# Electronic CRF Creation

## Purpose

To describe the process of creating an electronic case report form (CRF) by adding variables, units, ranges, and branching logic when appropriate.

## Scope

This SOP is intended for use by any clinical research staff who may be involved in the creation of CRFs.

## Responsibilities

#### Data Manager

* To provide guidance to Research Assistant(s) working on a CRF
* To designate the electronic data capture software that will be used to house the CRF

#### Research Assistant

* To create and maintain CRF(s) for any given study

## Procedure

1. Determine which CRF(s) will be created

* Data Manager will provide Research Assistant with paper or electronic copies of the CRF that is being created
  + If possible, the CRF should be annotated with desired variable names

1. Create variables

* Research Assistant will create electronic versions of each individual variable found the CRF
  + Variables should be given easy to reference variable names (such as ess\_1 rather than would\_you\_every\_fall\_asleep)
  + Variables should be designated the correct type (numeric, date, scale, etc.) prior to the start of data collection1
  + If possible, date and numeric variables should have established minimums and maximums to flag improbable or impossible values1
  + Variables should be given consistent units1
* For variables that contain option choices, these conventions should be followed whenever possible
  + For yes/no variables, yes should be coded as 1 and no should be coded as 0
  + For checked/unchecked variables, checked should be coded as 1 and unchecked should be coded as 0
  + The following missing codes have been established for use in all projects:
  + -10: Confusion
  + -9: Missing
  + -8: Not Applicable
  + -2: Don't Know
* Branching logic should be used judiciously to ensure that the flow of electronic form completion mimics that of the paper copy

## References

1 [Spout Style Guide](https://www.github.com/sleepepi/spout)

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