
</tr>
<tr>
<td>- Study Design</td>
<td>R, A</td>
<td>C</td>
</tr>
<tr>
<td>- Sponsor Information</td>
<td>R, A</td>
<td>C</td>
</tr>
<tr>
<td>- Define Keywords</td>
<td>R, A</td>
<td>C</td>
</tr>
<tr>
<td>- More Study Details</td>
<td>R, A</td>
<td>C</td>
</tr>
</tbody>
</table>

A = Accountable party  
C = consulting party  
I = party to be kept informed

**Appendix B: DEFINITIONS**

**PHASES:**  
0 – Exploratory trials involving very limited human exposure, with no therapeutic or diagnostic intent (e.g., screening studies, microdose studies). See FDA guidance on exploratory IND studies for more information.
Work Instruction Study Registration

0/I – The continuation of an exploratory trial involving very limited human exposure, with no therapeutic or diagnostic intent.
I – Includes initial studies to determine the metabolism and pharmacologic actions of drugs in humans, the side effects associated with increasing doses, and to gain early evidence of effectiveness; may include healthy participants and/or patients.
I/II – for trials that are a combination of phases 1 and 2
II – Includes controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks.
II/III – for trials that are a combination of phases 2 and 3
III – Includes expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather additional information to evaluate the overall benefit-risk relationship of the drug and provide an adequate basis for physician labeling.
IV – Studies of FDA-approved drugs to delineate additional information including the drug's risks, benefits, and optimal use.
Pilot – The initial study examining a new method or treatment.
Feasibility – Evaluation or analysis of the potential of a proposed project, to assess the overall viability and success rate of the proposed project.
N/A – For a Study that does not have phases.

TYPES OF INTERVENTIONAL STUDIES:

**Treatment** - protocol designed to evaluate one or more interventions for treating a disease, syndrome or condition

**Prevention** - protocol designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition

**Diagnostic** - protocol designed to evaluate one or more interventions aimed at identifying a disease or health condition

**Supportive Care** - protocol designed to evaluate one or more interventions where the primary intent is to maximize comfort, minimize side effects or mitigate against a decline in the subject's health or function. In general, supportive care interventions are not intended to cure a disease.

**Screening** - protocol designed to assess or examine methods of identifying a condition (or risk factors for a condition) in people who are not yet known to have the condition (or risk factor).

**Health Services Research** - protocol designed to evaluate the delivery, processes, management, organization or financing of health care.

**Basic Science** - protocol designed to examine the basic mechanism of action (e.g., physiology, biomechanics) of an intervention.

**EXAMPLES OF OBSERVATIONAL STUDIES:**

**Cohort** - group of individuals, initially defined and composed, with common characteristics (e.g., condition, birth year), who are examined or traced over a given time period
**Case-control** - group of individuals with specific characteristics (e.g., conditions or exposures) compared to group(s) with different characteristics, but otherwise similar

**Case-only** - single group of individuals with specific characteristics

**Case-crossover** - characteristics of case immediately prior to disease onset (sometimes called the hazard period) compared to characteristics of same case at a prior time (i.e., control period)

**Ecologic or community studies** - geographically defined populations, such as countries or regions within a country, compared on a variety of environmental (e.g., air pollution intensity, hours of sunlight) and/or global measures not reducible to individual level characteristics (e.g., health care system, laws or policies median income, average fat intake, disease rate)

**Family-based** - studies conducted among family members, such as genetic studies within families or twin studies and studies of family environment

**Appendix C: REFERENCES**

National Institute of Health:

- [www.nih.gov](http://www.nih.gov)
- [http://grants.nih.gov/grants/funding/funding_program.htm#u01](http://grants.nih.gov/grants/funding/funding_program.htm#u01)
- [http://grants.nih.gov/grants/acronym_list.htm](http://grants.nih.gov/grants/acronym_list.htm)
- [http://cancercenters.cancer.gov/documents/PeerReviewFundingOrganizations508C-1.pdf](http://cancercenters.cancer.gov/documents/PeerReviewFundingOrganizations508C-1.pdf)
- [https://clinicaltrials.gov/](https://clinicaltrials.gov/)