

SUB-STUDIES UNDERTAKEN WITHIN THE FRAMEWORK OF THE 45 AND UP STUDY

ROLES AND RESPONSIBILITIES

Sub-studies are projects that collect additional data from participants in the 45 and Up Study that are not part of follow-up or other activity of the Coordinating Centre. All sub-studies must adhere to the guidelines outlined in the 45 and Up Study Policy on Sub-studies.

Of particular note:

- Participation in sub-studies is voluntary. Informed consent to participate must be obtained for each sub-study.
- Invitations to participate in sub-studies will be forwarded by the Coordinating Centre. The names and contact details of 45 and Up Study participants will not be released to researchers without the participants' prior informed consent.
- All sub-study materials and the project protocol must be approved by the Coordinating Centre.
- Changes to the project protocol must be submitted to the Coordinating Centre as an amendment to an approved project.
- The roles and responsibilities of the Coordinating Centre and the researchers must be agreed at the outset and any changes should be agreed in writing. Changes may incur additional charges.

Role and responsibility of the researchers

The researchers own and are responsible for the project. They are responsible for ensuring the project is implemented according to the agreed protocol.

The researchers will:

- Assign a key contact within the team
- Produce a written document that outlines the project methods, including sample size required, sample selection requirements, expected response rate, numbers required to be invited, invitation methods, data collection methods etc
- Produce first drafts of all project materials, except for the invitation letter from the Coordinating Centre
- Sign off on project materials (content and design)
- Sign off on any approved quotes obtained on their behalf by the Coordinating Centre
- Ensure all purchasing meets the procurement guidelines for their institution
- Ensure approval has been granted for the use of any copyright or trademarked materials, including institutional logos
- Obtain ethical approvals as required for the project, including the project protocol and all project materials and any amendments thereof
- Be responsible for secure transfer and storage of data and any costs associated with this

Role and responsibility of the Coordinating Centre

The Coordinating Centre provides support and advice for project design and implementation. The Coordinating Centre is responsible for ensuring the project adheres to the Study's policies in relation to participant burden and confidentiality of data.

The Coordinating Centre will:

- Assign a key contact within the team
- Provide the researchers with advice on research methods to optimise the design of the project, response rates and quality of data collection
- Provide the researchers with examples of project materials
- Comment on project materials (5 day turnaround)
- Produce a first draft of the invitation letter from the Coordinating Centre
- Arrange for design of project materials if required
- Oversee invitations to participate in the project (email distribution, mail processing)
- Staff a Infoline to answer queries regarding the project
- Review consent from participants

Responsibility for obtaining quotes, for example for design, print or mail processing for the project, will be agreed at the project outset.