

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO

Work Instruction Study Registration

Velos - eResearch v10.0



Version: 1.0, 02/16/2018

Work Instruction Study Registration

Revision History			
Version/Amendment #:	Version Date:	Description:	Completed By:
Version 1.0	02/16/2018	Initial release	VPR CTO

Documentation of Change History:

Version 1.0, 02/16/2018: VPR CTO initial release of version 10.0 work instructions;

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:

- Study Protocol document
- Clinical Trial Agreement and Budget, or other Funding Agreement
- Other forms or documents, as applicable

<i>Role/Function</i>	<i>Description of Action</i>
<i>Study Entry Team</i>	<ol style="list-style-type: none">1. Log into eResearch2. Click the MANAGE button from the toolbar menu and select SEARCH under the STUDIES3. Enter any of the specific study-related information to search for study  Note: More Study Details field can be used to search for identifiers such as the HSC-IRB #, Sponsor Protocol number, or Study Short Title4. Click the SEARCH button.5. If the Study was found:<ol style="list-style-type: none">a. Review information to ensure it is correctb. Make corrections as neededc. Enter your e-Signature and click SUBMIT to ensure data is saved.6. If the Study was <u>NOT</u> found, please proceed to next section below.
<i>Does study already exist in eResearch?</i>	

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<p><i>Study Entry Team</i></p> <p>Register a New Study</p>	<ol style="list-style-type: none"> 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 eResearch. Mandatory fields are marked with an asterisk (*), and must be completed prior to submitting the Study.
<p><i>Study Entry Team</i></p> <p>Complete the Study Information</p>	<ol style="list-style-type: none"> 1. Study Entered By (REQUIRED) <ol style="list-style-type: none"> a. MODIFY the default name by clicking on the Select user link and searching for UT VPR Finance (First Name: UT, Last Name: VPR Finance). Once found, add this user for all Non-Cancer studies. b. (CANCER ONLY) – Following the steps above, search for UT CTRC Regulatory Affairs (First Name: UT, Last Name: CTRC Regulatory Affairs. Once found, add this user for all Cancer studies. <p>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”.</p> 2. Principal Investigator (REQUIRED) –Click the Select user link to select the name of the “Principal Investigator”. If the PI is not listed, select “UT User Not Listed” <p>NOTE: The individual in this section will automatically be added to the “Study Team” tab and given the role of “Principal Investigator”.</p> <p>EMAIL: If PI is NOT on the list, email ctms-support@uthscsa.edu to request the addition of a non-system user. Include the full name, email address, office number and cell number (if available). Once CTMS Support confirms addition of non-system user, return to the Study Summary page and add PI. Navigate to Study Team and delete Non-System User.</p> 3. If Other (OPTIONAL) – This field does not require data entry. 4. Study Contact (OPTIONAL) –This field does not require data entry. The “PI’s Point of contact” may be added here. <p>EMAIL: If POC is NOT on the list, email ctms-support@uthscsa.edu to request the addition of a non-system user. Include the full name, email address, office number and cell number (if available). Once CTMS Support confirms addition of non-system user, return to the Study Summary page and add POC.</p>

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<p><i>Complete the Study Information (cont.)</i></p>	<p>5. Select the Checkboxes as applicable to the study.</p> <p>a. <input type="checkbox"/> 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.</p> <p>b. <input type="checkbox"/> CTRP Reportable – This field MUST be checked for ALL Cancer Studies. <small>NOTE:</small> 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.</p> <p>c. <input type="checkbox"/> 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.</p> <p>d. <input type="checkbox"/> 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.</p>																		
<div style="border: 1px solid gray; padding: 2px;"> <input checked="" type="checkbox"/> IND/IDE Information Available? <table style="width: 100%; border-collapse: collapse; font-size: small;"> <tr> <td style="border-bottom: 1px solid gray;">IND/IDE Types*</td> <td style="border-bottom: 1px solid gray;">IND/IDE Number*</td> <td style="border-bottom: 1px solid gray;">IND/IDE Grantor*</td> <td style="border-bottom: 1px solid gray;">IND/IDE Holder Type*</td> <td style="border-bottom: 1px solid gray;">NIH Institution, NCI Division/Program Code (If applicable)</td> <td style="border-bottom: 1px solid gray;">Expanded Access?</td> <td style="border-bottom: 1px solid gray;">Expanded Access Type (If applicable)</td> <td style="border-bottom: 1px solid gray;">Exempt? (If applicable)</td> <td style="border-bottom: 1px solid gray; text-align: right;">+</td> </tr> <tr> <td>IND</td> <td></td> <td>Select an option</td> <td>Select an option</td> <td style="text-align: right;">Select</td> <td><input type="checkbox"/></td> <td></td> <td><input type="checkbox"/></td> <td style="text-align: right;">✖</td> </tr> </table> </div>		IND/IDE Types*	IND/IDE Number*	IND/IDE Grantor*	IND/IDE Holder Type*	NIH Institution, NCI Division/Program Code (If applicable)	Expanded Access?	Expanded Access Type (If applicable)	Exempt? (If applicable)	+	IND		Select an option	Select an option	Select	<input type="checkbox"/>		<input type="checkbox"/>	✖
IND/IDE Types*	IND/IDE Number*	IND/IDE Grantor*	IND/IDE Holder Type*	NIH Institution, NCI Division/Program Code (If applicable)	Expanded Access?	Expanded Access Type (If applicable)	Exempt? (If applicable)	+											
IND		Select an option	Select an option	Select	<input type="checkbox"/>		<input type="checkbox"/>	✖											
<p><i>Study Entry Team</i></p> <p><i>Complete the Study Definition</i></p>	<p>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 18-0023).</p> <p>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. <small>NOTE:</small> When the user connects with an existing IRB record, this field will be populated through the ORCA Interface, using the Protocol Title on file with the IRB. <small>REFER:</small> Appendix C for instructions on use of the ORCA Interface.</p> <p>3. Objective (REQUIRED) – Enter this information as specified in the “Primary Objective” of “Study Objectives” section of the “Study Protocol” document.</p> <p>4. Summary (REQUIRED) –</p>																		

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	<ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> i. Purpose of the study ii. Eligibility/Ineligibility criteria for candidates iii. Additional information, as needed <p>5. NCI Trial Identifier – Enter the Identifier provided by the National Cancer Institute if applicable (Cancer only).</p> <p>6. NCT Number – Enter the National Clinical Trials number, as applicable. This number is obtained by registering the study on ClinicalTrials.gov. If one does not exist, leave the field blank.</p> <p>7. Do you want information in this section to be available to the public? Y/N –</p> <ol style="list-style-type: none"> a. For Non-cancer: Defaults to No, as use for this has yet to be determined. 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.
<p><i>Study Entry Team</i></p> <p>Complete the Study Details</p>	<ol style="list-style-type: none"> 1. Primary Purpose (REQUIRED) <ol style="list-style-type: none"> a. For Non-Cancer: This is required for INTERVENTIONAL studies. This information can be found within the study Protocol, within Step 2 IRB Item 54 or the clinicaltrials.gov website. b. For Cancer: Select the applicable purpose: <ul style="list-style-type: none"> • Basic Science • Diagnostic • Health Services Research • Prevention • Screening • Supportive Care • Treatment • Other 2. Agent/Device (NOT REQUIRED) – Enter the agent or device being investigated by the Study. Enter the information as specified in the “Study Protocol” document.

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<p><i>Complete the Study Details (cont.)</i></p>	<ol style="list-style-type: none"> 3. Division (REQUIRED) – Select the appropriate Health Science Center – Department. <input type="checkbox"/> NOTE: Select “Cancer Center” for ALL cancer-related trials 4. Therapeutic Area/CDST (REQUIRED) – SELECT the most appropriate area from the drop-down menu. <input type="checkbox"/> NOTE: The options available in the drop down menu will change dependent on the “Division” selected. Please select most appropriate. 5. Disease Site (REQUIRED) – <ol style="list-style-type: none"> a. Non-cancer – Select the “N/A” option. 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” 6. Specific Sites (NOT REQUIRED) – This field has been deactivated, and will not be used. Do not select any information in the Specific Disease Site fields. 7. National Sample Size (REQUIRED) – Enter the information as specified in the “Study Protocol” document. <input type="checkbox"/> NOTE: The Local Sample Size will be entered once the Study Summary page has been completed and submitted. 8. Study Duration (REQUIRED) – Enter the Study Duration specified in the “Study Protocol” document or as listed on clinicaltrials.gov. 9. Estimated Begin Date (REQUIRED) – <ol style="list-style-type: none"> 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 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 10. CCSG Data Table 4 Reportable (Cancer only) – Check box on right side of screen, if appropriate 11. Do you want information in this section to be available to the public? Y/N <ol style="list-style-type: none"> a. For Non-cancer – Select the No option button. b. For Cancer - Select Yes for the information to be included in the Public Broadcast.
<p><i>Study Entry Team</i></p>	<ol style="list-style-type: none"> 1. Phase (REQUIRED) – Select the phase specified in the Study Protocol. <input type="checkbox"/> REFER: To the Phases in the Definitions section of this work instruction for further details.

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Complete the Study Design

2. **Study Source** (REQUIRED) – Select the applicable Study Source. Options available for selection are as follows:
 - a. **Externally Peer Reviewed** – R01s, SP0RES, 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: [Appendix D](#) 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

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Complete the Study Design (cont.)

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.
 - c. **Single** – The Subject does not know the treatment assignment but the Investigator does.
 - d. **Triple** – 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.
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.

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<p><i>Complete the Sponsor Information (cont.)</i></p>	<p>a. Funding Mechanism (REQUIRED) – The NIH provided activity code, which is used to differentiate supported research related programs. (3 - digit Alpha numeric combination)</p> <p> REFER: Appendix D References for further details.</p> <p>b. Institute Code (REQUIRED) – The NIH provided acronym, which represents the two-letter code for the NIH Institute or Center. (2 – digit Alpha combination)</p> <p> REFER: Appendix D References for further details.</p> <p>c. Serial Number (REQUIRED) – The NIH provided unique identifier, the “Serial Number” is composed of the following:</p> <ul style="list-style-type: none"> 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. <p>d. NCI Division/Program Code (REQUIRED) – The NCI provided acronym, which represent the NCI Institute or Center.</p> <p>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.</p>
<p><i>Study Entry Team</i></p> <p><i>Define Keywords and Save</i></p>	<p>1. Keywords (REQUIRED) – Enter keywords that will facilitate searching for the Study, Study Population, investigational article used in the study, etc.</p> <ul style="list-style-type: none"> 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. <p>2. Enter your e-SIGNATURE and click the SUBMIT button to SAVE the Study Summary information.</p>
<p><i>Study Entry Team</i></p> <p><i>Complete More Study Details</i></p>	<p> NOTE: Ensure you have saved the page prior to moving to More Study Details.</p> <p>1. Under More Study Details (bottom of page) enter the following:</p> <ul style="list-style-type: none"> 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).

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Complete More Study Details (cont.)

- i. For sponsor initiated studies, enter the study abbreviated name, if applicable. Example: INSPIRE
- ii. For investigator initiated studies, enter the Short IRB number unless otherwise specified by PI. Example: HSC 17-XXXX
- b. **Sponsor Protocol Number** – The sponsor’s standard reference number for the study, as applicable.
 - i. Reference (i) and (ii) in Short Title section above
- c. **IRB Number** – The HSCSA IRB Number. (Do not enter a central IRB number as this is maintained within the OIRB information.)

NOTE: Study summary page must be saved PRIOR to connecting to the ORCA Interface.

REFER: [Appendix C](#) for instructions on use of the ORCA Interface.

- d. **Short IRB Number** – (READ ONLY FIELD) The short version of the HSCSA IRB Number, populated after connection with HSCSA IRB Number is completed.

REFER: [Appendix C](#) for instructions on use of the ORCA Interface.

- e. **ORCA ID** - (Populated by ORCA upon connection)
- f. **Protocol Type Code** - (Populated by ORCA upon connection)
- g. **Protocol Type Descr** - (Populated by ORCA upon connection)
- h. **External IRB Name** – This field allows a user to document if the study is using an external IRB as the IRB of record.
- i. **External IRB Number** – This field allows a user to document an external IRB’s record number
- j. **PGID** – The OSP’s project or grant ID that is associated with the study.
- k. **Contract ID #** - (FIELD CURRENTLY NOT IN USE) This is a field that displays on the UT Shared Design Invoice Template.
- l. **Tax ID #** – (READ ONLY FIELD) Populated with the University’s Tax Identification number upon entering e-signature.

Bullets m-p are completed during Billing Risk Review. Leave these fields blank.

- m. **EPIC Study Name** – Completed during Billing Risk Review
- n. **EPIC Research Account Number** - The research account number created in EPIC, if required. Be sure to check OK to Send to EPIC
- o. **Patient Billing Risk** – Enter result of Billing Risk Review
- p. **Billing Risk Reason** – Enter reason for Billing Risk result
- q. **CTRC Number** (CANCER STUDIES ONLY) – Legacy CTRC# of the study. Current studies use auto generated CTMS number from eResearch.
- r. **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”.

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	<p>s. 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:</p> <ul style="list-style-type: none"> i. 1 (CDP) - Cancer Development and Progression ii. 2 (EDT) - Experimental and Developmental Therapeutics iii. 3 (CPPS) - Cancer Prevention and Population Science <input checked="" type="checkbox"/> EMAIL CancerResearch@uthscsa.edu If you are unsure of the program code. <p>t. Affiliate Information – The following sections allow for up to 3 affiliates and the Affiliate’s unique trial identifier to be tracked within eResearch.</p> <ul style="list-style-type: none"> i. Affiliate 1 ii. Affiliate 1 – Project ID iii. Affiliate 1 – Account Number iv. Affiliate 2 v. Affiliate 2 – Project ID vi. Affiliate 2 – Account Number vii. Affiliate 3 viii. Affiliate 3 – Project ID ix. Affiliate 3 – Account Number <p>u. Threshold Days – (OMIT) Reserved for future use</p> <p>v. CTX Study Number (READ ONLY FIELD) – This field is reserved for studies originating at Clinical Trials Xpress.</p> <p>2. Enter your e-SIGNATURE and click the SUBMIT button to SAVE the information and close the More Study Details form window.</p>
<p><i>Study Entry Team</i></p> <p><i>Return to Complete Local Sample Size</i></p>	<p>1. In the Study Details section, click on the Local Sample Size link and enter the Local Sample Size or Enrollment Target for “UTHSCSA”.</p> <p> NOTE: Any other organizations listed should be left blank as the system is not configured to utilize this feature in this manner.</p> <p>2. Enter your e-SIGNATURE and click the SUBMIT button to save the information and close the Local Sample Size form.</p>

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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

RACI Chart	Study Entry Team	Research Team	
		Principal Investigator	Research Team
STUDY REGISTRATION			
-Complete Study Summary tab			
-Study Information	R,A	C	C
-Study Definition	R,A	C	C
-Study Details	R,A	C	C
-Study Design	R,A	C	C
-Sponsor Information	R,A	C	C
-Define Keywords	R,A	C	C
-More Study Details	R,A	C	C

R = Responsible party
 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.
- 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.

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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

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Appendix C: O R C A Interface

Overview of the O R C A Interface Functionality:

- The Velos eResearch – ORCA interface will register an eResearch study with an existing IRB protocol with an ORCA ID. It will also allow users to request a **new** IRB ORCA ID for an existing eResearch study that is unmatched to an existing IRB Protocol.
- Once a user connects an eResearch study to ORCA, the interface will automatically populate the following:

In the eResearch **Study Definition** Section of the **Study Summary** page

- **Protocol Title** (This is updated with the **Protocol Title** that is found with in ORCA).

Study Definition

Study Number * CTMS 18-0004

Title * A multi-center, double-blind, placebo-controlled, Phase 4 study in patients with pulmonary arterial hypertension to assess the effect of selexipag on daily life physical activity and patient's self-reported symptoms and their impacts

In the eResearch **More Study Details** Section of the **Study Summary** page

- **IRB Number** field
- **Short IRB Number** field
- **ORCA ID** field
- **Protocol Type Code** field
- **Protocol Type Descr** field

More Study Details

Short Title TRACE

Sponsor Protocol Number AC-065A404

IRB Number 20170752HU-A multi-center

Short IRB Number 20170752HU

ORCA ID 28479

Protocol Type Code HU

Protocol Type Descr Human Study Requiring Consen

In the **Study Status History** grid of the **Study Status** page

- The current **IRB/UT** status and Effective Status Date found within ORCA.
- The current **HSC - Institutional status** and Effective Status Date found within ORCA.

Study Status History: [ADD NEW STATUS](#)

Organization	Study Status	Status Valid From	Status Valid Until	Meeting Date	Notes	Delete
UTHSCSA	HSC - New	01/12/2018	-	-	-	✕
	IRB - Draft Study Created/UT	01/12/2018	-	-	-	✕
	PRE-ACTIVATION/UT	01/12/2018	-	-	-	✕

- The interface will also update ORCA with any **Study Enrollment/UT** status and **Status Effective Date** that is added to the study within eResearch.

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- Users may modify an existing eResearch - ORCA connection by disconnecting and re-connecting the study. To disconnect, click the Disconnect IRB Number button which will automatically send a request to CTMS-Support@uthscsa.edu

More Study Details	
Short Title	<input type="text" value="TRACE"/>
Sponsor Protocol Number	<input type="text" value="AC-065A404"/>
IRB Number	<input type="text" value="20170752HU-A multi-center"/> <input type="button" value="Disconnect IRB Number"/>
Short IRB Number	<input type="text" value="20170752HU"/>

How to Connect a Study to ORCA using ORCA Interface:

Connecting an eResearch study to ORCA is a **Central Office** responsibility. The section below will guide users in establishing a study connection using two methods: Connecting to an Existing IRB Number record in ORCA or Creating a New IRB record in ORCA.

Connecting a Study with an Existing IRB Number:

- Search for the appropriate study and navigate to the **More Study Details** section of the **Study Summary** page.
 - If you have not already saved the page, enter your **e-Signature** and click **SUBMIT** at the bottom of the page.
- In the **IRB Number** field, and start typing the IRB number - starting with the year. The system will display a dropdown listing of IRB studies associated with the Principal Investigator - which are available for connection.

NOTE: The Principal Investigator's email address in eResearch and ORCA must match in order for this list to populate.

IRB Number

<input type="text" value="2014"/>
<input type="text" value="20140206HU-A Phase II, Op"/>
<input type="text" value="20140301HU-A221101 A Phas"/>
<input type="text" value="20140359HW-Outcomes among"/>
<input type="text" value="20140450XT-A Dual Phase 1"/>

- Select the correct study from the dropdown list by clicking on it.
- To finalize the connection, enter your **e-Signature** and click **SUBMIT**. The interface will automatically populate the **Short IRB Number**, **ORCA ID**, **Protocol Type Code** and **Protocol Type Descr** fields.

Work Instruction Study Registration

CREATING A NEW IRB RECORD WHEN ONE DOES NOT ALREADY EXIST:

1. To create a new record with the IRB when one does not already exist, go to **More Study Details** section of the **Study Summary Page** and select the **Create New** button

IRB Number

Create New

2. In the pop-up that appears, confirm you wish to proceed with creating a new record by entering your **e-Signature** and clicking the **Save** button. The record is then created in ORCA and an IRB number is returned to Velos eResearch.



Confirm Create New ORCA ID

Do you want to proceed with Create New ORCA ID?
Please enter eSignature and click Save to confirm.

e-Signature*

Save Cancel

Appendix D: REFERENCES

National Institute of Health:

www.nih.gov

http://grants.nih.gov/grants/funding/funding_program.htm#u01

http://grants.nih.gov/grants/acronym_list.htm

<http://cancercenters.cancer.gov>

<https://clinicaltrials.gov/>

END OF DOCUMENT