**Information on Qualitative Research Study Protocol Template – please read before starting**

This protocol template has been designed for qualitative clinical research studies that do not fall within the scope of the Medicines for Human use (Clinical Trials) Regulations 2004.

If you are unsure as to how to categorise your study, CTRG or R&D staff will be happy to advise you.

The template is available for use by all investigators who are carrying out clinical research studies sponsored by the University of Oxford if they so wish. However, there is no requirement to do so, provided that an alternative GCP-compliant protocol is used.

Note that some of the sections of this template may not apply to your study and may be deleted.

All advisory text and quotations from GCP are highlighted in yellow. These should all be deleted before finalising the document. All sample text is in ‘basic text’ style. This text of course will be altered or deleted as required while you produce the draft.

Repetition of information throughout the protocol is not necessary; it may be useful to cross-reference other sections of the protocol to avoid repetition.

Should you require any assistance, contact CTRG (University) as early as possible in the planning stage:

<http://www.admin.ox.ac.uk/researchsupport/ctrg/>

**Study Title:**  insert full title including brief reference to the design, disease or condition being studied, and primary objective

**Internal Reference Number / Short title:** This should be assigned by the investigator/department (may be deleted if not required)

**Ethics Ref:** Insert

**Date and Version No:** Insert

|  |  |
| --- | --- |
| **Chief Investigator:** | Insert name and contact details, including institutional affiliation |
| **Investigators:** | Insert names of key collaborators, including institutional affiliations |
| **Sponsor:** | University of Oxford/Oxford University Hospitals NHS Foundation Trust (Delete as appropriate) |
| **Funder:** | Insert details of organisation providing funding |
| **Chief Investigator Signature:** | The approved protocol should be signed by author(s) and/or person(s) authorised to sign the protocol |

Please declare any/no potential conflicts of interest.

**Confidentiality Statement**

This document contains confidential information that must not be disclosed to anyone other than the Sponsor, the Investigator Team, host organisation, and members of the Research Ethics Committee, HRA (where required) unless authorised to do so.

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# SYNOPSIS

It may be useful to include a brief synopsis of the study for quick reference. Complete information and, if required, add additional rows.

|  |  |  |
| --- | --- | --- |
| **Study Title** |  | |
| **Internal ref. no. / short title** |  | |
| **Study Design** |  | |
| **Study Participants** |  | |
| **Planned Sample Size** |  | |
| **Planned Study Period** |  | |
|  | **Objectives** | **Outcome Measures** |
| **Primary** |  |  |
| **Secondary** |  |  |

# ABBREVIATIONS

Define all unusual or ‘technical’ terms related to the project. Add or delete as appropriate to your study. Maintain alphabetical order for ease of reference.

|  |  |
| --- | --- |
| CI | Chief Investigator |
| CRF | Case Report Form |
| CTRG | Clinical Trials & Research Governance, University of Oxford |
| CUREC | Central University Research Ethics Committee |
| GCP | Good Clinical Practice |
| HRA | Health Research Authority |
| ICF | Informed Consent Form |
| NHS | National Health Service |
| NRES | National Research Ethics Service |
| PI | Principal Investigator |
| PIL | Participant/ Patient Information Leaflet |
| R&D | NHS Trust R&D Department |
| REC | Research Ethics Committee |
| SOP | Standard Operating Procedure |

# BACKGROUND AND RATIONALE

Include the following:

Brief background to the study, including justification for the research.

Outline of the main research questions.

Brief description of the intervention (if applicable).

Summary of findings from previous studies (if relevant) that potentially have significance. State any assumptions you are making, and any limitations to the project.

Summary of the known and potential risks and benefits, if any, to human participants.

Description of the population to be studied.

References to literature and data that are relevant to the study and that provide background for the study.

# AIM AND OBJECTIVES

Whereas clinical and other quantitative research is framed in terms of primary and secondary objectives with correlating outcome measures, qualitative work is usually organised according to its aims (overall purpose and research question) and objectives (questions or tasks to reach that aim).

The following is taken from <http://www.erm.ecs.soton.ac.uk/theme4/aims_and_objectives.html>

The wording of the aim and objectives should be clear, unambiguous and as specific as possible – the study will be judged on how, and how well, the objectives were satisfied. Complete table below with all relevant information.

|  |  |
| --- | --- |
| **Aim/Research Questions** | **Objectives** |
| Example:  To critically assess the relationship between the patient’s care within the NHS (by their care team) and outside the NHS (through mobile apps, online group support, voluntary sector services, etc). In other words, how do patients "transition" between different "modes" of service delivery? | Example:  Gather information about services used by patients Categorise and critically evaluate current points of connection or disjunction between services from view point of services and patients |
| **Secondary**  Example:  To explore how these "transitions" affect the work of the patients' care team | Example:  Survey/Interview care team workers about experiences of patient transitions. |

# STUDY DESIGN

Briefly describe the methodology and framework for your qualitative work, e.g., action research, grounded theory, interpretative phenomenological analysis or discourse analysis from published literature.

Explain why the approach proposed is appropriate to the aim/research questions

Describe processes for collecting data, and why this method will be used (e.g. questionnaire, interview schedule, observation schedule).

Give the expected duration of individual participation, number of visits/interviews or questionnaires, a description of the sequence and duration of all study periods e.g. screening, interview, review of transcripts, if applicable.

Include a flowchart for the project (here, or as an appendix), if appropriate.

# PARTICIPANT IDENTIFICATION

## Study Participants

Give an overall description of the study participants and sample size. It may not always be possible to estimate the size of a sample e.g. if you continue sampling until you reach saturation. In this case, describe how your sampling strategy will allow you to address your aim/research question.

Example:

X Participants with <<medical condition or particular experience >> of *xyz* severity and <<*other specific criteria, experience or expertise*> of <age range or other group definition>.

## Inclusion Criteria

Example criteria only (amend as appropriate):

* Participant is willing and able to give informed consent for participation in the study.
* Male or Female, aged 18 years or above.
* Diagnosed with required disease/severity/symptoms, or part of specific group to be studied
* Additional study specific criteria as required.

## Exclusion Criteria

Example criteria only (amend as appropriate):

The participant may not enter the study if ANY of the following apply:

* Specify any diseases/disorders/ conditions that would preclude entry into the study.
* Additional study specific criteria as required.

# STUDY ACTIVITIES

Add schedule of activities as an appendix, if appropriate.

## Recruitment

Describe how potential participants will be identified, approached, screened and recruited. Provide rationale for sampling strategy and how it accords with the methodological and theoretical framework for the study.

## Informed Consent

Specify who will take informed consent, how and when it will be taken. Informed Consent must be obtained prior to any study related activities being undertaken.

Example:

The \*participant must personally sign and date the latest approved version of the Informed Consent form before any study specific activities are undertaken.

Written and verbal versions of the Participant Information and Informed Consent will be presented to the participants detailing no less than: the exact nature of the study; what it will involve for the participant; the implications and constraints of the protocol; any risks involved in taking part. It will be clearly stated that the participant is free to withdraw from the study at any time for any reason without prejudice to future care, and with no obligation to give the reason for withdrawal.

The participant will be allowed as much time as wished to consider the information, and the opportunity to question the Investigator, their GP or other independent parties to decide whether they will participate in the study. Written Informed Consent will then be obtained by means of participant dated signature and dated signature of the person who presented and obtained the Informed Consent. The person who obtained the consent must be suitably qualified and experienced, and have been authorised to do so by the Chief/Principal Investigator. A copy of the signed Informed Consent will be given to the participant. The original signed form will be retained at the study site.

\*can be substituted parent/guardian or legally authorised representative, as appropriate, make sure that the term is consistent throughout the document.

## Screening and Eligibility Assessment

Specify the maximum duration allowed between screening and recruitment (if applicable).

Describe the screening procedures in detail (if relevant) such as demographics, medical history, questionnaires, mental capacity assessment.

## Subsequent Visits

**Clearly number these visits.** Specify when and where participants will be followed up and what further questionnaires, interviews or observations. Specify if they will take place in a clinic or research facility, by telephone, in a participant’s home or other. Add window periods if applicable.

## Discontinuation/Withdrawal of Participants from Study

Example:

Each participant has the right to withdraw from the study at any time. (In addition, the Investigator may discontinue a participant from the study at any time if the Investigator considers it necessary for any reason including:

delete/add as appropriate

* Ineligibility (either arising during the study or retrospectively having been overlooked at screening)
* Significant protocol deviation
* Significant non-compliance with study requirements
* Withdrawal of Consent
* Loss to follow up

State whether withdrawal from the study will result in exclusion of the data for that participant from analysis. In particular, consideration to audio recordings must be made. If an audio recording has already been transcribed and anonymised, would you be able to exclude their data? Where participants were part of a focus group, consider whether  an individual’s data impinges on/is directly related to that of other participants.

State whether or not withdrawn participants will be replaced.

The reason for withdrawal by researcher (and by participant, if this information is volunteered) will be recorded in a study file.

## Definition of End of Study

The definition of end of study must be provided. In most cases the end of study will be the date of the last visit of the last participant.

Example:

The end of study is the date of the last visit / telephone follow up / home visit of the last participant.

# ANALYSIS

The sub-headings given below are suggestions. Add/delete as appropriate.

## Description of Analytical Methods

Describe the methods to be employed, including timing of any planned interim analysis(es), and any statistics, if relevant.

## The Number of Participants

State the approximate number of participants required to complete (commence). This may be influenced by the quality of data, scope of the study (whether broad or in-depth) the nature of the topic, dstudy design and qualitative method (s). See Morse, J.M. (2000) “Determining Samples Size” *Qualitative Health Research* 10 (1), 3-5

## Data Analysis

Describe method of analysis for objectives (eg content analysis, constant comparative method, framework analysis, interpretive phenomenological analsyis) and how this is most appropriate for kind of data collected.

Include details as to what participant data will be used and any software proposed.

# DATA MANAGEMENT

## Access to Data

Direct access will be granted to authorised representatives from the Sponsor or host institution for monitoring and/or audit of the study to ensure compliance with regulations.

## Data Recording and Record Keeping

Describe method(s) of data collection, entry and management, including details of data management tools, etc. Describe where, and for how long, data will be retained. Ensure compliance with the relevant Sponsor organisation’s policy.

# QUALITY ASSURANCE PROCEDURES

Provide details of how data monitoring and other quality control measures will be performed.

Example:

The study may be monitored, or audited in accordance with the current approved protocol, GCP, relevant regulations and standard operating procedures.

# ETHICAL AND REGULATORY CONSIDERATIONS

Describe ethical considerations relating to the study. Include general and study specific ethical considerations.

Examples below:

## Declaration of Helsinki

The Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki. NB. The 2008 Declaration of Helsinki provides detail on what must be included in a protocol: funding, sponsorship, affiliations and potential conflicts of interest, incentives to participate and compensation for harm.

## Guidelines for Good Clinical Practice

The Investigator will ensure that this study is conducted in accordance with relevant regulations and with Good Clinical Practice.

## Approvals

Consider the following text:

The protocol, informed consent form, participant information sheet and any proposed advertising material will be submitted to an appropriate Research Ethics Committee (REC), HRA (where required), and host institution(s) for written approval.

The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

## Reporting

The CI shall submit once a year throughout the study, or on request, an Annual Progress report to the REC Committee, HRA (where required), host organisation and Sponsor. In addition, an End of Study notification and final report will be submitted to the same parties.

## Participant Confidentiality

Example:

The study staff will ensure that the participants’ anonymity is maintained. The participants will be identified only by a participant ID number on all trial documents and any electronic database, with the exception of the CRF, where participant initials may be added. All documents will be stored securely and only accessible by study staff and authorised personnel. The study will comply with the Data Protection Act, which requires data to be anonymised as soon as it is practical to do so.

## Expenses and Benefits

Detail all intended payments to participants and any other benefits (Declaration of Helsinki requirement).

Example:

Reasonable travel expenses for any visits additional to normal care will be reimbursed on production of receipts, or a mileage allowance provided as appropriate.

## Other Ethical Considerations

Include any other ethical considerations specific to the study e.g. involvement of vulnerable participants, or participants who are unable to consent for themselves; possibility of criminal disclosure or issues of safeguarding.

# FINANCE AND INSURANCE

## Funding

Describe financing arrangements.

## Insurance

Describe insurance arrangements (include the following statement):

The University of Oxford maintains Public Liability and Professional Liability insurance which will operate in this respect.

# PUBLICATION POLICY

The publication policy should cover authorship, acknowledgements, and review procedures for scientific publications. If there is a department or institution policy, or agreement, the protocol can refer to it. Ensure that the publication policy stated here is consistent with any contract applicable to the study. Consider describing how study results may be disseminated to study participants.

Example:

The Investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authors will acknowledge that the study was funded by < >. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged.

# REFERENCES

Insert references used in text (preferably in alphabetical order of first author).

# APPENDIX A: STUDY FLOW CHART

Optional

# APPENDIX C: AMENDMENT HISTORY

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Amendment No.** | **Protocol Version No.** | **Date issued** | **Author(s) of changes** | **Details of Changes made** |
|  |  |  |  |  |

List details of all protocol amendments here whenever a new version of the protocol is produced. This is not necessary prior to initial REC submission.