Amsterdam Public Health

Amsterdam UMC University Medical Centers | VU Vrije Universiteit Amsterdam | University of Amsterdam

Checklist Documentation

An aid to document all important steps of a research project.

Folder structure and File names

- Are folders and files stored on the network and accessible for all project members?
- Is a clear version numbering used in your file names?

Protocols, ethics, laws

- Is your project registered with the "Centraal Meldpunt Gegevensbescherming"?
- Are the application, communication and reviews of the ethical committee (Medical Ethical review Board: METc or Ethics Review boards or committees; ERB) properly archived?
- Are changes (amendementen) in the research protocol accorded by the METc?
- Is your project registered with the Privacy officer (Functionaris Gegevensbescherming)?

Project Planning and work deliberation

- Is a project plan drawn and kept up to date?
- Are all decisions with impact on your project properly noted?

Logbook(s)

- Is a general index maintained?
- Does the index contain decisions with impact on content and or execution?
- Are references to deliberations on decisions given?
- Are references to other (sub)logbooks registered in the index?

Inclusion of study participants

- Are possible changes in the in- and exclusion criteria documented, including the reasons why?
- Do you register non-responders, dropouts and if possible the reason for non-response or drop out?
- Is the randomization procedure written down, including possible changes?
- Are the arrangements with the independent person who performs the randomization documented?

Questionnaires

- Are the choices made in the selection of questionnaires well documented? E.g.: validity, reliability, translation, suitability for your outcomes and your study population
- Don't forget to document why questionnaires are rejected.

Physical measurement instruments

- Have the desired accuracy, measurement range and error been determined?
- Does the instrument satisfy these criteria?
- Has the instrument been calibrated and has its functioning been regularly checked?
- Has this been clearly recorded (in a logbook)?
- Is there a clear measurement protocol?
- Has the inter- or intra-observer reliability been determined?

Data Collection

- Are research assistants trained according to a training protocol?
- Is noted who has trained the assistants?
- Are problems and their solutions recorded in a logbook?
- Is the intra- and inter-observer reliability documented?

Data processing

- Is the reliability of the data entry checked by comparison of a (partial) double data entry?
- Are the raw data stored in a separate map and is a copy delivered to the research data management department?
- Is the data cleaning clearly documented (e.g. in a syntax)?
- Are cleaned data recognizable?
- Has the data transformation been documented (e.g. in a syntax)?
- Is ensured that transformations are reversible?
- For qualitative research: Has the coding process been well documented?

Analysis and Publication

- Has an analysis plan been created for each publication, including a clear research question?
- Are transformed or changed data files saved as a new file with a different name?
- Are the final versions of the publication, analysis plan, annotated syntax and data files used all stored together in one folder?

Finalizing

- Is all the documentation properly archived and/or handed over to the Principal Investigator?
- Logbooks, documentation of the analysis, and articles/reports handed over to the Principal investigator's?
- At the end of a study the researcher needs to properly archive all aspects of the study to meet requirements from relevant regulations and guidelines (e.g. AVG/GDPR, WMO, NFU guidelines) codes of conduct, and, where applicable, funder's requirements.