

16.1 Generating Annotated eCRFs

This article describes a method for generating annotated CRFs (a/k/a “aCRFs”) by using OpenClinica’s spreadsheet form definition. In short, it entails adding columns to the form definition spreadsheet in order to insert annotations into the existing labels, so that the resulting form looks something like this:

Demographics and History

[Variable Name: RACE] [Type: begin group]

Participant's racial background (check all that apply) [Variable Name: PTRACE] [Type: select_multiple RACES] [Required: yes]		
<input type="checkbox"/> American Indian/Alaskan Native [1]	<input type="checkbox"/> Asian [2]	<input type="checkbox"/> Black/African American [3]
<input type="checkbox"/> Native Hawaiian/Pacific Islander [4]	<input type="checkbox"/> White/Caucasian [5]	<input type="checkbox"/> Other [6]
Hispanic or Latino ethnicity? [Variable Name: HISP] [Type: select_one HISPYN] [Required: yes]		
<input type="radio"/> Yes [1]	<input type="radio"/> No [0]	<input type="radio"/> Prefer not to say [2]
Participant's sex [Variable Name: PTSEX] [Type: select_one MF] [Show when: not(\${PTSEXELC} = 1 or \${PTSEXELC} = 2)]		
<input type="radio"/> Male [1]	<input type="radio"/> Female [2]	

This annotated view of the eCRF shows variable names, picklist codes, relevant logic, constraints, calculations, and required. You can choose how much or how little detail to include. [Here is the template file used to produce the above.](#) **Step 1: Build your form.** You can do this either in Form Designer or directly in the spreadsheet template. Once your form is nicely polished, download your form definition to Excel and proceed to step 2. **Step 2: Add annotation “helper columns”** to your form’s spreadsheet definition, which you can obtain from the “aCRF Template” Excel file (the helper columns are green). There are columns to add to both the survey and choices sheets. When you paste them into your form, make sure the helper columns reference the correct columns in the form definition (in case the columns are in a different order in the spreadsheet you're using). Depending on which annotations you actually care about, you may want to paste all of the annotation helper columns over. Keep in mind that any columns you remove may still be referenced in the final annotated label assembly formula, so those formulas may need updating. Give this form a new version name (e.g. v1-aCRF). **Step 3: Rename your original label columns** on the survey and choices sheets. The helper columns added in Step 2 include new label columns. The original label columns need to be renamed (try “label-old” for the columns titles) so that newly added annotation helper label is used. **Step 4: Upload and print.** Rather than uploading the aCRF as a version to the real form (which could have implications for future form updates), we recommend creating an “aCRFs” Event, and uploading each aCRF to this event as a new form version (or new form, if needed). Then, print it from the form preview, and then archive that entire event before publishing the study so that it will never make its way to runtime.

Approved for publication by Ben Baumann. Signed on 2021-04-02 2:07PM

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