



## Velos eResearch SOPs

Policy or Procedure Title:  
**Minimum Data Entry Requirements**

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### Introduction:

This protocol details the minimum data that users of the LCRC Clinical Trails Management System (Velos eResearch) should enter when performing data entry activities on the Velos system.

### Entering Required Data:

Users do not always have to type in data in a field in the Velos eResearch. Data entering is based on the type of field. There are six types of fields for the fields that the LCRC requires to enter data. They are: 1) text, 2) number, 3) date, 4) checkbox, 5) dropdown, and 6) lookup.

The fields' type text, number, date, and checkbox are typed in or checked by the user. The fields' dropdown and lookup are based on data currently available in the system that the user needs to choose from. Dropdowns are customizable and users are encouraged to identify additional values for those fields. Lookup are fields that look for information that has been entered in the system and can be used to populate a field. An example of a lookup field would be the PI in a Study. Only PIs added to the system will be available to fill in the PI field.

Please see the Data Upload Template Attachment for more detailed information on the required fields, their fields' types, and the values for dropdown fields.

### Minimum Data Entry Requirements:

Data Entry Users are required to fill in all the fields listed below on the different sections of the system:

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Study Summary:

Study Number, More Study Details, Study Title, Study Entered By, Therapeutic Area, Phase, PI, Research Type, Study Type, Sponsor, PI Major Author, Disease Site, and Study Contact.

More Study Details (see Summary 4 Options below for instructions):

Study type (Summary 4): Agent or Device, Trials Involving other Interventions, Epidemiologic or other Observational Studies, Companion, Ancillary or Correlative Studies, Program Code

**Summary 4 Options:**

These are specific instructions for selecting Summary 4 Options in the *More Study Details* form.

You will have to CHECK ONE of the 4 (four) following checkboxes and FILL-IN the Program Code field for every study. The checkboxes you need to choose from are: 1) Study type (Summary 4): Agent or Device, 2) Trials Involving other Interventions, 3) Epidemiologic or other Observational Studies, and 4) Companion, Ancillary or Correlative Studies. You need to fill in the Program Code field with 01, 02, or 03. You have to fill in the field Program Code with 01 when the study is of Basic Sciences, 02 when of Clinical Sciences, and 03 when of Population Sciences. See Table 1 below.

**Program (Prog):** Provide the program code at your center that includes this protocol or study. Use the codes defined in below:

**Table 1:**

<u>Program Code</u>	<u>Program Name</u>
01	Basic Sciences
02	Clinical Sciences
03	Population Sciences

***Trial/Study Type (Type): Identify the type of trial or clinical research study, as follows:***

Therapeutic (The) Trial: Clinical trials with therapeutic intent using drugs, radiation, surgery, other biological agents, or behavioral or other interventions.

Prevention (Pre) Trial: Clinical trials for the modulation of cancer risk and inhibition of cancer progression using chemoprevention drugs, nutritional, dietary, behavioral, or other interventions.

Supportive Care (Sup) Trial: Clinical trials intended to improve the comfort and quality of life for the patient using drugs, nutritional, dietary, behavioral or other interventions.

Screening (Scr), Early Detection (Det), or Diagnostic (Dia) Trials: Clinical trials directly testing the efficacy of devices, techniques, procedures; or tests for earlier or more accurate detection or diagnosis of disease.

Epidemiologic (Epi), Observational (Obs), or Outcome (Out) Trials: Studies among cancer patients and healthy populations that involve no intervention or alteration in the status of the participants, e.g., surveillance, risk assessment, outcome, environmental, and behavioral studies.

Ancillary (Anc) Trial: Auxiliary studies that 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 included must be linked to an active trial or epidemiologic or other study and should include only patients accrued to that trial or study. Only studies that can be linked to individual patient or participant data should be reported.

Correlative (Cor) Trial: 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.

**End of Summary 4 Options**

Arm Definition:

Study Number, and Arm Name

Study Status:

Study Number, Organization, Study Status, Status Valid From, and Entered By

Study Team:

Study Number, Study Team User, Study Team Role, and Study Team Status

Study Sites:

Study Number, Organization, Site Type, and Local Sample Size

Patient Demographics:

Patient ID, Date of Birth, Site, Survival Status, First Name, Last Name, Middle Name/Initial (optional), Gender, Primary Ethnicity, Primary Race

Patient Enrollment:

Patient ID, Study Number, Patient Status, Status Date, Enrolled By, and Patient Study ID

Patient Arm:

Patient ID, Study Number, and Arm Name

**End of Protocol.**