Introduction to Velos e-Research

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Key Information

- Velos e-Research
  https://utmbprod.veloseresearch.com/

- InfoEd IRB Portal
  https://rdhs.utmb.edu/

- Office of Clinical Research
  https://research.utmb.edu/OCR

- IRB
  https://research.utmb.edu/IRB

- InfoEd Training Guides
  https://research.utmb.edu/infoedtraining

Contents

- Velos eResearch Key Contacts (page 3)

- Notes Page (page 5)

- Using Velos eResearch Tip Sheet (page 7)

- Before You Submit a Study (page 13)

- Naming Conventions (page 14)
Key Contacts

Office of Clinical (OCR) Research
(*Help with Velos and Clinical Trials*)
- **Lori Simon**, Director of the Office of Clinical Research
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- **Lisa Hernandez Garcia**, Research Operations Manager
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- **Kelli Hunt**, Clinical Research Billing Specialist
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- **Hema Ramnauth**, Clinical Trial Information Specialist
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Institutional Review Board (IRB)
(*Help with InfoEd and IRB Submissions*)
- **Anne Clark**, Director, Human Research Protection Program
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- **Heidi Sperger**, IRB Coordinator
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Can’t Log In?
UTMB Help Desk
- (409) 772-5200
- (281) 557-7777
- (888) 898-2401
Required Items for Initial Submissions

Before you sit down to initiate a protocol in Velos, you will want to make sure you have the following information and documents. Also, check that your sponsor is in Velos prior to starting your new forms.

List of documents required for initial submissions

Industry
- Protocol
- ICF
- Budget
- Contract to be uploaded
- Completed submission form

Non industry
- Protocol
- ICF
- OSP routing form (if applicable)
- Contract (if applicable)

Required fields for Summary Page in Velos

- Study Entered By
- Principal Investigator
- Study Contact
- IRB Number (generated by Velos upon successful completion of the summary page)
- Full Study Title
- Objective/Summary
- NCT Number
- Department
- Division
- Therapeutic Area
- National Accrual
- Phase
- Study Funding Source
- Study Type
- Sponsor Name
- Sponsor Project Manager
- Sponsor Project Manager Phone
- Sponsor Project Manager Email
Naming Conventions

Velos e-Research will provide a place to archive all documents associated with a study. To do that properly, the Office of Clinical Research has established a set of naming conventions for coordinators to use when uploading documents. Please refer to and use these formats for all documents uploaded to Velos.

Initial Submissions
- Protocol_VersionNumber_DateofProtocol
- ICF_SponsorTemplate_Date
- Budget_SponsorTemplate_Date
- Contract_SponsorTemplate_Date

Subsequent Protocols
- Protocol_Version_ProtocolDate

Amended or annual ICFs
- ICF_versionnumber_Date

Signed Patient Consent Forms that are uploaded into Velos
- ICF_PatientInitials_DateConsentSigned

Regulatory Documents/Other
- 1572_Datesigned
- TrainingLog_Date(of training)
- DOR_Date(date signed by PI)
- FinancialDisclosure_Initials_Date(signed by individual)
- TelephoneScript_PtInitial_Dateofcall
- LabManual_Version_Date
- SponsorMemo_Date
Introduction to Velos

Velos e-Research is a tool to help investigators and coordinators manage the daily tasks of conducting clinical trials and research involving human subjects. UTMB uses Velos to manage its clinical trials on campus. The IRB uses InfoEd to manage the protocols it reviews.

Please follow this step-by-step guide to navigate through registering your study in Velos and initiating your IRB review.

Step 1. Log in to Velos

Type https://utmbprod.velosereresearch.com/ into your browser and use your UTMB Users-M login and password to access Velos.

TIP:
Be sure you allow for pop-up windows in your browser before logging in.

Step 2. Open a New Study

Once logged in, select NEW from the Studies section of the MANAGE menu.

TIP:
Verify that your sponsor is in Velos prior to starting your new form. You cannot move forward, save data or forms if you don’t have a sponsor. Gather all important information before starting.
Step 3. Complete the Study Summary Tab

This opens the Study Summary Tab. Complete all fields as they apply to your study, ensuring you complete anything with an asterisk that is required.

**Study Information**

- **Study Entered By**: Your name should appear in the **Study Entered By** field. Fill in the empty boxes with the appropriate individuals. Principal Investigator and Study Contact MUST be two separate individuals.

Next up, complete the Study Definition area. While the IRB number field is marked required, leave it blank. It will self-populate once you hit the submit button. When you create a study in Velos, the system generates your IRB number to use when referencing the study or looking for the protocol in InfoEd.

**Study Definition**

- **NCT Number**: Refers to registry with clinicaltrials.gov. This is a required field. If your study is registered with clinicaltrials.gov, you enter the NCT number here. If it is not, it is still a required field and you will enter NCT00000000.

The ICMJE defines a clinical trial as "any research project that prospectively assigns people or a group of people to an intervention, with or without concurrent comparison or control groups, to study the cause-and-effect relationship between a health-related intervention and a health outcome."

If you are conducting an interventional clinical trial funded by NIH, or studying an FDA regulated drug product (including biological) you must register the study on clinicaltrials.gov. Visit the NIH website to determine whether or not you need to register your NIH funded study on clinicaltrials.gov.

If you are planning to publish the results of the study, most Journals require clinical trials to be registered prior to enrolling subjects.
Step 3. Complete the Study Summary Tab

Complete the Study Details section. Be sure to set your national accruals here. You will complete the local accrual information once the study has been submitted and created in Velos.

Enter the sponsor details. The Office of Clinical Research needs the sponsor name, as well as the contact information for the person at the sponsoring agency who will be working with you on this study. If you have no external funding, select Department Account as your sponsor and list the PI or your faculty advisor information in the contact fields. **NOTE: As a reminder, if your sponsor is not listed in the drop down menu, please work with the Office of Clinical Research to have your sponsor listed.**
Step 3. Complete the Study Summary Tab

The More Study Details section adds other critical information to your protocol record. Answer the pull-down items that are marked with a red asterisk.

![More Study Details Table]

Step 4. Complete Your E-Signature

When you have completed the form, enter your e-Signature to save and submit your document.

![E-Signature Entry]

**TIP:**
You can change your e-Signature to a number you are likely to remember. Select PERSONALIZE from the main menus, then e-Sign. Follow the prompts to change your e-Signature.
Step 6. Complete your InfoEd Submission to the IRB

Don’t forget! Submitting a new study is a two-part process. Complete the form in Velos, then when you have an IRB number generated, continue the process with an InfoEd application. Login to the InfoEd eRA Portal at http://rdhs.utmb.edu/.

Under the My Human Subjects section, search for your study using the IRB number assigned in Velos after you submitted the New Study form.

Select your study from the list of results and complete the necessary IRB forms, according to IRB policies and procedures.

Congratulations. You have now submitted a new study.