

VAMHCS RESEARCH SERVICE HOT TOPIC

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Documenting Inclusion and Exclusion Criteria

- ▣ Research participants' safety and the scientific integrity of your studies depend on the proper inclusion and exclusion of research participants.
- ▣ The HRPO requires that research staff print out or copy the "Inclusion/Exclusion Checklist" from the approved BRAAN application and use it as a checklist for screening subjects. It must be signed by the investigator and filed in the research record for every subject.
- ▣ *There must be source documentation to corroborate the checkmarks made on the checklist!*
- ▣ The checklist itself cannot be a data collection tool. It is meant to summarize the results of screening tests and to document that the PI has reviewed those results and can therefore certify that the participant is eligible or ineligible for the study.
- ▣ Audits by the Office of Research Compliance have revealed the following common errors:
 - ▣ No source documents to support the checkmarks on the checklists.
 - ▣ Expired or incorrect checklists, especially for research programs where several similar projects are being conducted. One reason that this can occur is that the checklists are not labeled with the name of the project or version of checklist.
- ▣ The Office of Research Compliance recommends the following actions:
 - ▣ Adapt study screening forms to collect information specific to inclusion & exclusion criteria. Be sure to

design the forms to prompt notes or answers to questions that will document the presence or absence of specific conditions, therapies, histories, etc.

- For example, rather than using a generic “Medical History / Physical Exam” form that has a simple checkmark for “cardiac disease”, a study’s inclusion or exclusion decision might depend on specific categories of cardiac disease (MI, CAD, HTN, etc.). A good screening form would break out the categories of cardiac disease, *OR* prompt the examiner to comment on specific aspects of the participant’s cardiac history.
- When an auditor or monitor looks at your research charts, they should be able to find a lab result, a note (even if it’s in CPRS), or a screening form to corroborate every inclusion and exclusion criterion.

▣ Adapt the *approved* Inclusion/Exclusion Checklist (from BRAAN) in the following ways:

- Place a header or other label that states the name of the study protocol to which the checklist applies.
- Place a footer or other label that states the version of the checklist. If modifications are later made to inclusion or exclusion criteria, it will thus be more likely for staff to identify and use the correct checklist.
- Place columns to the left or right of the table (or establish a practice of simply writing in the margins) that capture: “Source Document is in study binder...Yes...No”.

▣ Establish a “Master Documents” file or folder for the study that contains the current versions of all study checklists, data collection documents, and informed consent document. Remove all outdated documents from this file/folder and file those in an archive file/folder.

- Be wary of copying a large store of study checklists, data collection documents, and informed consent documents. While this may be efficient when a large number of individuals are being screened over a short period of time, it can lead to future errors if outdated checklists, forms and documents are easily accessible to staff who assume that they are using correct versions.

For questions concerning this or other Research Service Hot Topics, contact:

Jessica Mendoza, RN, BSN, CCRC
Research Compliance Specialist
VA Maryland Health Care Systems
10 North Greene St
Baltimore Maryland 21201
Rm 3-A-125
(410) 605-7000 x5591
jmend001@umaryland.edu