Case Report Form (CRF) QC Checklist

Instructions: Review each CRF for common features and quality as outlined below. Obtain Statistician approval to ensure that the required data is captured for all primary and secondary objectives of the study prior to distributing to the Principal Investigator and obtaining PI approval.

Note: This is not an exhaustive list, and is intended only as a guide.

PI: _____ **Protocol: _____**

Date/Version of CRF: _____ **Date Reviewed: ___/___/___**

HEADER AND FOOTER – Are all of the following included in either the header or footer?	**YES**	**NO**
Study name (first page only)		
Form name		
Version date		
Page number		
Space to enter **Study ID number** (on all pages, except first page)		

SECTION FORMATTING	**YES**	**NO**
Is your CRF broken down into sections to group similar topics?		
Are your questions assigned consecutive section letters and item numbers with no gaps for easy navigation?		
Do you use skip logic to direct the flow of data collection?		
Does your skip logic make sense and is it easy to follow?		

GENERAL INFORMATION – Do you collect all of the following information?	**YES**	**NO**
Study ID number		
Initials of person completing the CRF		
Date form is completed		
Date of visit (if applicable)		
Visit (if applicable)		

CONTENT	YES	NO
Do the questions on your CRF help you to answer the research question?		
Are items corresponding to the primary/secondary outcomes correctly specified per protocol?		
There are no double-barreled questions. (i.e. questions that inquire about more than one issue, but allow only a single response)		
Are you asking each question one time?		
Is the accuracy of digits, decimal places, and units of measurement clearly indicated by specifying the number of significant figures? *(Use: __ __ . __* kg *instead of* _____ kg *)*		
Do all measurements have units specified and are they consistent?		
Are you collecting continuous data instead of grouping them into categories? *Example1: Instead of collecting **Hypertension Yes/No**, collect **systolic BP** & **diastolic BP**.* *Example2: Collect exact lab values instead of grouping them (0-10mg, 11-20 mg, etc)*		
Do you limit the use of open-ended (free-text) response questions? *Free-text should only be used if planning to perform qualitative analyses.*		

WRITING STYLE / FORM LAYOUT	YES	NO
Are all the questions written in the same verb tense?		
Are similar fonts styles and sizes consistently applied ?		
Are CRFs formatted properly and consistently (headers, footers, pagination, layout).		
Are CRF sections are in numerical and/or alphabetical order, and outlines, bullets and numbering sequential and consistent?		
CRFs checked for typographical / spelling errors?		
Are any cross-references are correct?		
Are Visit nomenclature (e.g., Screening, Baseline, Follow-up) and procedures are clear, accurate and consistent?		

ELIGIBILITY	YES	NO
Do the eligibility (inclusion/exclusion) criteria match those listed in the protocol?		

DEMOGRAPHIC DATA	YES	NO
Have you considered collecting the following common demographic data? *DOB, Sex, Ethnicity, Race, Education level*		
Are you collecting Date of Birth instead of age? *(Note: You should <u>not</u> collect both DOB and age.)* *Age should only be collected if there are issues collecting PHI.*		
Does the Ethnicity (Hispanic or Latino) question precede the Race question?		
Have you determined the best way to collect Race data? (i.e. 'select one' vs 'select all that apply') *If collecting data from a patient chart / EMR, then collect the data the way it is collected in the chart* *If collecting the data directly from the patient, use 'Check all that apply'* *If using the 'Select one' method, include a 'mixed race' option*		

CODING	YES	NO
Are your categorical variables coded consistently throughout all CRFs in your study?		
Sex is coded as 1=Male | 2=Female		
Yes/No questions are coded as 1=Yes | 0=No		
Do you need "missing" categories for each question? *(i.e. n/a, refused, unknown, missing)*		
Will your 'missing' value codes not be confused with your real data?		

Standard CRC Missing data codes

-3 = Not applicable
-5 = Refused
-8 = Unknown
-9 = Missing

APPROVAL

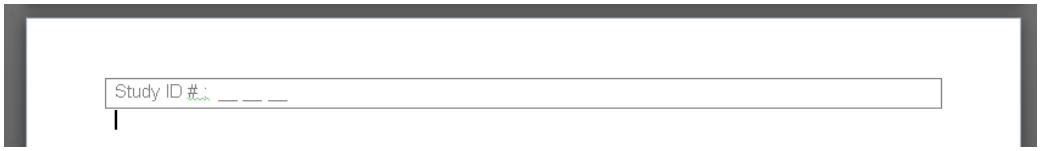
STATISTICIAN APPROVAL
Signature
Name / /
Date *Via Email [ ]* *Date of Email* _____/_____/_____

PRINCIPAL INVESTIGATOR APPROVAL
Signature
Name / /
Date *Via Email [ ]* *Date of Email* _____/_____/_____

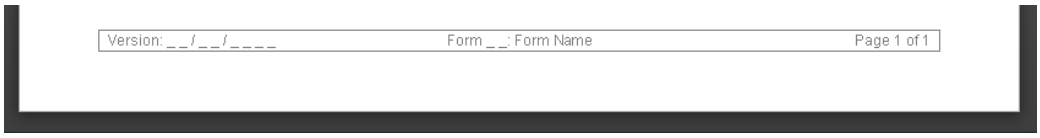
Example header and footer:

- Example of header for first page:

- Example of header for remaining pages:



- Example of footer for all pages



See **RPG-02 Guidelines for Developing Case Report Forms (CRFs)** for more details: http://www.childrenshospital.org/~/media/Research%20and%20Innovation/Research%20Centers/Clinical%20Research%20Center/RPG_02_2011.ashx

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