Planning a New Qualitative Study with Children, Young People and Families

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Planning a New Qualitative Study with Children, Young People and Families

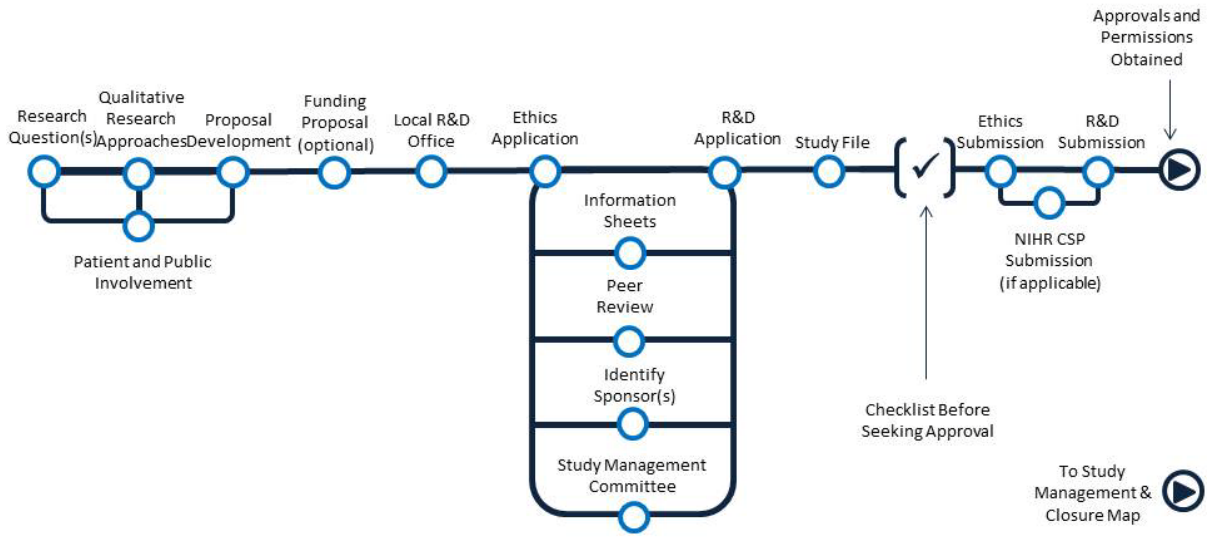
Is this map for you?

This is a map that gives pointers and details on how to develop and undertake a research study using qualitative methods. While it will be helpful to all qualitative researchers, it has a particular focus on health related research with children and young people.

When undertaking a research study using qualitative methods there is a need to be flexible and responsive as a researcher; however, there are identifiable stages that should be considered when developing a qualitative research project. The stages are best understood as individual stations in a map that follow the research process. See the map below.

Note: Preparing all of the necessary documentation and gaining ethical approval and research governance approval can take three months or more. While procedures are in place to streamline the process of gaining National Health Service (NHS) ethics and research and development (R&D) approvals on the Integrated Research Application System (IRAS) website (https://www.myresearchproject.org.uk/), it is advised that researchers start speaking with the relevant R&D departments very early on in the research process.

MAP 1: PLANNING A NEW QUALITATIVE STUDY



Stations

Station	MAP VIEW NAME	LIST VIEW NAME
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12.	R&D APPLICATION	PREPARING YOUR RESEARCH AND DEVELOPMENT (R&D) APPLICATION
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17.	R&D SUBMISSION	SUBMITTING YOUR R&D APPLICATION
18.	APPROVALS AND PERMISSIONS OBTAINED	APPROVALS AND PERMISSIONS OBTAINED
19.	GO TO STUDY MANAGEMENT AND CLOSURE MAP	GO TO STUDY MANAGEMENT AND CLOSURE MAP

STATION 1: CREATING RESEARCH QUESTIONS

A research question is a statement about the main issues that the researcher will explore during the research process. Studies can have one or more guiding questions. The question(s) will provide you with focus for your study, but may change as you start shaping your research proposal or reviewing the literature. Your research question(s) will have a significant influence on the research design and aim(s) of the study.

In order to shape your research question(s), you will need to know what other researchers have already examined in the area so that your study is relevant and important.

RESOURCES

- **List of qualitative research question references**
  Some relevant reference materials to help write your research question.
  Stations this resource found in: Research Question(s)

STATION 1: CREATING RESEARCH QUESTIONS

Open-access articles

Agee J. (2009) Developing qualitative research questions: a reflective process. *International Journal of Qualitative Studies in Education.* 22(4): 431-447. http://www.tandfonline.com/doi/abs/10.1080/09518390902736512

Bufkin A. (2006) Qualitative Studies: Developing Good Research Questions. *ERIC.* http://www.eric.ed.gov:80/ERICWebPortal/search/detailmini.jsp?_nfpb=true&_&ERICExtSearch_SearchValue_0=ED494335&ERICExtSearch_SearchType_0=no&accno=ED494335

Articles that require subscriptions

Law R. (2005) From research topic to research question: a challenging process. *Nurse Researcher.* 11 (4): 54-66.

Books

Creswell JW. (2003) *Research design: Qualitative, quantitative, and mixed method approaches.* Thousand Oaks, CA: Sage Publications.

Holloway I, Wheeler S. (2010) Qualitative Research in Nursing and Healthcare, 3rd ed. Oxford: Wiley-Blackwell.

- **RD Info research process flow chart** http://www.rdinfo.org.uk/flowchart/flowchart.html
  Useful information for all research projects.
  Stations this resource found in: Research Question(s)

- **Research Ethics Guidebook** http://www.ethicsguidebook.ac.uk/
  A resource for social scientists that describes how to write your research proposal (and gives guidance on the research process).

Stations this resource found in: Research Question(s), Proposal Development, Funding Proposal, Ethics Application, Approvals and Permissions Obtained

- **List of open access journals** http://www.doaj.org/
  Use the Directory of Open Access Journals (DOAJ) to search for journals that do not require a subscription to read their full-length articles (e.g. BMC Nursing). Browse by category to find journals related to nursing, medicine and public health.
  Stations this resource found in: Research Question(s)

- **NHS Evidence** https://www.evidence.nhs.uk/nhs-evidence-content/journals-and-databases
  An online source for journals and databases that you can search with an NHS Athens account.
  Stations this resource found in: Research Question(s)

STATION 2: INVOLVING PATIENTS AND THE PUBLIC IN YOUR RESEARCH

It is good practice to involve potential participants of your study in your study design. This is called Patient and Public Involvement (PPI) or Patient Focus and Public Involvement (PFPI) in Scotland. Below you will find information links that describe PPI and why it is important to research.

For ethics review and for most public funding bodies it is essential to demonstrate how PPI has informed the study, or clear justification of why this has not happened.

- **INVOLVE** www.invo.org.uk
  Information and resources on patient and public involvement in research, including how to get people involved in your research and how much to compensate them for their time if you have a budget to do so.
  Stations this resource found in: Patient and Public Involvement

- **Patient and Public Involvement Explained**
  http://www.rds-yh.nihr.ac.uk/patient-and-public-involvement.aspx
  The Research Design Service describes PPI and provides useful links to organisations involved in improving PPI in research.
  Stations this resource found in: Patient and Public Involvement

- **Why PPI?** http://www.nihr.ac.uk/awareness/Pages/default.aspx
  NIHR details the reasons it believes PPI is important in research.
  Stations this resource found in: Patient and Public Involvement

STATION 3: CHOOSING QUALITATIVE RESEARCH APPROACHES

You may find the documents and links below helpful in understanding the differences in qualitative approaches in research. This station provides resources that may help you to choose the following: a research paradigm, a research tradition, data collection methods, and analysis methods.

RESOURCES

- **List of qualitative study references**
  A list of relevant reference materials to help with choosing a research approach (and a data collection method) for your study. The list includes open-access articles, articles that require institutional passwords, and books.

Stations this resource found in: Qualitative Research Approaches, Proposal Development

Resource 3a

STATION 3: CHOOSING QUALITATIVE RESEARCH APPROACHES

Open access articles

Broad descriptions of qualitative research approaches

Frankel RM, Devers KJ. (2000) Study design in qualitative research—1: Developing questions and assessing resource needs. *Education for Health.* 13: 251-261. http://drhornsby.com/uop/QNT%20575/week%201/readings/study%20design%20in%20qual%20research%20-%201.pdf

Griffiths F. (1996) A summary of the panel discussion at the conference 'Exploring qualitative research in general practice'. *Family Practice*. 13(1): S27-S30. http://fampra.oxfordjournals.org/content/13/supp1/27.full.pdf

Kuper A, Lingard L, Levinson W. (2008) Critically appraising qualitative research. *British Medical Journal*. 337: a1035. http://www.bmj.com/content/337/bmj.a1035

Kuper A, Reeves S, Levinson W. (2008) An introduction to reading and appraising qualitative research. *British Medical Journal.* 337: a288. http://www.bmj.com/content/337/bmj.a288

Ploeg J. (1999) Identifying the best research design to fit the question. Part 2: qualitative designs. *Evidence-Based Nursing*. 2: 36-37. http://ebn.bmj.com/content/2/2/36.full

Reeves S, Albert M, Kuper A, Hodges BD. (2008) Why use theories in qualitative research? *British Medical Journal*. 337: a949. http://www.bmj.com/content/337/bmj.a949

Articles that focus on particular approaches or data collection methods

Action Research
Meyer J. (2000) Using qualitative methods in health related action research. *British Medical Journal*. http://www.bmj.com/content/320/7228/178.1.full

Case Studies
Flyvberg B. (2006) Five misunderstandings about case study research. *Qualitative Inquiry*. 12(2): 219-245. http://qix.sagepub.com/content/12/2/219.short

Discourse Analysis
Hodges BD, Kuper A, Reeves S. (2008) Discourse Analysis. *British Medical Journal*. 337: a879. http://www.bmj.com/content/337/bmj.a879

Ethnography
Reeves S, Kuper A, Hodges BD. (2008) Qualitative research methodologies: ethnography. *British Medical Journal*. 337:a1020. http://www.bmj.com/content/337/bmj.a1020

Focus-group Interviews (and their analysis)

Gibbs A. (1997) Focus Groups. Social Research Update, Issue 19, University of Surrey. http://sru.soc.surrey.ac.uk/SRU19.html

Grounded Theory
Lingard L, Albert M, Levinson W. (2008) Grounded theory, mixed methods, and action research. *British Medical Journal*. 337: 39602.690162.47
http://www.bmj.com/content/337/bmj.39602.690162.47

Interpretative Phenomenological Approach
Fade S. (2004) Using interpretive phenomenological analysis for public health nutrition and dietetic research: a practical guide. *Proceedings of the Nutrition Society.* 63: 647-653.
http://www.columbia.edu/~mvp19/RMC/M5/QualPhen.pdf

Online Research
Elgesem D (nd) What is special about the ethical issues in online research? Available at:
http://www.nyu.edu/projects/nissenbaum/ethics_elg_full.html

Sample size calculations
Baker SE, Edwards R. (2012) *How many qualitative interviews is enough*. Discussion Paper. National Centre for Research Methods. http://eprints.ncrm.ac.uk/2273/

Serial Interviews
Murray SA, Kendall M, Carduff E, Worth A, Harris FM, Lloyd A, Cavers D, Grant L, Sheikh A. (2009) *British Medical Journal*. 339: b3702. http://www.bmj.com/content/339/bmj.b3702

Specialised Texts (Qualitative research in Africa)
Department of International Health, Johns Hopkins University. (2000) *Qualitative research for improved health programs: a guide to manuals for qualitative and participatory research on child health, nutrition and reproductive health*. Washington, DC: US Agency for International Development.
http://sara.aed.org/publications/cross_cutting/qualitative/qualitative.pdf

Articles that require subscriptions

Starks H, Trinidad SB. (2007) Choose Your Method: A Comparison of Phenomenology, Discourse Analysis, and Grounded Theory. *Qualitative Health Research.* 17(10): 1372-1380.

Books

Charmaz K. (2006) *Constructing grounded theory: a practical guide through qualitative analysis*.
London: Sage.

Crabtree BF, Miller WL. (1992) *Doing Qualitative Research. Research Methods for Primary Care,* Volume 3. Newbury Park, CA: Sage.

Denzin NK, Lincoln YS. (1994) *Handbook of Qualitative Research*. Thousand Oaks, CA: Sage.

Green J, Thorogood N. (2009) *Qualitative methods for health research,* 2nd Edition. London, Sage.

Holliday AR. (2007) *Doing and Writing Qualitative Research,* 2nd Edition. London: Sage.

Holloway I. (2008) *A-Z of qualitative research in healthcare*, 2nd Edition. Oxford: Wiley-Blackwell.

King N, Horrocks C. (2010) *Interviews in Qualitative Research.* London: Sage.

Miles MB, Huberman AM. (1994) *Qualitative data analysis: An expanded sourcebook,* 2nd Edition. Thousand Oaks, CA: Sage.

Patton MQ. (1990) Qualitative Evaluation and Research Methods, 2nd Edition. Newbury Park, CA: Sage.

Books with a focus on mental health

Fischer CT. (2005) *Qualitative research methods for psychologists: Introduction through empirical studies.* Academic Press.

Harper D, Thompson AR. (2011) *Qualitative Research Methods in Mental Health and Psychotherapy: A Guide for Students and Practitioners.* West Sussex, UK: John Wiley and Sons.

- **Qualitative Studies** http://www-fhs.mcmaster.ca/rehab/ebp/pdf/qualguidelines.pdf
  A document that summarises research approaches and data collection methods written as guidelines for critical review of qualitative research.
  Stations this resource found in: Qualitative Research Approaches, Peer Review

- **Brief overview of qualitative research**
  http://nursingplanet.com/research/qualitative_research.html
  Nursing Research Journal webpage on qualitative research approaches used in nursing.
  Stations this resource found in: Qualitative Research Approaches

- **Research paradigms** http://www.qualres.org/HomePhil-3514.html
  Common research paradigms detailed by the Robert Wood Johnson Foundation.
  Stations this resource found in: Qualitative Research Approaches

- **Research traditions/approaches** http://www.qualres.org/HomeComm-3582.html
  Common research traditions detailed by the Robert Wood Johnson Foundation.
  Stations this resource found in: Qualitative Research Approaches

- **Data collection methods** http://www.qualres.org/HomeExem-4288.html
  A list of references for particular data collection methods (e.g. interviewing, focus groups, observation, mixed methods) detailed by the Robert Wood Johnson Foundation.
  Stations this resource found in: Qualitative Research Approaches

- **Common pitfalls** http://www.qualres.org/HomeComm-3869.html
  Common pitfalls in qualitative research detailed by the Robert Wood Johnson Foundation.
  Stations this resource found in: Qualitative Research Approaches

- **Ensuring rigour** http://www.qualres.org/HomeEval-3664.html
  Guidelines for ensuring rigour in your qualitative study.
  Stations this resource found in: Qualitative Research Approaches, Peer Review

- **Reference list of studies that have involved children**
  A list of relevant reference materials for research that involves children. The list includes open-access articles, articles that require institutional passwords, and books.
  Stations this resource found in: Qualitative Research Approaches

Resource 3b

STATION 3: CHOOSING QUALITATIVE RESEARCH APPROACHES

Articles that require subscriptions

Research methods used with child participants

Darbyshire P, MacDougall C, Schiller W. (2005) Multiple methods in qualitative research with children: more insight or just more? *Qualitative Research*. 5(4): 417-436.

Fargas-Malet M, McSherry D, Larkin E, Robinson C. (2010) Research with children: methodological issues and innovative techniques. *Journal of Early Childhood Research*. 8(2): 175-192.

Gibson F. (2007) Conducting focus groups with children and young people: strategies for success. *Journal of Research in Nursing*. 12(5): 473-483.

Children as co-researchers

Bergmark U, Kostenius C. (2009) Listen to me when I have something to say: students' participation in research for sustainable school improvement. *Improving Schools*. 12(3): 249-260.

Coad J, Coad N (2008) Children and young people's preference of thematic design and colour for their hospital environment. *Journal of Child Health Care*. 12(1): 33-48.

Lundy L, McEvoy L. (2011) Children's rights and research processes: assisting children to (in)formed views. *Childhood*. doi: 10.1177/0907568211409078.

Lundy L, McEvoy L & Byrne B (2011) Working with young children as co-researchers: an approach informed by the United Nations Convention on the Rights of the Child. *Early Education & Development*. 22(5): 714-736.

Turtle K, McElearney A, Scott J. (2010) Involving Children in the Design and Development of research instruments and data collection procedures: a case study in primary schools in Northern Ireland. *Child Care in Practice*. 16(1): 57-82.

Research with children with disabilities

Beresford B, Tozer R, Rabiee P, Sloper P. (2004) Developing an approach to involving children with autistic spectrum disorders in a social care research project. *British Journal of Learning Disabilities.* 32: 180-185.

Germain R. (2004) An exploratory study using cameras and talking mats to access the views of young people with learning disabilities on their out-of-school activities. *British Journal of Learning Disabilities.* 32: 170-174.

Lewis J & Porter J. (2004) Interviewing children and young people with learning disabilities: guidelines for researchers and multi-professional practice. *British Journal of Learning Disabilities.* 32: 191-197.

Lightfoot J & Sloper P. (2006) Having a say in health: involving young people with a chronic illness of physically disability in local health services development. *Children & Society*. 17(4): 277-290.

Morris J. (1998) *Don't leave us out: Involving children and young people with communication impairments*. Joseph Rowntree Foundation: York.

Rabiee P, Sloper P, Beresford B. (2005) Doing research with children and young people who do not use speech for communication. *Children & Society*. 19(5):385-396.

Ward L. (1997) *Seen and heard: Involving disabled children and young people in research and development projects*. Joseph Rowntree Foundation: York.

Books

Tisdall EKM, Davis JM, Gallagher M. (2009) *Researching with children and young people: research design, methods and analysis*. London: Sage.

STATION 4: DEVELOPING A RESEARCH PROPOSAL

A proposal (also referred to as a protocol) is required for ethics review (NHS and/or University) and research and development approval. Your proposal should display a version number that changes as aspects of the study develop or change. Unlike medical research trials there are no strict UK regulations that describe what your qualitative research proposal should include. It is good practice however to include information about the background of the study, aims of the study, methods (research design, sample, sampling, recruitment, informed consent, data collection and analysis methods), project management, ethical considerations and approvals, costings, possible implications of the study, a study timeline, and references. You may want to visit the Recruitment and Consent station to begin thinking about how to write about these aspects of your proposal. The proposal will take time to finalise, allow sufficient time if funding or approval deadlines are relevant.

It can be helpful to review guidelines on how to report qualitative research while writing your research proposal in order to better understand the details that are important. It is argued that all research should be methodologically sound because if not, it imposes an unjustifiable burden on participants and/or can imply outcomes that are not justified. For these reasons,

you should have as many colleagues and supervisors comment on your proposal as possible. See the EQUATOR and COREQ guidelines below.

RESOURCES

Resources on the Ethics of Conducting Research with Children and Young People

- **National Society for the Prevention of Cruelty to Children (NSPCC) Ethical Issues in Research with Children**
  http://www.nspcc.org.uk/Inform/research/reading_lists/ethical_issues_in_research_with_children_wda55732.html
  A reading list that provides numerous references (books, articles, web resources) for learning about ethical issues related to research with children.
  Stations this resource found in: Proposal Development

- **The Ethics of Social Research with Children: Practical Experiences**
  http://www.younglives.org.uk/our-publications/working-papers/the-ethics-of-social-research-with-children-and-families-in-young-lives-practical-experiences
  A working paper for Young Lives that is particularly useful for researchers looking to better understand the ethics of research with children.
  Stations this resource found in: Proposal Development

- **Research Ethics Guidebook** http://www.ethicsguidebook.ac.uk/Research-with-children-299
  A reading list that provides numerous references for learning about ethical issues in research with children.
  Stations this resource found in: Research Question(s), Proposal Development, Funding Proposal, Ethics Application, Approvals and Permissions Obtained

General Resources

- **Guidelines on writing a research proposal (not specifically qualitative)**
  http://projects.exeter.ac.uk/prdsu/helpsheets/Helpsheet08-Feb03-Unlocked.pdf
  A help sheet written by Peninsula Research and Development Support Unit.
  Stations this resource found in: Proposal Development

- **Writing a proposal** http://www.meaning.ca/archives/archive/art_how_to_write_P_Wong.htm
  A webpage of guidance on how to write a research proposal.
  Stations this resource found in: Proposal Development

- **Research Ethics Guidebook** http://www.ethicsguidebook.ac.uk/
  A resource for social scientists that details how to write your research proposal (and gives guidance on the research process). See the 'Writing your proposal' section.
  Stations this resource found in: Research Question(s), Proposal Development, Funding Proposal, Ethics Application, Approvals and Permissions Obtained

- **EQUATOR guidelines**
  http://www.equator-network.org/resource-centre/library-of-health-research-reporting/reporting-guidelines/qualitative-research/
  Guidelines for reporting qualitative research detailed by the EQUATOR Network (with links to helpful open access articles).
  Stations this resource found in: Proposal Development

- **COREQ Guidelines** http://intqhc.oxfordjournals.org/content/19/6/349.abstract
  Guidelines for reporting qualitative research called the 'Consolidated Criteria for Reporting Qualitative Research' (COREQ).
  Stations this resource found in: Proposal Development

- **List of qualitative study references**
  A list of relevant reference materials to help with choosing a research approach for your study. The list includes open-access articles, articles that require institutional passwords, and books.
  Stations this resource found in: Qualitative Research Approaches, Proposal Development

- **Reference list of studies that have involved children and disabled children**
  A list of relevant reference materials for research that involves children. The list includes open-access articles, articles that require institutional passwords, and books.
  Stations this resource found in: Qualitative Research Approaches, Proposal Development

STATION 5: WRITING A FUNDING PROPOSAL

Not all research is specifically funded. This station only needs to be considered if you are applying for funding for your research study.

If you are writing a proposal for funding it can be written in parallel to the development of the research proposal. The funding proposal can often even be used as a start-off point for your research proposal. Funding bodies may also have specific guidance about how to structure your proposal. The resources below give information on the structure of a proposal for funding, as well as possible areas of funding.

RESOURCES

Application Guidance

- **Writing a qualitative funding proposal** http://vchri.ca/i/pdf/WritingQualitative.pdf
  A slideshow on 'how to write a research proposal with aims of getting it funded' produced by Joan L Bottorff at University of British Columbia.
  Stations this resource found in: Funding Proposal

- **Research Ethics Guidebook** http://www.ethicsguidebook.ac.uk/
  A resource for social scientists that details how to write your research proposal (and gives guidance on the research process). See the 'Research Topics and Funders' section.
  Stations this resource found in: Research Question(s), Proposal Development, Funding Proposal, Ethics Application, Approvals and Permissions Obtained

- **NIHR Research Design Service (RDS)** http://www.ccf.nihr.ac.uk/Pages/RDSMap.aspx
  The RDS website where you can see details about how the RDS helps researchers prepare for NIHR applications.
  Stations this resource found in: Funding Proposal

- **Medical Research Council (MRC) Assessment Procedure for Research Grant Applications**
  http://www.mrc.ac.uk/Fundingopportunities/Applicanthandbook/Grantcalls/Assessmentprocedure/index.htm

Medical Research Council guidance on their criteria for evaluating research grant applications. This is useful information regardless of which funding body you are applying to.
Stations this resource found in: Funding Proposal

Sources of Funding

- **RDFunding** http://www.rdfunding.org.uk/queries/ListCharities.asp?type=NA
  A list of grants available to researchers on the RD Funding website.
  Stations this resource found in: Funding Proposal

- **National Institute for Health Research (NIHR) Research Programmes**
  http://www.nihr.ac.uk/research/Pages/programmes_research_programmes.aspx
  A webpage listing all National Institute of Health Research funded research programmes.
  Stations this resource found in: Funding Proposal

- **National Institute for Health Research (NIHR) Fellowships (England)**
  http://www.nihrtcc.nhs.uk/nihrfellow/
  National Institute of Health Research website with a list of fellowships and deadlines.
  Stations this resource found in: Funding Proposal

- **National Institute for Health Research (NIHR) Fellowships (Northern Ireland, Scotland, Wales)**
  http://www.nihrtcc.nhs.uk/nihrfellow/devolvedadministration
  National Institute of Health Research funding details for devolved administration applicants.
  Stations this resource found in: Funding Proposal

STATION 6: CONSULTING YOUR LOCAL RESEARCH AND DEVELOPMENT (R&D) OFFICE

It will be necessary that you contact your local research and development (R&D) office to determine its registration and approval requirements for qualitative research. You will likely need to complete an application form and submit documentation including your research proposal. The application may require signatures from senior managers within your department. Be aware that the documentation and approval requirements might differ from one local office to another.

The local R&D office can also be of assistance with a number of issues, including:

- Determining who the sponsor(s) of your study should be;
- Detailing your occupational health clearance requirements (if necessary);
- Ordering your Criminal Records Bureau (CRB) check (if necessary);
  - It is advised that you speak to your R&D office about this early on in your research, as it often takes one month or more for your CRB to arrive.
- Organising the approval of your research passport.

If your study requires you to gain further approvals via the NHS/University Research Ethics Committee process, you are required to update your local R&D office about all study-related activity.

RESOURCES

- **Institutional Requirements** http://www.ethicsguidebook.ac.uk/Institutional-requirements-77

Guidance on who to speak with about ethics procedures.
Stations this resource found in: Local R&D Office

- **Information on the Criminal Records Bureau Check**
  http://www.direct.gov.uk/en/Employment/Startinganewjob/DG_195809
  Information about who needs a CRB generally and who can request them from the Direct.Gov webpage.
  Stations this resource found in: Local R&D Office

- **Criminal Records Bureau**
  http://www.homeoffice.gov.uk/agencies-public-bodies/crb/
  Information on application guidance and online tracking of your application.
  Stations this resource found in: Local R&D Office

- **Disclosure Scotland** http://www.disclosurescotland.co.uk/
  Information on application guidance in Scotland.
  Stations this resource found in: Local R&D Office

- **Research Passports**
  http://www.nihr.ac.uk/systems/Pages/systems_research_passports.aspx
  The Research in the NHS - Human Resource (HR) Good Practice Resource Pack describes the Research Passport system.
  Stations this resource found in: Local R&D Office, R&D Application, R&D Submission

STATION 7: PREPARING YOUR ETHICS APPLICATION

Check whether you study requires ethical approval (NHS and/or University) using the following NHS link http://www.nres.nhs.uk/applications/approval-requirements/ethical-review-requirements/ and, if not required for the NHS, you should contact your academic institution for guidance (where applicable).

Your NHS Trust or university ethical approval (local approval)

It is advised to start speaking to the research and development (R&D) office or department in your academic institution or NHS Trust as soon as possible, especially if uncertain about ethics approval requirements. If you are a researcher within an academic institution, you may need ethical review or approval from the University research ethics committee prior to submission to the NHS. See the station Consulting your Local R&D Office for more information.

Please note that studies involving only NHS staff as research participants are no longer automatically required to undergo the NHS ethical approval process. This type of a study will only need approval from the institution where the research will be conducted.

NHS Research Ethics Committee (NHS REC) approval

If your study requires recruitment of participants by virtue of their use of the NHS (e.g. patients or carers) you will be required to go through the NHS ethical approval process. There are a number of resources below that can help you navigate the process. When your study gains NHS ethical approval, it is generally a requirement that you update your academic

institution's ethics committee, regardless of preceding approval processes.

The Integrated Research Application System (IRAS) form must be used to apply for NHS Research Ethics Committee (REC) approvals in England, Northern Ireland, Scotland and Wales. IRAS is a single system for applying for the NHS R&D, NHS REC, and other permissions and approvals for health and social/community research in the UK. It streamlines the process so you enter details for a single project in one coordinated application form. See the R&D Application station for more information. Access IRAS here and for further guidance regarding the application process; please visit the IRAS website or brochure.

There is a proportionate review option for research studies that contain 'no material ethical issues' (i.e. there is minimal risk, burden or intrusion for the participants). These studies can be reviewed and approved by a proportionate review sub-committee on behalf of the NHS REC. The aim of proportionate review is for studies which present minimal risk or burden for participants to be reviewed within 14 days of receipt of a valid application.

Furthermore, studies that involve the secondary use of information previously collected in the processes of normal care are generally excluded from NHS REC review. This is only if patients and/or service users are not identifiable to the research team.

RESOURCES

General Ethical Approval

- **Ethics Principles** http://www.ethicsguidebook.ac.uk/EthicsPrinciples
  An online tool that outlines the six principles in the ESRC Framework for Research Ethics.
  Stations this resource found in: Ethics Application, Ethics Submission

- **Research Ethics Guidebook** http://www.ethicsguidebook.ac.uk/
  A resource for social scientists. See the 'Applying for ethics approval' section.
  Stations this resource found in: Research Question(s), Proposal Development, Funding Proposal, Ethics Application, Approvals and Permissions Obtained

- **EQUATOR guidance** http://www.equator-network.org/resource-centre/library-of-health-research-reporting/research-ethics-publication-ethics-and-good-practice-guidelines/#etguid
  International guide on research ethics, publication ethics and good practice guidelines and resources suggested by the EQUATOR Network.
  Stations this resource found in: Ethics Application, Ethics Submission

- **Secondary Research** http://www.lancs.ac.uk/researchethics/6-1-secdata.html
  Guidance on the ethical considerations for secondary data sources.
  Stations this resource found in: Ethics Application, Ethics Submission

- **Web-based Research** http://www.lancs.ac.uk/researchethics/7-1-webres.html
  Guidance on the ethical considerations for web-based research studies.
  Stations this resource found in: Ethics Application, Ethics Submission

- **List of references**
  A list of relevant reference materials to help with understanding the ethical considerations of qualitative research. The list includes open-access articles, articles that require institutional passwords, and books.
  Stations this resource found in: Ethics Application, Ethics Submission

Resource 7a

STATION 7: PREPARING AND REGISTERING FOR YOUR ETHICS APPROVAL

Open access articles

Grinyer A. (2002) The anonymity of research participants: assumptions, ethics and practicalities. *Social Research Update*. 36. http://sru.soc.surrey.ac.uk/SRU36.html

Orb A, Eisenhauer L, Wynaden D. (2000) Ethics in qualitative research. *Journal of Nursing Scholarship*. 33(1): 93-96. http://www.columbia.edu/~mvp19/RMC/M5/QualEthics.pdf

Ramcharan P, Cutcliff JR. (2001) Judging the ethics of qualitative research: considering the 'ethics as process' model. *Health and Social Care in the Community*. 9(6): 358-366. http://www.sanpad.org.za/portal/images/databases/policybriefs/ethics%20of%20qualit%20research%20-%20lecture%201.pdf

Articles that require subscriptions

Head E. (2009) The Ethics and Implications of Paying Participants in Qualitative Research. *International Journal of Social Research Methodology*. 12(4): 1464-5300.

Richards HM, Schwartz LJ. (2002) Ethics of qualitative research: are there special issues for health services research? *Family Practice*. 19(2): 135-139.
Tilley L, Woodthorpe K. (2011) Is it the end for anonymity as we know it? A critical examination of the ethical principle of anonymity in the context of twenty first century demands on the qualitative researcher. *Qualitative Research*. 11(2): 197–212.

Books

Mauthner M, Birch M, Jessop J, Miller T. (2002) *Ethics in qualitative research*. London: Sage.

Ethics Considerations for Research with Children and Young People

- **National Society for the Prevention of Cruelty to Children (NSPCC) legal definition of a child**
  http://www.nspcc.org.uk/Inform/research/questions/definition_of_a_child_wda59396.html
  The details of the laws associated with child protection, age of consent, etc.
  Stations this resource found in: Ethics Application, Ethics Submission

- **List of references**
  A list of relevant reference materials to help with understanding the ethical considerations of research with CYPs. The list includes open-access articles, articles that require institutional passwords, and books.

Stations this resource found in: Ethics Application, Ethics Submission

Resource 7b

STATION 7: PREPARING AND REGISTERING FOR YOUR ETHICAL APPROVAL APPLICATION

Articles that require subscriptions

Hadjiconstantinou M, Forbat L. (2012) Understanding and securing ethical permissions to conduct paediatric research across the UK. *Nursing Children and Young People.* 24(1): 22-25.

Wendler D, Rachoff J, Emanuel E, Grady G. (2002) Commentary: the ethics of paying for children's participation in research. *Journal of Pediatrics.* 141(2): 166-171.

Books

Alderson P, Morrow V. (2011) *The ethics of research with children and young people: A practical handbook*. London: Sage.

NHS Research Ethics Committee (NHS REC) Approval

- **Integrated Research Application System (IRAS)**
  https://www.myresearchproject.org.uk
  The link that takes you to the Integrated Research Application System for research in the NHS.
  Stations this resource found in: Ethics Application, R&D Application, Ethics Submission, R&D Submission

- **Integrated Research Application System (IRAS) Training Portal**
  https://www.myresearchproject.org.uk/ELearning/IRAS_E_learning.htm
  A one-hour training module that will provide interactive sessions on how to complete the required forms. Training is applicable to all researchers, not specifically qualitative researchers.
  Stations this resource found in: Ethics Application, Ethics Submission, R&D Application

- **National Research Ethics Service (NRES)** http://www.nres.nhs.uk/applications/
  The National Research Ethics Service (NRES) website is essential to explore throughout the research process.
  Stations this resource found in: Ethics Application, Ethics Submission, R&D Application

- **Proportionate Review** http://www.nres.nhs.uk/applications/proportionate-review/
  A National Research Ethics Service (NRES) webpage that describes the proportionate review process.
  Stations this resource found in: Ethics Application, Ethics Submission

STATION 8: CREATING STUDY INFORMATION SHEETS FOR YOUR RESEARCH PARTICIPANTS

You will need to create a number of important documents for your research study to ensure that participants fully understand what your study is about and what their involvement would

entail. Each different type of participant (e.g. child, parent, health professional, etc.) in your study will require tailored information and consent forms pitched at an appropriate reading level. Depending on your participants you may need to create several variations of the same form.

The forms most often required of researchers include:

- Consent forms (written confirmation that participants understand the purpose of research, the risks and benefits, the voluntary nature of participation);
- Letters of invitation (written invitation to participants to join the study from the chief investigator); and
- Study information sheets (also known as patient/participant information sheet or PIs are written information about the study for participants that details the purpose of research and their involvement, the risks and benefits).

RESOURCES

General

- **Reference list of articles that discuss information sheets**
  A list of relevant reference materials for academic articles and web resources that discuss information sheets. The list includes open-access articles, articles that require institutional passwords, and books.
  Stations this resource found in: Information Sheets

Resource8

STATION 8: CREATING STUDY INFORMATION SHEETS FOR YOUR PARTICIPANTS

Open access articles

Moult B, Franck LS, Brady H. (2004) Ensuring quality information for patients: development and preliminary validation of a new instrument to improve the quality of written health care information. *Health Expectations*. 7: 165-175.

Books

Alderson P, Morrow V (2011) *The ethics of research with children and young people: A practical handbook*. London: Sage.

- **Informed Consent** http://www.nres.nhs.uk/applications/guidance/consent-guidance-and-forms/
  National Research Ethics Service (NRES) guidance on writing participant information sheets and consent forms.
  Stations this resource found in: Information Sheets

- **Informed Consent** http://www.lancs.ac.uk/researchethics/1-3-infcons.html
  The key issues of consent outlined on one helpful webpage.
  Stations this resource found in: Information Sheets

Example Information Sheets

- **Sample Information Sheets** http://www.lancs.ac.uk/researchethics/1-4-samples.html
  A sample of various information sheets and consent forms used in previous research at Lancaster University.
  Stations this resource found in: Information Sheets

- **Example Information Sheet for Parents (The Care Pathways and Outcomes Study)**
  http://www.qub.ac.uk/research-centres/TheCarePathwaysandOutcomesStudy/Filestore/Filetoupload,135918,en.pdf
  An example information sheet for research interviews with parents. See the online version of the same information sheet here: http://www.qub.ac.uk/research-centres/TheCarePathwaysandOutcomesStudy/Informationforparticipants/Parentsinformationpage/
  Stations this resource found in: Information Sheets

Information for Research with Children and Young People

- **Example Information Sheet (The Care Pathways and Outcomes Study)**
  http://www.qub.ac.uk/research-centres/TheCarePathwaysandOutcomesStudy/Filestore/Filetoupload,135917,en.pdf
  An example information sheet for research interviews with children and young people. See the online version here: : http://www.qub.ac.uk/research-centres/TheCarePathwaysandOutcomesStudy/Informationforparticipants/Parentsinformationpage/FAQ1-10/#d.en.90724
  Stations this resource found in: Information Sheets

- **Example Information Video for Participants (The Care Pathways and Outcomes Study)**
  http://www.qub.ac.uk/research-centres/media/Media,101191,en.wmv
  A video produced by a research team at Queen's University Belfast that provides information about the study.
  Stations this resource found in: Information Sheets

STATION 9: GETTING YOUR PROJECT PEER REVIEWED

Peer review a process whereby experts in the field scrutinise the study for any or all of quality, management of ethical issues, feasibility and value for money. This is normally done within the funding or ethical approval process. Where peer review has not been conducted as part of the funding process, your academic institution or the NHS organisation can assist in arranging this. The links below highlight the importance of peer review, and give guidance on reviewing research proposals.

External peer review is often needed (i.e. outside of the NHS organisation or academic institution), however, student projects are usually facilitated by the academic supervisor within the institution. Ask your local R&D office about their specifications for peer review.

RESOURCES

- **Ensuring RIgour** http://www.qualres.org/HomeEval-3664.html
  Guidelines for ensuring rigour in your qualitative study.
  Stations this resource found in: Qualitative Research Approaches, Peer Review

- **Assessing Qualitative Articles** http://www.qualres.org/HomeGuid-3934.html
  A worksheet that is used for assessing qualitative articles created by Crabtree and Miller (1999) hosted on the Robert Wood Johnson Foundation website.
  Stations this resource found in: Peer Review

- **Critical Review Form** http://www-fhs.mcmaster.ca/rehab/ebp/pdf/qualguidelines.pdf
  A document that summarises research approaches and data collection methods written as guidelines for critical review of qualitative research.
  Stations this resource found in: Qualitative Research Approaches, Peer Review

- **COREQ Guidelines** http://intqhc.oxfordjournals.org/content/19/6/349.abstract
  Guidelines for reporting qualitative research called the 'Consolidated Criteria for Reporting Qualitative Research' (COREQ).
  Stations this resource found in: Peer Review, Proposal Development

- **EQUATOR Guidelines**
  http://www.equator-network.org/resource-centre/library-of-health-research-reporting/reporting-guidelines/qualitative-research/
  Guidelines for reporting qualitative research detailed by the EQUATOR Network.
  Stations this resource found in: Proposal Development, Peer Review

STATION 10: IDENTIFYING A SPONSOR

The sponsor of your research is the named individual at your workplace of place of study who is willing and able to cover the insurance and indemnity for you to conduct your research study. The sponsor is often a senior member in the research division of your organisation or institution. The sponsor needs to provide a signature (sometimes a handwritten signature, as opposed to an electronic signature) on both NHS Research Ethics Committee and NHS Research and Development (R&D) approval applications. At some R&D offices, multiple signed copies of your applications (and other relevant documents) may be required, hence it is important to determine what is required before contacting the Sponsor.

Sponsorship is required for studies that fall within the scope of the UK Regulations or the Research Governance Framework for Health and Social Care and Welsh/Scottish/Northern Irish equivalents. It may take some time to secure a Sponsor for your study, so start early in the planning process.

Within NHS organisations and universities there are research and development offices or that advise on regulatory and governance issues, in particular with respect to sponsorship responsibilities.

The document below outlines what is possible under the regulations and provide information about insurance and indemnity.

RESOURCES

- **NHS Indemnity Arrangements for Clinical Negligence Claims in the NHS**
  http://www.nhsla.com/home.htm

The NHS Litigation Authority website.
Stations this resource found in: Identify Sponsor

STATION 11: CREATING A STUDY MANAGEMENT COMMITTEE

Studies of any size should have an identified committee to help manage the project. The committee should include all the people named on the proposal, at least one external expert member and at least one member who provides the perspective of the patient (e.g. child and/or parent/carer) or the public, to ensure that all relevant areas of the research are covered.

Student researchers should involve their supervisor and if necessary another person who is an expert in either the methods used in the study or the population being investigated.

Study management committees meet as frequently as required to monitor and troubleshoot study progress, this would be at least twice during a short study but more often in complex or lengthy studies. They should also offer general advice on how to undertake the study.

If you are unsure of whom to invite to sit on your study's committee, seek advice from your R&D office, line manager or supervisor.

STATION 12: PREPARING YOUR RESEARCH AND DEVELOPMENT (R&D) APPLICATION

Your NHS Trust or university R&D approval (local approval)

It is advised to start speaking to the research and development (R&D) office or department in your institution or Trust as soon as possible, especially if uncertain about governance approval requirements. See the station Consulting your Local R&D Office for more information.

NHS R&D approval

NHS organisations and universities have R&D offices (or equivalents) that are good sources of advice to help with regulatory and governance issues. These offices need to be made aware of all research projects that involve their organisation's staff or resources, in order to ensure:

- appropriate negotiations are initiated with relevant NHS or university departments
- appropriate arrangements are put in place to support the research
- risk management measures are in place, in particular appropriate insurance or indemnity provision

If you are conducting research involving the NHS, you should identify a lead NHS R&D office (often where you are based, or the main site for your study) that can ensure that there will be no practical difficulties with conducting your research in the NHS, and also to advise on the application and approvals processes.

The Integrated Research Application System (IRAS) form should be used to apply for NHS R&D approvals in England, Northern Ireland, Scotland and Wales. IRAS is a single system for applying for the permissions and approvals for health and social/community research in the UK. It streamlines the process for seeking relevant approvals as you do not need to enter

the details for a single project in separate application forms. For access to the IRAS form and further guidance regarding the application process, please visit the IRAS website or brochure.

Site-Specific Assessment (SSA) is needed from each NHS site at which you plan to collect data (e.g. undertake an interview). It may not be required if you are planning to conduct research off-site, for example, at participants' homes. You will need a Research Coordinator at each site and may need to submit a new R&D application in each PCT, unless you use the CSP framework described below.

Researchers working in England whose study is eligible for the NIHR portfolio will be able to seek NHS permission through the NIHR Coordinated System for gaining NHS Permission (CSP) accessed through IRAS –check eligibility here: http://www.crncc.nihr.ac.uk/about_us/processes/portfolio/p_eligibility/ineligible.htm . You will need to submit a Portfolio Adoption Form (PAF). A PAF is generated on IRAS and should be submitted to the CSP Unit. The CSP Unit will inform you if your study is to be adopted onto the NIHR portfolio, and if so how you should proceed with obtaining NHS R&D permission, when you are ready to do so.

One of the first steps you will have to take for the R&D approval process is to apply for a research passport. That is, unless you have a substantive or honorary contract with an NHS Trust. The passport is valid for the length of your study or for the length of your employment contract. If based at a university, you may need to get occupational health clearance from the NHS before conducting research in the NHS.

RESOURCES

- **Integrated Research Application System (IRAS)**
  https://www.myresearchproject.org.uk
  The link that takes you to the Integrated Research Application System for research in the NHS.
  Stations this resource found in: Ethics Application, R&D Application, Ethics Submission, R&D Submission

- **IRAS Training Portal**
  https://www.myresearchproject.org.uk/ELearning/IRAS_E_learning.htm
  This one-hour training module will provide information that is applicable to all researchers, not specifically qualitative researchers.
  Stations this resource found in: Ethics Application, R&D Application, Ethics Submission, R&D Submission

- **NRES** http://www.nres.nhs.uk/applications/
  National Research Ethics Service is essential website to understanding how to get started on your research. It provides a flowchart that will help you understand the processes required.
  Stations this resource found in: Ethics Application, R&D Application, Ethics Submission, R&D Submission

- **NHS R&D Forum Website** http://www.rdforum.nhs.uk/001.asp
  A forum for researchers that encourages the sharing of best practice
  Stations this resource found in: R&D Application, R&D Submission

- **NIHR** http://www.nihr.ac.uk/systems/Pages/systems_research_passports.aspx
  Website for NIHR Good Practice for Research in the NHS
  Stations this resource found in: R&D Application, R&D Submission

STATION 13: ORGANISING A STUDY FILE

It is good practice to set up a study file at the beginning of a study, when you begin creating the research proposal and going through the approvals process. The essential documents that make up the file should be kept in a secure but accessible manner and the purpose of each document should be clearly described. Essential documents serve a number of important purposes: they can help with efficient study management, independent audit, and 'close-out' and archiving. All essential documents should be legible and accurate, it should be held at the principal site (Chief Investigator's office) and copies of relevant documents should be kept at participating sites.

RESOURCES

- **Study File Document List**
  A list of documents that should be kept in your study file
  Stations this resource found in: Study File

Resource13

STATION 13: ORGANISING A STUDY FILE

The appropriate documentation will vary according to the study, but essential documents might include:

- **All versions of the study proposal**
- The version numbers on your proposal should change every time that you make changes to the way your study will be carried out. Even if only a few words are changed, a new study proposal version number is required.
- **The operating procedures of the study**
- Operating procedures are an important part of good practice in research. They are especially important when undertaking multi-site research studies. Operating procedures are essentially a number of protocols on how you plan to undertake the research project and standard definitions for relevant items. For example, you may need operating procedures on how you plan to approach potential participants (e.g. Who is allowed to give the letter of invitation? When will researchers be allowed to approach potential participants?), or how you plan to deal with participants who are visibly stressed during data collection (e.g. What will you say to them? Who will you contact to help?). It is likely that you will need to outline a number of operating procedures. These should all be dated and stored together.
- **All versions of the participant information sheets and consent forms**
- See the station 'CREATING STUDY INFORMATION FOR PARTICIPANTS' for more information.
- **Your funding application (if one was written)**
- **Your research passport application**
- See the station R&D Application for more information.
- **Your ethical approval application**
- You should scan or save the final versions with signatures for future reference.

- **Your R&D application**
- You should scan or save the final versions with signatures for future reference.
- **All Site-Specific Information forms**
- You should scan or save the final versions with signatures for future reference.
- **All communications (formal letters and emails) with any research ethics committees, R&D coordinators, and research sites**
- Keep hard copies and soft copies.
- **Any substantial amendments (and their approvals)**
- **Recruitment records**
- **Progress reports**

For auditing and budgeting purposes, it may also be useful to keep all invoices and copies of expenses receipts in the documentation file.

STATION 14: COMPLETING THE CHECKLIST BEFORE SEEKING APPROVAL

The checklist for Chief Investigators is a means of checking that you have the documentation required for the permissions and approvals process.

Note: For IRAS applications, the CI on undergraduate and masters-level student projects is the supervisor. At the doctoral level, the student is usually the CI.

The specific documents you need are listed in the IRAS Checklists resource below. If you are undertaking a qualitative study that does not itself involve an investigation of a medicinal product, your study will be categorized as a Non-CTIMP. Check the relevant checklists for your study (e.g. REC Form - Non CTIMP, NHS R&D- Non CTIMP, etc).

Where IRAS is not involved, your local institution will have similar checklists you are advised to obtain to ensure that you have completed all necessary stages and documentation.

RESOURCES

- **IRAS Checklists** https://www.myresearchproject.org.uk/help/IrasCheckLists.aspx
  IRAS links to checklists for all relevant ethics and R&D processes
  Stations this resource found in: Checklist

STATION 15: ETHICS SUBMISSION

Your NHS Trust or university ethical approval (local approval)

It is advised to follow the procedures laid out by the research and development (R&D) office or department at your institution or Trust.

NHS Research Ethics Committee (NHS REC) approval

First, ensure that you have read the Ethics Application station guidance and looked at all of the relevant resources. Once you have completed the checklist (see the Checklist station), then you can submit your application. You will need to first need to find your local committee (or another suitable committee), and then examine when they are meeting. Once you know that you are available on that date, you should ring the local allocation service to

book in your application. See the resource below for the necessary contact details.

RESOURCES

- **NRES Research Ethics Committees Directory**
  http://www.nres.nhs.uk/contacts/#ContactsApplicants
  National Research Ethics Service (NRES) directory of all ethics committees across the UK, and all necessary contact details to book your application in for review.
  Stations this resource found in: Ethics Submission

STATION 16: SUBMITTING YOUR NIHR CSP APPLICATION (IF APPLICABLE)

If your study involves recruitment of participants from multiple NHS organisations or will take place on multiple NHS premises, it is useful for your R&D application to be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP). NIHR CSP standardises and streamlines the process of gaining NHS R&D approval across sites. Your study must first be accepted in the NIHR portfolio. You can ensure that your study is considered by answering yes to IRAS Project Filter question 5a.

RESOURCES

- **NIHR Coordinated System for gaining NHS permission (CSP)**
  Website for NIHR Coordinated System for gaining NHS Permission (CSP)
  Stations this resource found in: CSP Application

STATION 17: SUBMITTING YOUR R&D APPLICATION

Your NHS Trust or university R&D approval (local approval)

All NHS Trusts and universities must give their permission before studies can begin (this is in addition to ethical approval). Without their approval, insurance and indemnity cannot be assumed to be in place to cover the proposed research activity. Once you have fulfilled their processes, you can submit all documentation

NHS R&D approval

First, ensure that you have read the R&D Application station guidance and looked at all of the relevant resources. Ensure that you have completed the Integrated Research Application Service NHS R&D application and filled out the relevant checklist (see Checklist station). Be aware that if your study is taking place in England, it may be eligible for the NIHR portfolio, at which point you will be able to seek NHS permission through the NIHR Coordinated System for gaining NHS Permission (CSP). See the CSP Application station.

RESOURCES

- **RDForum** http://www.rdforum.nhs.uk/044.asp
  RDForum website that provides contact details for R&D offices across the UK
  Stations this resource found in: R&D Submission

STATION 18: APPROVALS AND PERMISSIONS OBTAINED

Your study cannot begin until all of the relevant approvals and permissions have been obtained. When approvals have been granted, the study's Chief Investigator will receive notification via email and post; however, the letter may request for changes to be made to the study or for aspects of the study to be more clearly defined before continuing.

Note that before commencing the study the chief investigator and the research team will need to ensure that all that the study documentation has been finalised and that all study sites have been fully informed.

On the next map called Study Management and Closure the first station provides a checklist for you to complete to ensure that everything has been done before the study can begin.

- **Research Ethics Guidebook** http://www.ethicsguidebook.ac.uk/
  A resource for social scientists. See the 'Ethics Committee Responses' section to determine how to reply to committees who request changes to your research.
  Stations this resource found in: Research Question(s), Proposal Development, Funding Proposal, Ethics Application, Approvals and Permissions Obtained

Planning a New Qualitative Study with Children, Young People and Families

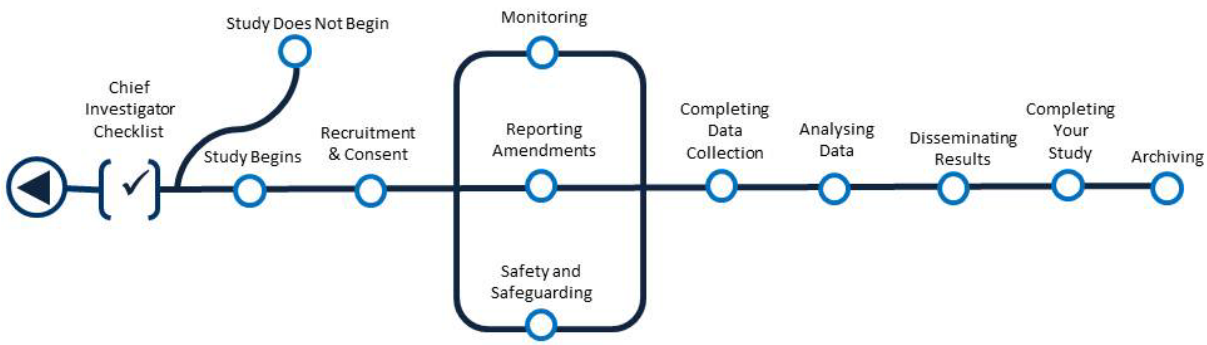
Is this map for you?

This is a map that gives pointers and details on how to develop and undertake a research study using qualitative methods. While it will be helpful to all qualitative researchers, it has a particular focus on health related research with children and young people.

When undertaking a research study using qualitative methods there is a need to be flexible and responsive as a researcher; however, there are identifiable stages that should be considered when developing a qualitative research project. The stages are best understood as individual stations in a map that follow the research process. See the map below.

Note: Preparing all of the necessary documentation and gaining ethical approval and research governance approval can take three months or more. While procedures are in place to streamline the process of gaining NHS ethics and R&D approvals on the IRAS website (Integrated Research Application System) (https://www.myresearchproject.org.uk/), it is advised that researchers start speaking with the relevant R&D departments very early on in the research process.

MAP 2: STUDY MANAGEMENT AND CLOSURE



MAP 2 (STUDY MANAGEMENT AND CLOSURE)

NO.	MAP VIEW NAME	LIST VIEW NAME
1.	CHIEF INVESTIGATOR CHECKLIST	CHIEF INVESTIGATOR CHECKLIST
2.	STUDY DOES NOT BEGIN	STUDY DOES NOT BEGIN
3.	STUDY BEGINS	STUDY BEGINS
4.	RECRUITMENT & CONSENT	CREATING RECRUITMENT AND CONSENT STRATEGIES
5.	MONITORING	MONITORING AND AUDITING PROGRESS
6.	REPORTING AMENDMENTS	REPORTING AMENDMENTS TO YOUR STUDY
7.	SAFETY AND SAFEGUARDING	REPORTING ON SAFETY AND SAFEGUARDING
8.	COMPLETING DATA COLLECTION	COMPLETING DATA COLLECTION
9.	ANALYSING DATA	ANALYSING DATA
10.	DISSEMINATING RESULTS	DISSEMINATING YOUR RESULTS
11.	COMPLETING YOUR STUDY	COMPLETING YOUR STUDY
12.	ARCHIVING	ARCHIVING YOUR STUDY FILE AND DATA

STATION 1: CHIEF INVESTIGATOR CHECKLIST

The resource below is a checklist to ensure that Chief Investigators (CIs) and the research team have done everything they need to before the study can commence. It is good practice for the CI to complete this checklist.

CIs of multi-site studies should ensure that all study sites have the information they need to conduct the study at that specific location.

RESOURCES

- **Chief Investigator Checklist**
  A checklist that will help you better understand whether you are prepared to begin your research study.
  Stations this resource found in: Chief Investigator Checklist, Study Begins

Resource1

STATION 1: CHIEF INVESTIGATOR CHECKLIST

There are a number of practicalities that should be considered before you begin your study. These are:

Communication and Data Exchange
- ✓ Decide collectively within your research team on the best method of communication
- ✓ Share contact details amongst team members
- ✓ Ensure that there are secure electronic methods of discussing and sharing sensitive information between team members
- ✓ Ensure that all transfers of research participants' personal data are conducted using secure methods (e.g. encrypted memory stick)

Confidentiality
- ✓ Ensure that you have protocols in place that protect participants' identities before, during and after the study

Securing success at research sites
- ✓ Organise meetings with managers of research sites to explain the study and to answer any questions

Documentation
- ✓ Ensure that you have a study file (hard copy and electronic) to store together all relevant documentation
- ✓ Ensure that the relevant authorities have the final versions of all study documents (e.g. study proposal, study information sheets for participants)
- ✓ Ensure that research sites have all relevant study documents (e.g. study proposal, study information sheets for participants) and that documents have been adapted to suit each specific site (if necessary)

Recruitment and Consent
- ✓ Provide training to researchers/research site staff who will be involved in the recruitment and/or consent of study participants involved in your study

- ✓ In addition to general training, provide study-specific training to researchers/research site staff who will be involved in the recruitment and consent of study participants. This may involve the dissemination of step-by-step instructions and/or mock facilitations

Data Collection

- ✓ Ensure that you have a final draft of your data collection instrument
- ✓ Practice using your data collection instruments (e.g. interview schedule/focus group topic guide) with colleagues or friends to ensure its fluidity and to increase your confidence
- ✓ Ensure safety of researchers collecting data off-site by creating a protocol on communication (e.g. the researcher in the field should telephone another research team member when arriving and leaving a data collection site [i.e. a participant's home or a hospital] and report any issues to the Chief Investigator immediately upon return)

Storage of Data

- ✓ Ensure that you have a secure area to store hard and soft copies of personal information of participants and study data (i.e. hard copies should be locked filing cabinet in locked research office, and soft copies stored on password protected computers)

Several steps should additionally be taken to ensure that children taking part in a research study are protected. You should:

- ✓ Be familiar with national and local policies about safeguarding children
- ✓ Be appropriately trained in research and in working with and communicating with children
- ✓ Be aware of the limits of their expertise
- ✓ Take into account the cumulative medical, emotional, social and psychological consequences of the child being involved in research
- ✓ Ensure that all members of the team have undergone a Criminal Records Bureau Check

STATION 2: STUDY DOES NOT BEGIN

There are also a number of reasons that the start of a study can be delayed. For example, the delayed start of a study could be recommended by the sponsor or by another governance body. Alternatively, the start of a study could be delayed for reasons unrelated to the ethical or governance procedures, such as difficulty in hiring the appropriate personnel to undertake data collection, personal reasons (e.g. researcher's family issues), or other work obligations, etc. All sites involved and all relevant authorities should be made aware of changes to the timelines of study progress. It is especially important to inform relevant authorities if you foresee that the study will not finish within the original predicted timeframe.

There are also times when studies do not begin altogether because they never receive ethical approval. Studies that do not have the appropriate approvals should not be carried out.

STATION 3: STUDY BEGINS

You may receive a number of letters or emails as you begin to receive approvals from different authorities. The official start date of the study is considered the date that you received the last approval (i.e. when you complete all approval requirements). Ensure that you keep paper and electronic copies of approval letters or emails.

Starting the study process begins once all of the relevant approvals are in place, all documentation has been finalised, and all participating sites (if the research is happening at more than one site) have the information they need and know so that the study can begin.

See the Chief Ivestigator checklist to ensure that you have taken the correct actions into consideration.

- **Chief Investigator Checklist**
  A checklist that will help you better understand whether you are prepared to begin your research study.
  Stations this resource found in: Chief Investigator Checklist, Study Begins

STATION 4: CREATING RECRUITMENT AND CONSENT STRATEGIES

It is important to develop a recruitment strategy that is clear and concise. The research site should be given an opportunity to comment on your strategy before you begin recruiting participants. Consent is also important to 'get right'. See the guidance below for the basics in developing recruitment and consent processes.

RESOURCES

Recruitment

- **Essential Recruitment Guidance**
  Guidance on how to undertake recruitment generally, including what types of materials to use (e.g. posters, websites). As well as specific advice on: recruiting children and recruiting participants at multiple sites.
  Stations this resource found in: Recruitment & Consent

Resource4a

STATION 4: CREATING RECRUITMENT AND CONSENT STRATEGIES

An introduction to recruitment

It is advised that a person who is not on the research team make first contact with the potential participants in your study. For example, if your study takes place in a hospital and involves interviews with families, you could ask a staff nurse to be on your research team, and once trained, to give your study information sheets to potential participants alongside a short verbal introduction to the study. The staff member could then close the conversation by asking whether the potential participants would like you (i.e. the researcher) to come speak with them and answer questions. Alternatively, you can provide your contact details on the study information sheet, so that potential participants can contact you with questions. Studies that involve one-off questionnaires or brief interactions with participants may not need the involvement of someone other than the researcher for first contact. If you are unsure of what type of approach would work best for your study, it is advised that you speak with your NHS Trust or university's local research and development office.

Recruitment materials (posters/emails/websites)

In addition to a face-to-face approach (or as an alternative to), you may also decide to recruit participants using posters, websites or emails. This is a decision you should have made when applying to ethics approval, as all research ethics committees involved will want to see a

copy of your poster, website or other materials. If you would like to use a poster to recruit participants, you should discuss this with a staff member at the site first.

Recruitment with children and young people

Children

If your study involves children, it is advised that you or the person making first contact on your behalf speak with the child's parents/guardians first. When you approach parents/guardians, you should summarise the relevant study information and allow time for questions and then ask permission to speak with the child about the study. You should also discuss with the parents the type of language you will use (i.e. whether to avoid particular words related to illnesses, for example 'cancer') and show the parents the information sheets you will use to explain the research study to determine whether they are happy with the documents being given to their children.

Young People

When gaining consent from young people it is also important to take into consideration the family context. If young people are aged 16 years or more, it is generally accepted that they should be the first people you speak with, however, it is extremely important to involve other family members who would like to be included in discussions.

Recruitment at multiple research sites

If your study involves multiple sites, you may not be able to speak with each participant joining the study. You should appoint one or two people at each site to act as site recruitment coordinators. It is advised that your research team decide on a recruitment protocol that includes a first contact strategy, an introduction script for the study, and then share this with the site recruitment coordinators via a training session. Ensure that you have discussed the recruitment approach with site managers to ensure that they approve of the methods you plan to use. This will all have been approved as part of the ethics and governance processes.

- **Recruitment Materials**
  http://iris.uwaterloo.ca/ethics/human/application/SampleRecruitmentMaterials.htm
  A set of recruitment materials, including items such as a telephone recruitment script and poster templates.
  Stations this resource found in: Recruitment & Consent

Consent

- **Essential Consent Guidance**
  Guidance on how to undertake recruitment generally, including what types of materials to use (e.g. posters, websites). As well as specific advice on: recruiting children and recruiting participants at multiple sites.
  Stations this resource found in: Recruitment & Consent

Resource4b

STATION 4: CREATING RECRUITMENT AND CONSENT STRATEGIES

An introduction to consent

It is generally understood that researchers should give participants at least 24 hours to decide whether they would like to participate in a research study, although this is not always

necessary or feasible – this is a decision that will be made prior to you gaining ethics approval. For example, if you have provided study information sheets and answered all of the potential participants' questions, the first time you can ask them to provide written or verbal consent is 24 hours later. This allows potential participants time to consider the risks and benefits of taking part and to consult with others about their decision. There are, however, exceptions to this. It would be best to develop a consent process based on guidance, and then discuss any concerns with your NHS Trust, university, the research site(s), and your local research and development office or department.

Consent with children and young people
When deciding whether a child is capable of giving valid (informed) consent three main elements should be considered:

- Is the child or young person capable of making that particular decision (competent)?
- Are they acting voluntarily – that is not being coerced?
- Have they been provided with sufficient comprehensible information to enable them to make an informed decision?

Competent children and young people should always be asked for their consent to participate in research. However, it is best practice to talk to parents about the research study first and seek permission to approach their child (as mentioned above). Children can give consent if they are capable of choosing between alternative courses of action. The researcher should also assess to see if a child demonstrates understanding of the issues involved including the purpose of the research and any potential risks. An individual assessment should be made because the age at which children are able to provide informed consent will vary. It is wrong to assume that young children or children with learning disabilities are incompetent to consent or to refuse their consent.

In England, Wales and Northern Ireland children under the age of 16 years can give their consent to take part in a research study if they satisfy the criteria of Gillick competence and they:

- have been counseled and to do not wish to involve their parents;
- have sufficient maturity to understand the nature, purpose and likely outcome of the proposed research.

Similar provision is made in Scotland by The Age of Legal Capacity (Scotland) Act 1991.

- **Informed Consent**
  http://www.nres.npsa.nhs.uk/applications/guidance/consent-guidance-and-forms/
  NRES guidance on writing participant information sheets and consent forms.
  Stations this resource found in: Recruitment & Consent

- **Department of Health Consent Guidelines**
  http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Publichealth/Scientificdevelopmentgeneticsandbioethics/Consent/Consentgeneralinformation/index.htm
  An archived webpage that lists all of the Department of Health's guidance on consent for adults, children, parents, etc. The documents were created for consent processes in relation to medical treatment, however many of the suggestions made are relevant to research, as well.
  Stations this resource found in: Recruitment & Consent

- **Informed Consent** http://www.lancs.ac.uk/researchethics/1-3-infcons.html

The key issues of consent outlined on one helpful webpage.
Stations this resource found in: Recruitment & Consent, Information Sheets

- **Sample consent forms** http://www.lancs.ac.uk/researchethics/1-4-samples.html
  A sample of various consent forms and information sheets used in previous research at Lancaster University.
  Stations this resource found in: Recruitment & Consent, Information Sheets

STATION 5: MONITORING AND AUDITING PROGRESS

Progress Monitoring and Reporting

It is important to establish how you will communicate with all relevant authorities at the outset of a study. That is, you should know whether you are expected to hold meetings, write formal reports or give presentations to various authorities, such as your study management committee, funders, R&D office, ethics committee(s) and all research study sites. For example, your study management committee (aka: advisory board, steering committee) may ask you to document study progress by writing formal progress reports or providing updates in the form of meetings (with accompanying meeting minutes). The funders of your study may additionally require telephone or email updates on progress, an end of study report, or a formal presentation. It is your responsibility to determine what is desired from individual authorities. Keep in mind that each report you write about your study will need to be different, and likely tailored to the authority requesting the document.

If you were required to gain NHS approval (in addition to your local approvals), you will be required to provide annual updates to NHS R&D departments and the NHS Research Ethics Committee. See the 'Annual Progress Reports' resource for more information.

Audit

Funders, sponsors and NHS R&D departments may want to conduct an audit of your study, where the study file will need to be presented. Local R&D offices undertake audits on research studies occurring in their NHS Trust as part of their responsibilities under Research Governance Framework. R&D Offices are reviewed in the same way as the rest of the NHS, through the Care Quality Commission in England, the Healthcare Inspectorate in Wales, and Audit Scotland in Scotland.

RESOURCES

- **Annual Progress Reports**
  http://www.nres.npsa.nhs.uk/applications/after-ethical-review/annual-progress-reports/
  NRES guidance on how to report back to your REC one year after your study started.
  Stations this resource found in: Monitoring, Completing Your Study

STATION 6: REPORTING AMENDMENTS TO YOUR STUDY

It is likely that during the course of your study some elements will change. For example, you may make changes to your participant information sheets or your study proposal because the recruitment methods or sample included in the study need to be changed to improve the

study. See the first resource below to help you make a decision whether the change to your study is considered a substantial or a non-substantial amendment.

If you decide that your changes are non-substantial it is your responsibility to inform all relevant authorities (and send copies of updated documents, if applicable), especially your NHS research ethics committee of the changes. If you decide that your changes are substantial there is a formal procedure to follow. See the resources below for more information.

RESOURCES

- **National Research Ethics Service notification of amendments**
  http://www.nres.nhs.uk/applications/after-ethical-review/notification-of-amendments/
  Examples of substantial and non-substantial amendments, how to submit notices of amendment.
  Stations this resource found in: Reporting Amendments

- **Substantial Amendments**
  http://www.nres.nhs.uk/applications/guidance/trials-and-procedure-flowcharts/?1312190_entryid62=67037

  This flowsheet shows the process behind having a substantial amendment reviewed.
  Stations this resource found in: Reporting Amendments

STATION 7: REPORTING ON SAFETY AND SAFEGUARDING

It is extremely important that you continually monitor the safety and wellbeing of the participants, as well as the research team staff and research site staff in your study. This may include the monitoring and reporting of poor practice among staff. It will also include ensuring the safeguarding of participants in your study, by ensuring that they are not negatively affected by having taken part in your data collection activity (e.g. interview, focus group, etc.). Following any incidents of concern, it is important to record your initial impressions of the events and then report serious concerns (if any) to the appropriate authorities. You may also need to take action to modify the study and follow up with participants. You should keep a record of all reported incidents in your study file.

STATION 8: COMPLETING DATA COLLECTION

Post-participation debrief
At the end of data collection it is important to let participants know that they their involvement was appreciated. This can be said verbally or written in a letter or leaflet (i.e. a lay summary of the research report). You may also give them a token of appreciation in the form of money or a voucher; however, this should have been agreed upon before they began participating and have been noted in your ethics application.

In studies where deception was used (i.e. when the true purpose of the research study was not revealed to participants before they took part), it is extremely important that researchers explain the true nature of the study during the debrief. This information should also be provided in a written form so that participants have the information available at a later time. See the resources below for an example of a debriefing letter.

- **Debriefing letter**
  http://iris.uwaterloo.ca/ethics/human/application/samples/D10_1DebriefingLetterandConsentForm.htm
  An example of a debriefing letter given to participants after deception was employed in a study.
  Stations this resource found in: Completing Data Collection

STATION 9: ANALYSING DATA

The data analysis method you use depends on the type of data collected and the perspective taken. See the Qualitative Approaches station in the Planning a New Qualitative Study Map to read more about some of the most common analysis techniques.

Some researchers use computer software to assist in organising the data analysis process. Some of the most popular software at the moment include: NVivo and CAQDAS.

It is important that decisions are recorded on how data is transformed into codes, themes and categories during analysis. This written documentation forms the basis of an 'audit trail', one of many techniques used to validate analyses. When writing up your study for publication, your audit trail will also help you describe each analysis phase in detail.

Analysis involving Children and Young People
Involving children and young people who participated in your study in the interpretation and analysis of your research findings is important to some researchers. See the list of references for more information about how to involve children in analysis.

RESOURCES

- **List of references on data analysis**
  A list of references on data analysis.
  Stations this resource found in: Analysing Data

Resource9

STATION 9: ANALYSING DATA

General sources

Open access articles

Mays N. (2000) Assessing quality in qualitative research. *British Medical Journal*. 320: 50.1. http://www.bmj.com/content/320/7226/50.1

Pope C, Ziebland S, Mays N. (2000) Analysing qualitative data. *British Medical Journal*. 320: 114.
http://www.bmj.com/content/320/7227/114

Seers K. (2012) Qualitative data analysis. *Evidence Based Nursing*. 15(2). Doi: 10.1136/ebnurs.2011.100352. http://ebn.bmj.com/content/15/1/2.extract.

Thorne S (2000) Data analysis in qualitative research. *Evidence Based Nursing*. 3:68-70. http://ebn.bmj.com/content/3/3/68.full

Articles that require subscriptions

Braun V, Clarke V. (2006) Using thematic analysis in psychology. *Qualitative Research in Psychology*. 3: 77-101.

Sources for data analysis with children and young people

Articles that require subscriptions

Coad J, Evans R. (2008) Reflections on practical approaches to involving children and young people in the data analysis process. *Children & Society*. 22(1): 41-52.

Clavering EK, McLaughlin J. (2010) Children's participation in health research: from objects to agents? *Child: care, health and development*. 36(5): 603-611.

Anderson K, Baladin S. (2011) The storybook method: research feedback with young participants. *Augmentive and Alternative Communication*. 27(4): 279-291.

Books

Alderson P, Morrow V. (2011) *The ethics of research with children and young people: A practical handbook*. London: Sage.

- **Data Analysis** http://www.qualres.org/HomeGuid-3868.html
  A website that provides guidelines on analysis and describes common pitfalls.
  Stations this resource found in: Analysing Data

STATION 10: DISSEMINATING YOUR RESULTS

It is important to disseminate the results of research, not only to the research community, but to the general public as well. The obvious route to inform the research community is through publication in scientific journals. Leaflets or websites written in lay language are the most common dissemination methods for study participants and the general population. Disseminating your findings is not only good practice, but also one of your primary responsibilities as a researcher.

It is important to establish at the outset whether a participant will want to be informed of study findings, or whether he or she would like the onus to be left with them to obtain results themselves, if they should wish to.

It is good practice for investigators to check whether the relevant authorities that gave approval require copies of any publications or reports.

Dissemination of Research to Children

Two factors need to be taken into account during the writing up of a research study that involved children. Firstly, children's right to anonymity should be respected throughout the study unless they choose otherwise. Children should also have the opportunity to be listed as participants and as authors of research reports (if they contributed) using their full names or using pseudonyms if they

would like to be. This may be a point of contention with the ethics and research and development committees, in which case, it can be suggested that panels or groups of children or families can be named.

Secondly, any potential damage to children should be considered and reasonably allayed in the reporting (without changing the nature of the results), for example the potential for perpetuating negative stereotypes of young people or potential for the media to misrepresent or misreport findings in a derogatory manner. This of course is standard practice for any worthwhile research activity.

The offer to return research results to participants is increasingly recognised as an ethical obligation, founded on the principle of respect for persons. An informed discussion between researcher(s) and participants should occur close to when the offer to share results is made; this should include discussion regarding any potential risks and benefits.

The researcher needs to decide, based on the nature of a study if results are shared either before or after the results are published/peer reviewed. Sharing results might include the following:

- a number of age-appropriate written reports produced in a language and style suitable for children, without being over-simplified or patronising
- access to technical literature, for example a published paper, on request
- a website to offer optional review of detailed results
- other novel/evolving methods such as poetry or drama

RESOURCES

- **Anonymity in research findings** http://sru.soc.surrey.ac.uk/SRU36.html
  A University of Surrey Social Research Update on anonymity of research participants
  Stations this resource found in: Disseminating Results

- **RDInfo on Disseminating your Research Findings**
  http://www.rdinfo.org.uk/flowchart/section10.htm
  RDInfo general guidance on what to do with analysed data (i.e. how to write it up and disseminate to the relevant people).
  Stations this resource found in: Disseminating Results

- **Qualitative research review guidelines** http://www.biomedcentral.com/info/ifora/rats
  The RATS guidelines are modified here for BioMed Central. The original guidelines can be found in Clark JP: How to peer review a qualitative manuscript. In Peer Review in Health Sciences. Second edition. Edited by Godlee F, Jefferson T. London: BMJ Books; 2003:219-235.
  Stations this resource found in: Disseminating Results

- **Working with the media** http://www.lancs.ac.uk/researchethics/8-1-mediapub.html
  Tips and guidance on working with the media to promote your research.
  Stations this resource found in: Disseminating Results

- **Example Dissemination Web Page (The Care Pathways and Outcomes Study)**
  http://www.qub.ac.uk/research-centres/TheCarePathwaysandOutcomesStudy/Publications/
  An example of an excellent way to disseminate your research findings to the wider public.
  Stations this resource found in: Disseminating Results

STATION 11: COMPLETING YOUR STUDY

At the end of the study the Chief Investigator must inform the NHS Research Ethics Committee that the study has ended using a written form. A copy of the final report from the study should also be sent to the local research and development (R&D) office.

Your local R&D office may have additional end of study reporting procedures that should also be sent to your study's sponsor upon completion.

RESOURCES

- **End of study and final report**
  http://www.nres.nhs.uk/applications/after-ethical-review/endofstudy/
  NRES guidance on how to declare the end of the study and submit your final report back to your REC one year after your study started.
  Stations this resource found in: Completing Your Study

STATION 12: ARCHIVING YOUR STUDY FILE AND DATA

All study-related documents should be collated and saved as hard and soft copies after the study has ended. Depending on the type of research and the population you sampled, these documents should be saved for a number of years. If you are uncertain about the length of time that you need to archive data for, speak to your local research and development office about the local policies on archiving. Not only is it good practice to keep all study documents, it is also possible that your study may be audited after it has closed. It is best to be prepared.

The Chief Investigator and/or Principal Investigator are responsible for following local and national archiving procedures, as archiving applies to both the investigator sites and the central study co-ordinating office.

Institution-based Archives

After approximately 5 years (for non-intervention studies) or 15 years (for intervention studies) (or another appropriate amount of time requested by your local research and development department) you are able to destroy hard and soft copies. If you are a student, you may come across difficulty in securing storage for your study under your name, as some research centres do not have archiving space available to students. If your supervisor or head of department agrees, you can alternatively store materials under their name to ensure its long-term safekeeping.

Public Archives

If appropriate, it is also advised that you place your research findings in a public repository. This allows for other researchers to use your datasets. One of the most common archive sites is UK Data Archive (see the resource).

RESOURCES

- **UK Data Archive** http://www.data-archive.ac.uk/
  A research project that allows you to deposit your data to ensure that they will be professionally curated and accessible.
  Stations this resource found in: Archiving