

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT SAN ANTONIO

Work Instruction Study Activation

Velos - eResearch v10.0



Version: 1.0, 02/16/2018

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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;

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PURPOSE

The purpose of this work instruction is to walk the user through activating a study in Velos eResearch to allow patient enrollment and provide an overview of the management of study statuses.

RESPONSIBILITY

It is the responsibility of the Clinical Trials Office (CTO) to monitor and provide overall management of study statuses in Velos eResearch as a centralized process. The CTO shall set the Overall/UT and Funding statuses. The study Data Manager shall set the Study Enrollment/UT status. The Office of the Institutional Review Board (OIRB) shall set the IRB/UT and HSC-Institutional statuses through interface connectivity with the ORCA application. Additional statuses may be needed based on the requirements for the study [ex. Protocol Review Committee (PRC) for cancer trials], which are managed in a centralized manner.

ENTRY/PREREQUISITE CRITERIA


Prior to performing the tasks described in this work instruction the following must be completed:

- The Study Summary Page within eResearch has been fully completed.
- The Study has a calendar and budget completed.
- The Study has transitioned through the appropriate reviews and has been deemed ready for activation.

REFERENCE DOCUMENTS

- Committee approvals or documentation supporting current status, as applicable.

WORK INSTRUCTIONS

Role/Function	Description of Action
<i>All Roles</i>	<ol style="list-style-type: none">1. Log into eResearch.2. ENTER the study number in the Search a Study field located near the top of the Home Page, then click the SEARCH button.
<i>Navigate to the Study</i>	<ol style="list-style-type: none">3. CLICK the Clipboard icon  for quick access to the Study Summary tab.4. Click on the Study Status tab

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Screenshot Reference: Study Status Tab

The screenshot shows the 'Study Status' tab for study CTMS 16-0124. It includes a navigation menu, a left-hand sidebar with 'Study Initiation', 'Study Activation', and 'Study Closure' sections, and a main content area with a search bar, a status summary table, and a 'Study Status History' table. Callouts 1-5 point to the current status, the status history table, the 'ADD NEW STATUS' link, the 'Open to Enrollment/UT' status in the history table, and the 'Study Initiation' sidebar respectively.

Organization	Study Status	Status Valid From	Status Valid Until	Meeting Date	Notes	Delete
UTHSCSA	Open to Enrollment/UT	02/09/2017	-	-	-	✕
	ACTIVE/UT	01/31/2017	-	-	-	✕
	Study Created in EMR	01/25/2017	-	-	-	✕
	Fund - Exec/Awarded	01/07/2017	-	-	-	✕
	IRB - Approved/UT	12/15/2016	-	-	-	✕
	PRE ACTIVATION/UT	11/02/2016	-	-	-	✕

All Roles

Study Status Overview and eResearch Functionality

Image Item 1: Current status of the study will be visible in the status bar near the top of the **Study >> Status** page (Top Right).

Image Item 2: The **Study Status History** section of the page (Center), click on any status in the Study Status column to review the details for the status.

Image Item 3: The **ADD NEW STATUS** link allows users to add a new status to the study. User rights determine a user's ability to add new statuses and determine the status they are allowed to add.

Image Item 4: The **Study Enrollment/UT Type** has one status that impacts eResearch functionality:

1. **Open to Enrollment/UT** – Permits patient enrollment

Image Item 5: The **Study Workflow Panel**, is visible on all study pages and displays a limited dataset of the Study Lifecycle .

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Screenshot Reference: Add New Status

Current Page: Study >> Status Details

You are working on study: CTMS 16-0124

Summary Forms Versions Admin Schedule Study Setup Milestones Notifications **Study Status** Reports Broadcast Study Team

Study Initiation

Study Submitted
IRB Approved

Study Start Date :02/09/2017 Study End Date :

Please enter status details:

Organization * **A** UTHSCSA

Status Type * **B** Overall/UT

Study Status * **C** Select an option

Documented By * **D** Marie Curie (Velos Train 90) [Select User](#)

Assigned To **E** [Select User](#)

Status Valid From * **F**

Status Valid Until **G**

Meeting Date **H**

Review Board **I** Select an option

Outcome **J** Select an option


Notes **K**

L This is study's Current Status
 Organization specific current reportable status

e-Signature *

**CTO (Central Office)
/ Data Manager**

**Adding a New
Study Status**


 Please refer to the [Appendix B](#) and [Appendix C](#) for the definitions and requirements for Study Statuses.

1. From the **Study Status** tab, click on the [ADD NEW STATUS](#) link
2. COMPLETE the following information in the **Study >> Status Details** page
 - A. **Organization (REQUIRED)** – SELECT 'UTHSCSA'
 - B. **Status Type (REQUIRED)** – SELECT the desired Status Type to display the related Study Statuses
 - C. **Study Status (REQUIRED)** – SELECT the status to be entered
 - D. **Documented By (REQUIRED)** – by default the current User will be listed in this field. If you would like to select a different user, CLICK the [Select User](#) link.
 - E. **Assigned To** – Click the [Select User](#) link to assign the status to a User, if needed
 - F. **Status Valid From (REQUIRED)** – SELECT the date the status is valid from
 - G. **Status Valid Until (OPTIONAL)** – SELECT the date the status is valid until. This field should be completed when the status is no longer valid to indicate an end date to that status. This field is especially important for IRB Approval statuses to indicate IRB Approval expiration.


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Adding a New Study Status (cont.)

- H. **Meeting Date (REQUIRED for Cancer studies)** - Complete when populating data for Review Board and Outcome below, as needed.
- I. **Review Board (REQUIRED for Cancer studies)** – Complete ONLY when a study is closed to accrual either temporarily or permanently due to safety, study accrual met, study not meeting accrual expectations or other reason for closure. SELECT the appropriate option that relates to the Requestor (Review Board) for the study closure.
- J. **Outcome (REQUIRED for Cancer studies)** – SELECT appropriate reason for closure as described above.
- K. **Notes (Strongly Recommended)** – ENTER any notes for the status
- L. **Current Study Status** – By default this checkbox will be marked
 - a. Leave checkbox marked if the status is an **Overall/UT** Status type
 - b. UNCHECK if the STATUS TYPE being added is NOT the **Overall/UT** Status.

 NOTE: For Ad-Hoc Query reporting purposes any status can temporarily be identified as a study's Current Status, otherwise Current Study Status is reserved for Study Statuses under the Overall/UT Status Type.

- 3. ENTER your **e-Signature** and CLICK the **SUBMIT** button to save the status.

 NOTE: After a status has been saved to the system, the user may edit various fields by **clicking** the on the **Status** link from the **Study Status History** section of the Status page. Organization, Status Type and Study Status are READ-ONLY and cannot be edited after initial entry.

 **CAUTION:** Study Start Date and Study End Date are automatically populated based on setting the Study Status to Open to Enrollment/UT and CLOSED/UT. DO NOT CHANGE THESE DATES.

Current Status	Study Start Date	Study End Date	Change Dates
Open to Enrollment/UT	05/25/2017		

EXIT CRITERIA

When this work instruction is complete, the user should be able to update study statuses. When reviewing the Study Status tab, it should contain the appropriate statuses to indicate that the study has transitioned through the various review boards and committee processes to gain final Institutional approval. At that time central office staff can set the Study Status to Active/UT and release to the study team to update and maintain the patient enrollment statuses.

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APPENDIX A: ROLES & RESPONSIBILITIES

RACI Chart	CTO (Central Office)	Research Team		
		Data Manager	Principal Investigator	Research Team
STUDY ACTIVATION				
-Patient Registration				
-Study Status Overview and eResearch Functionality	R,C	R	I	I
-Navigate to the Study	R,C	R	I	I
-Adding a New Study Status	R,C	R	I	I

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

APPENDIX B: DEFINITIONS

Status Type and Study Status – Within eResearch, Status Types categorize Study Statuses. The combination of the Status Type and the Study Status provide the user with the current status of the Study, which defines where a study is within its lifecycle.

Status Types and their corresponding Study Statuses that are shared across UT Systems are: Overall/UT, IRB/UT and Study Enrollment/UT. Status Types and Study Statuses that are shared across UTHSCSA are: HSC-Institutional, Funding, CTRP, CTOR Reg Affairs, CTOR CTOR and CTOR PRC. The following status only apply to Cancer studies: CTRP, CTOR Reg Affairs, CTOR Operations and Logistics, CTOR CTOR and CTOR PRC.

The tables on the following pages provide further definition of all Status Types and their corresponding Study Statuses.

Status Type	Study Status	Study Status Definitions
Overall/UT	PRE-ACTIVATION/UT	The ethical, scientific, and operational aspects of the study are in review by applicable offices, officials, and committees according to institutional policy. When this Status is active for a study, the system prohibits patient enrollment. The Status Valid From and Status Valid Until dates for this status can provide an overall time to activation.
	WITHDRAWN/UT	The study has been stopped, prior to activation and enrollment of the first participant.
	ACTIVE/UT	The study conduct is in progress. The sub-statuses may change depending on other factors (e.g., amendments, suspensions). When the authorized official/office transitions to Active, the Study Enrollment Status Type is changed to Open to Enrollment.
	CLOSED/UT	All activity relative to the study conduct, reconciliation, and close-out has been completed.

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Status Type	Study Status	Study Status Definitions
IRB/UT	IRB – Draft Study Created/UT	A draft application is in initial review for approval by the IRB.
	IRB – Withdrawn/UT	The PI has withdrawn a draft application from further consideration prior to initial IRB review or approval.
	IRB – Disapproved/UT	A draft application reviewed by the IRB is rejected.
	IRB – Approved/UT	A protocol is approved by the IRB for a specific period of time (approval period). A key business rule is that a “Status Valid From” date and a “Status Valid Until” date must both be entered.
	IRB – Lapsed/UT	A previously approved protocol that has not been reapproved before the end of the approval period. The Study Enrollment Status must be set to Enrollment Temp Closed.
	IRB – Suspended/UT	A previously approved protocol that has been temporarily suspended by the IRB. The Study Enrollment Status must be set to Enrollment Temp Closed.
	IRB – Inactivated/UT	A previously approved protocol that has been inactivated at the PI’s request.
	IRB – Terminated/UT	A previously approved protocol that has been permanently halted by the IRB. The status of Enrollment Closed should be set as a result.
Status Type	Study Status	Study Status Definitions
HSC – Institutional	HSC – New	A draft application is in initial review for approval by OCR and other applicable HSC offices/officials.
	HSC – Withdrawn	The PI has withdrawn a draft application from further consideration prior to initial HSC review or approval.
	HSC – Active	A protocol is approved by the OCR/Institution
	HSC – Suspended	A previously approved protocol that has been temporarily suspended by the OCR/Institution.
	HSC – Inactivated	A previously approved protocol that has been inactivated at the HSC at the PI’s request.

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Status Type	Study Status	Study Status Definitions
Funding	Fund - In Review	The proposed funding instrument(s) (grant or contract) is in review by applicable internal/external offices or agencies; if the study is institutionally funded (e.g. School, Center, or Department), the applicable reviews are in progress.
	Fund - Withdrawn	The PI stops the funding review process prior to award, and the study does not move forward to activation.
	Fund - Rejected	The proposed funding instrument (grant or contract) has not been approved. The study has not reached Active status due to lack of funding.
	Fund - Executed/Awarded	The funding instrument(s) have been fully executed (contracts and/or grants) allowing the study to become Active. (A 'Status Valid Until' date may be useful for this Study Status.)
	Fund - Modification	A change/amendment for an active study is in progress that requires modification to the funding agreement(s).
	Fund - Suspended	Funding has been temporarily halted in either from either the sponsor or from the recipient of the funding.
	Fund - Terminated	The funding source(s) stops the funding for an active study, or a non-funding related aspect results in early closure of the study and halts the study funding.
	Fund - In Reconciliation	The study conduct is completed, and a final reconciliation of the study finances is being conducted.
	Fund - Closed	All study conduct is complete, final reconciliation is complete, funding instruments (grants or contracts) are no longer active, and the associated financials are archived.

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Status Type	Study Status	Study Status Definitions
Study Enrollment/UT	Approved - Not Recruiting/UT	The trial has been reviewed and Approved by The IRB, but is Not currently seeking subjects for Study participation.
	Identifying Prospective Subjects/UT	Screening activities are limited to obtaining existing information or the results of procedures performed as part of the practice of medicine for the purpose of identifying prospective subjects.
	Open to Enrollment/UT	Recruitment activities are active; screened participants are enrolled if they are consented with eligibility verified.
	Enrolling by Invitation/UT	Subjects are selected from a pre-determined population. Screened participants are enrolled if they are consented with eligibility verified.
	Temporarily Closed to Accrual/UT	Enrollment of new subjects has been temporarily halted. There are no limitations on study activities for subjects already enrolled.
	Temporarily Closed to Accrual and Intervention/UT	Enrollment of new subjects has been temporarily halted. Use of the intervention being tested on subjects already enrolled has been temporarily halted. There are no limitations on other study related activities/procedures such as safety monitoring or monitoring for efficacy endpoints.
	Permanently Closed to Accrual/UT	Enrollment of new subject has been halted permanently. There are no limitations on study activities for subjects already enrolled.
	Permanently Closed to Accrual and Intervention/UT	Enrollment of new subject has been halted permanently. Use of the intervention being tested on subjects already enrolled has been permanently halted. There are no limitations on other study related activities/procedures such as safety monitoring.
	Administratively Complete/UT	Premature end to study before all objectives are met. Enrollment of new subject has been permanently halted. Use of the intervention being tested on subjects already enrolled has been permanently halted. All other study related activities/procedures have been permanently halted.
	Complete/UT	End to study (all objectives met), enrollment of new subjects has been permanently halted. Use of the intervention being tested on subjects already enrolled has been permanently halted. All other study related activities/procedures have been permanently halted.

Velos Status
Functionality:

1. active: Allows patients to be enrolled on a study.
2. prmnt_cls: Permanent Close – Permanently prohibits patient enrollment at study completion or retirement; sets the study end date.
3. active_cls: Active Close – When study set-up “Flag to Allow Patient Accrual” is set to “Organization Specific,” active_cls stops patient accrual for the organization that is specified.

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Applicable to CANCER CENTER Studies Only		
Status Type	Study Status	Study Status Definitions
Clinical Trials Operations Committee	CTOC – In Review	Protocol is currently scheduled for or in review by CTOC.
	CTOC – Approved	Protocol has been approved by CTOC.
	CTOC – Declined	Protocol has been declined by CTOC.
	CTOC – Appealed	A protocol has been declined by the CTOC and the principal investigator has appealed the decision.
	CTOC – Withdrawn	The protocol has been withdrawn from CTOC or further Cancer Center committee review.
Applicable to CANCER CENTER Studies Only		
Status Type	Study Status	Study Status Definitions
CTRP	CTRP - In Review	Trial is currently under IRB review.
	CTRP - Withdrawn	Trial has been withdrawn from development and review prior to enrollment of the first participant.
	CTRP - Approved	Trial has been approved, but is not yet recruiting or enrolling participants.
	CTRP - Active	Trial is open for accrual and enrollment.
	CTRP - Enrolling by Invitation	Participants are being (or will be) selected from a predetermined population.
	CTRP - Temporarily Closed to Accrual	Participant recruitment or enrollment has been halted prematurely but may resume. Participants already on trial continue to receive intervention.
	CTRP - Temporarily Closed to Accrual & Intervention	Participant recruitment or enrollment has been halted prematurely but may resume. Participants already on trial do not receive intervention.
	CTRP - Closed to Accrual	Trial has been closed to participant accrual, but trial is ongoing (i.e., participants continue to receive treatment and/or examination).
	CTRP - Closed to Accrual & Intervention	Trial has been closed to participant accrual. Participants already on trial do not receive treatment, but continue to be monitored for endpoints such as long-term survival.
	CTRP - Administratively Complete	Participant recruitment or enrollment has been halted prematurely (for example, due to poor accrual, insufficient drug supply, IND closure, etc.), and will not resume. Participants already on the trial do not receive further treatment or examination.
	CTRP - Completed	Trial has been closed to accrual and follow-up. Participant treatment/intervention has been completed and participants are no longer monitored for trial endpoints (i.e., last patient's visit has occurred). The trial has met its objectives.

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Applicable to CANCER CENTER Studies Only		
Status Type	Study Status	Study Status Definitions
CTRC Reg. Affairs	Reg Affairs – Pending Review	Trial is currently undergoing CTRC internal reviews (CDST, O&L, CROC, PRC)
	Reg Affairs – Submitted	Trial has been submitted to the IRB for review and approval.
	Reg Affairs – Approved	Trial has been IRB approved.
	Reg Affairs – Inactivated	Trial has been IRB approved for inactivation.
	Reg Affairs – Withdrawn	Trial has been withdrawn from development and review prior to enrollment of the first participant.
	Reg Affairs – Closed	Trial has been closed to participant accrual, but trial is ongoing (i.e., participants continue to receive treatment and/or examination).
	Reg Affairs – Storage	Trial has been approved for IRB inactivation and all study files are in off-site long-term storage.

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Applicable to CANCER CENTER Studies Only		
Status Type	Study Status	Study Status Definitions
PRC	PRC Review New	A study requiring Protocol Review Committee scientific review (e.g. cancer studies, departments/institutes requiring scientific review) has been submitted and is scheduled for review per applicable processes, this would equal the PRC receive date.
	PRC Conditionally Approved	A study has received Protocol Review Committee review, however the PRC has requested either additional information or revisions to the protocol before the protocol can be approved. Protocol will be approved upon satisfactory response to stipulations set by the committee.
	PRC Withdrawn	The submitting PI or the Operations and Logistics Committee removes the study for consideration by the scientific review committee; the study does not move forward to activation.
	PRC Tabled	The Protocol Review Committee has determined in its scientific review that pending resolution of issues identified must be corrected prior to activation.
	PRC Disapproved	There are major scientific or ethical issues that require modification of the protocol. A protocol that is disapproved may be resubmitted at a later date for review.
	PRC Approved	The reviewing scientific committee approves the study for activation.
	PRC Approved/In Revision	An active study has an amendment that requires further scientific review.
	PRC ON HOLD	The PRC has identified issue(s) - e.g. requiring a temporary halt to study conduct; study conduct cannot re-initiate without approval by the scientific review committee.
	PRC Closed	All study conduct is complete, all PRC activities are complete, and the associated records are final.
	PRC Terminated	The PRC stops study conduct prior to completion of study objectives due to accrual review; it may not be re-activated.

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APPENDIX C: REQUIRED TYPES & STATUSES FOR STUDY ACTIVATION

Required Statuses for Study Activation				
Status Type	IRB/UT*	HSC – Institutional*	Overall/UT	Study Enrollment/UT
Study Status	IRB-Approved/UT*	HSC-Active*	Active/UT	Open to Enrollment/UT

*Status expected to be automatically set via eResearch – ORCA interface

END OF DOCUMENT