How to guide: Following protocols

A protocol is the description of everything which will take place within a research project.

- The protocol is the instruction manual for a research project.
- It should contain all of the things that you need to do.
- It is the reference guide for all activities which have been approved to take place.
- You should not undertake any activity not in the protocol.
- It should be kept up to date; when there are any changes, a new version of the protocol should be issued and an amendment submitted to approve the changes.

Full guide

Format

- The protocol is not always in a standard format – although the Health Research Authority (HRA) does recommend a template for CTIMPs and qualitative research: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/protocol/

Contents

- Participants must be fully informed and in a position to consent (having capacity to consent).

Keeping records

- The protocol should be kept in the site file.
- Superseded versions should be kept in the file but crossed through (or marked as superseded if kept electronically).
- Staff involved in the study must have access to the site file to enable them to refer to the protocol.

Glossary of Acronyms and Terms

HRA	Health Research Authority
CTIMP	Clinical Trial of an Investigational Medicinal Product