Dartmouth Clinical Trials Office: Velos eResearch Policies and Procedures

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The policies and procedures are designed to promote quality data capture and protect subject confidentiality.

Basic Use Guidelines

Contents

Scope

These policies and procedures apply to all users of Velos eResearch within Dartmouth-Hitchcock Medical Center. Additional information about Velos eResearch can be found in the Velos Users Manual.

Data Entry Expectations

Description

Official institutional reports on the status of a study and corresponding enrollments cite data collected in Velos eResearch. Complete reporting relies on up to date data being entered into Velos eResearch.

Procedure

The Velos team runs regular reports and PIs, and study team members will be notified if information is not up to date. Data are expected to be updated upon notification.

User Accounts

User Account and Login Requests/Activation

Description

A variety of Dartmouth and DHMC personnel need access to Velos eResearch to perform their job duties and as such an account is required.

Procedure

Accounts can be requested by emailing Velos.NCCC@Dartmouth.EDU.

Include in the account request email the reason why Velos eResearch access is needed and the role the Velos eResearch user serves in research.

An account will be created after the following three criteria are met:

- Supervisor signature on an account request form
- Successful completion of Velos eResearch training
- Electronic signing of the policies and procedure manual

Account Deactivation

Description

There are a limited number of Velos eResearch user licenses available.

Procedure

Accounts will be deactivated under the following conditions

- A user leaves the institution
- A user has a change in job duties which no longer require access to Velos eResearch
- An account has been inactive for 90 or more days
- Abuse of account privileges (e.g. unauthorized sharing of passwords/viewing of data)

Study Information

Study Entry

Description

The Clinical Trials Office (CTO) is charged with collecting information on all clinical research at Mary-Hitchcock Memorial Hospital and the other legal entities located at Dartmouth-Hitchcock Medical Center (Dartmouth-Hitchcock Clinic, Dartmouth Medical School and the Veterans Administration Medical Center) and maintaining a registry of this information. Additionally, the Norris Cotton Cancer Center needs to track cancer related research to report to the NCI, Dartmouth and other agencies.

Procedure

Any study that meets ONE of the following criteria is required to be entered into Velos eResearch:

1) Any research studies designed to evaluate the safety and effectiveness of medical care that require full board or expedited IRB review ("clinical research"), with the exception of unfunded registry studies, medical chart reviews, data and tissue repositories, and those originating from certain non-clinical departments/divisions from the College including Arts & Sciences, the Thayer School of Engineering, and the Tuck School of Business.

Study Numbers

Description

Study numbers are used to uniquely identify research studies.

Procedure

Study Numbers are assigned based upon the following rule:

Review Type	Study Number
CCRC Reviewed	Assigned centrally at NCCC
Non-CCRC Reviewed	Assigned centrally at CTO

Required Study Information

Description

Velos eResearch provides a large number of fields to describe a particular study. The minimal set of field information required is described here.

Procedure

The following fields are required to be maintained:

Field	Comments

Study Number	Centrally assigned
Study Title	Official title taken from the protocol
Principal Investigator	
Primary Coordinator	
Regulatory Specialist	
Research Nurse	
Statistician	For Dartmouth-initiated studies
Co-Investigators	For delegation of authority, 1572s
Therapeutic Area	Disease team
Disease Site(s)	
National sample size	
Local sample size	
Target accrual per year	
Study scope	Multi-center or single center
Study type	Therapeutic, observational, etc
Account numbers	MHMH account number Dartmouth account number Hitchcock Foundation account number Clinical Trials Office account number
IND / IDE number and holder	
CPHS Number	
ClinicalTrials.gov ID	
Funding Source	Name of funding source: CALGB, Sanofi-Aventis, etc.
Other DHMC sites/affiliates opened at	DHMC/Manchester DHMC/Keene DHMC/St. Johnsbury DHMC/VA
Publish to NCCC website?	Should the study be listed on the NCCC website?
Treatment Arms	Detailed listing of treatment arms being investigated
Phase	I, II, III, etc
Research Type depending on funding source	Federal, Industry, etc.

Documents

Document Management

Description

Velos eResearch is able to store a variety of documents including, but not limited to:

- Informed Consent Documents
- Protocols
- Investigators Brochure
- Billing Plan [MCA review]

Procedure

In the case of draft documents, they need to be watermarked.

All filenames should follow the procedure outlined in the Velos Users Manual.

Required Documents

Description

A variety of documents are currently able to be stored within eResearch. This policy sets out the minimal set of documents that need to be attached to a study.

Procedure

Documents are named according to the naming convention established in the Velos Users Manual.

The minimal sets of documents that are required to be uploaded into Velos are:

- Contract
- MCA/Billing Plan Protocol
- Consent Forms
- IRB Approval Letters
- Investigators Brochure
- CCRC Approval Letter
- Budget

The most current version of these documents needs to be uploaded as changes occur.

Study Statuses

Initial Study Activation

Description

A minimal set of fields need to be recorded in Velos eResearch before a study can be opened for enrollment. Collection of information documents that proper review has occurred before study activation.

Procedure

The following steps need to occur before a study can be activated (opened for enrollment):

- Site Initiation Visit (SIV) completed, when required
- IRB Approval
- Biosafety Committee Approval must be obtained, when required
- Radiation Safety Approval must be obtained, when required
- Contract executed
- Patient calendar created and approved, when required by research team policies
- Account numbers assigned

Active/Enrolling Study Status

Description

A study may begin accruing participants when it has an Active/Enrolling status in Velos eResearch. Before a new study can be activated, many steps need to occur. To determine that all steps have been followed in the opening of a study, the activation has been centralized.

Procedure

Initial study activation depends upon who is managing the study:

- **CTO-Managed Cancer Studies**
  The CTO Business Operations Associate assigned to the study enters the initial Active/Enrolling status

The study coordinator to do? Study Statuses Minimal Set

Description

Velos eResearch is configured with over 60 study statuses. This policy sets out the minimum required set of study statuses that need to be maintained in real-time.

Procedure

The following study statuses are required to be maintained as they change:

- Active/Enrolling (subsequent to initial activation by the finance group)
- Active/Closed to Enrollment
- Suspensions: Active/Enrollment Suspended, Sponsor, SDMC and IRB
- Study Completed/Retired
- Withdrawn
- On Hold
- IRB – Approval Dates [expiration dates must be updated after each review]
- All IRB approvals (not just initial)

For intervention trials:

- CCRC Approvals
- SDMC Approvals

Patient/Research Participant Information

Velos eResearch uses the word “patients” to refer to study participants.

Patients

Description

Velos eResearch provides the ability to capture research patient demographic information and associate them to studies containing forms.

Procedure

Non-research patients will not be tracked or recorded in Velos eResearch.

Patients who are being pre-screened will not be tracked in Velos eResearch.

The only patients who have demographic information captured in Velos eResearch are those who either:

1) Have signed a research Informed Consent document
2) Have had consent waived by the Dartmouth Committee for the Protection of Human Subjects (CPHS)

If the study involves a large number of subjects or is a questionnaire study, please contact Mark Carey (Mark.Carey@Dartmouth.EDU) about alternatives.

Patient Statuses

Description

Velos eResearch is configured with a variety of patient study statuses. This policy defines the minimal set that is required for tracking of a patient on a study.

Procedure

The minimal set of patient study statuses that need to be maintained are:

- Informed Consent Signed
- Screen Failure
- Enrolled
- Off Study

DH1 Entry

Description

The DHMC billing system keeps track of patients enrolled in research. This linking serves many purposes, including:

- It flags services to be reviewed for correct billing to the appropriate payer
- Sets the patient research flag in CIS

Procedure

Upon receipt of an Informed Consent Signed status in Velos eResearch, the patient will be associated into DH1 by Velos personnel. Upon study completion (Off Study or Screen Failure), the patient will be disassociated from DH1 by Dartmouth Clinical Trials Office Velos personnel.

DH4 Entry

DH4 is the southern DHMC billing system and it keeps track of patients enrolled in research. This linking serves many purposes, including:

- It flags services to be reviewed for correct billing to the appropriate payer
- Sets the patient research flag in CIS

Procedure

Upon receipt of an Informed Consent Signed status in Velos eResearch, the patient will be associated into DH4 **AND** DH1 (if they have an MRN in the north) by Cancer Center personnel. Upon study completion (Off Study or Screen Failure), the patient will be disassociated from DH1 **AND** DH4 by Dartmouth Clinical Trials Office Velos personnel.

ICD9 Form for Studies with Multiple Disease Sites

Description

In the case of a study that recruits from a variety of disease sites (e.g. Phase I), it is important to know the primary clinical or pathological diagnosis that a patient had upon entry into the study. This diagnosis is used in reporting as well as assigning the correct research nurse.

Procedure

Patients on studies that recruit from multiple disease sites need to have the Patient Diagnosis form completed to record the ICD9 code of the primary diagnosis. See the Velos Users Manual for form completion instructions.

Miscellaneous

Notes in System

Description

Many portions of Velos eResearch allow the user to enter notes about a particular event, e.g.

- A study status
- A patient status
- A document

Procedure

All notes or text entered into Velos eResearch are to be written in a professional manner and end with the initials of the person entering the note.

Data Entry Timing

Description

Much of the data collected in Velos eResearch is time-sensitive:

- Consent documents
- Study or patient statuses
- Patient Schedule events

and many personnel at Dartmouth and DHMC rely upon this data to be accurate and up to date

Procedure

All data entered into Velos eResearch must be entered immediately when the event or status change takes place.

Audits

Description

Users who are not members of a research team may have access to other research studies due to staff coverage needs.

Procedure

Dartmouth Clinical Trials Office Velos personnel perform routine Velos view audits and check user authorization.

Electronic Case Reports Forms (eCRFs)

Description

Velos eResearch provides the ability to create electronic case report forms and attach them to patients on a study.

Procedure

Before a set of electronic case report forms are put in production on Velos eResearch, the statistician and PI that are listed on the Study Team must electronically sign off on the forms from within Velos eResearch. The sign off procedure documents that the CRFs have all the data that are needed for statistical purposes. Electronic case report forms will not be put into production on Velos eResearch without the electronic signature of the statistician and PI. Additionally, fields used to capture data will be taken from the caBIG Common Data Elements (CDE) library.