![EMGO+ Institute for Health and Care Research]

Mnemonic Documentation

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

Folder structure and File names

- ☐ Are folders and files accessible for all project members?
- ☐ Is the EMGO+ template used?
- ☐ Is a clear version numbering used in your file names?

Protocols, ethics, laws

- ☐ Are the reviews of the science committee and ethical committee properly archived?
- ☐ Are changes (amendementen) in the research protocol accorded by the Medical Ethical review Board (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 randomisation procedure written down, including possible changes?
- ☐ Are the arrangements with the independent person who performs the randomisation 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 data management department?
- ☐ Is the data cleaning clearly documented (e.g. in a syntax)?
- ☐ Are cleaned data recognisable?
- ☐ 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

- ☐ Are the following materials archived?
- ☐ Paper questionnaires in an archive room?
- ☐ Logbooks, documentation of the analysis, and the electronic version of articles/reports in the Principal investigator's possession?
- ☐ At the end of a study the researcher needs to provide the D&S department with a several items.

For more information, visit http://www.emgo.nl/kc