THE beatson
WEST OF SCOTLAND CANCER CENTRE

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Research Information and Contacts Handbook

Research Information and Contacts Handbook (RICH)

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INTRODUCTION

This handbook has been developed for individuals who are required to undertake a research project, either as part of a postgraduate degree, or as a stand-alone, self or external- funded study.

For experienced researchers and novices alike, the research process can be challenging for a variety of reasons. Within the Beatson West of Scotland Cancer Centre (BWoSCC), it was becoming increasingly apparent that students required guidance and assistance at certain stages of the research process, especially when dealing with ethical approval. For this reason, a multidisciplinary meeting was held, involving key personnel from all departments whom students would come in to contact with during the course of their project. The collaborative effort that ensued resulted in this handbook, a 'Research Information Resource' to help guide the individual researcher from conception to completion of a research project. Such a handbook can never fully provide all possible information and is therefore only a guide. However, where necessary, the handbook will direct you to links and online resources where you may find more in-depth information.

What do I do now?

The research process can also be thought of as specific stages. If you are a student you will probably have been given some preliminary guidance by your University. This handbook is structured in such a way as to guide you through each of the main stages in this process.

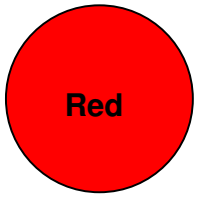
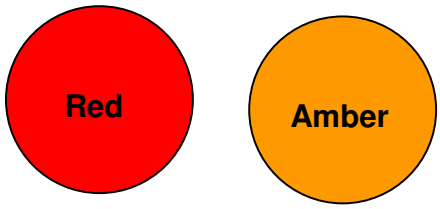
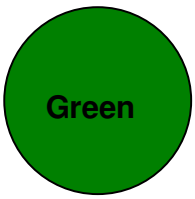
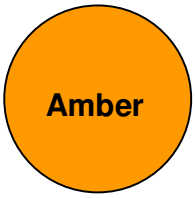
There are four sections in this handbook, represented as a traffic light sequence:

Section 1: FORMING: planning your study (RED)
Section 2: NORMING: approving your study (RED & AMBER)
Section 3: STORMING: doing your study (GREEN)
Section 4: PERFORMING: disseminating your study (AMBER)

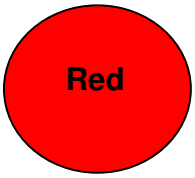
These sections are named after Bruce Tuckman's (1965) four-stage model of group/ team development, designed to tackle the problems and challenges of team or project work. The original stage sequence of Tuckman's original model is 'Forming, Storming, Norming, and Performing'. As student research projects are individual rather than team-based, Tuckman's stages have been adapted and sequence altered for this handbook to suit the particular problems and challenges inherent in conducting a research project. However, if you would like to read more about the Tuckman model refer to:

Rickards, T and Moger, S (2000) Creative leadership processes in project team development- an alternative to Tuckman's stage model British Journal of Management Part 4 pp273-283.

This handbook consists of four sections as follows:

1. FORMING (planning and design) 	• What is research? • Turning your idea into a research question • Reviewing the literature • Choosing the appropriate method and design • Preparation and function of a proposal
2. NORMING (approving the study / methodology) 	• Seeking Funding (if appropriate) for your study • Cancer Education Initiative Fund Information • Preparing for BWoSCC in-house approval of your study (IHTAB, CTEC) • Preparing for NHS Research Ethics approval • NHS R&D Management approval • Various guidance on completing and booking a research study through IRAS
3. STORMING (doing your study) 	• Informing clinical and professional 'gatekeepers' • Practical issues • Producing data trail • Analysing data
4. PERFORMING (disseminating your study) 	• Providing updates / end–of-study reports • Writing for publication • Making a poster presentation

CHAPTER 1: FORMING



What is research?

How do you know your project is a research project and not just a clinical audit or service evaluation? Table 1 provides definitions of each concept. Table 2 provides distinguishing features of each concept to further clarify differences.

If you think your project is an audit or service evaluation you should contact the Clinical Governance department for further guidance. This service can be found on the local intranet pages at www.staffnet.ggc.scot.nhs.uk. Click on the header tab 'Clinical Governance' under 'Corporate Services' for an electronic version of this information. If however, you have identified your study as a research project, it is essential to have an idea of what is involved.

Table 1: Definitions

DEFINITIONS		
RESEARCH	**CLINICAL AUDIT**	**SERVICE EVALUATION**
Aims to derive new knowledge which is potentially generalisable or transferable.	Aims to improve the quality of local patient care and clinical outcomes through peer-led review of practice against evidence-based standards and implement change where indicated.	Aims to improve patient care through continuous improvement of clinical outcomes and patient experience, focusing on quality, safety, productivity, efficiency.
Asks: What is best practice?	Asks: Are we following best practice and what is happening to patients as a result?	Asks: How can we make this service for patients safer, more efficient, or better?

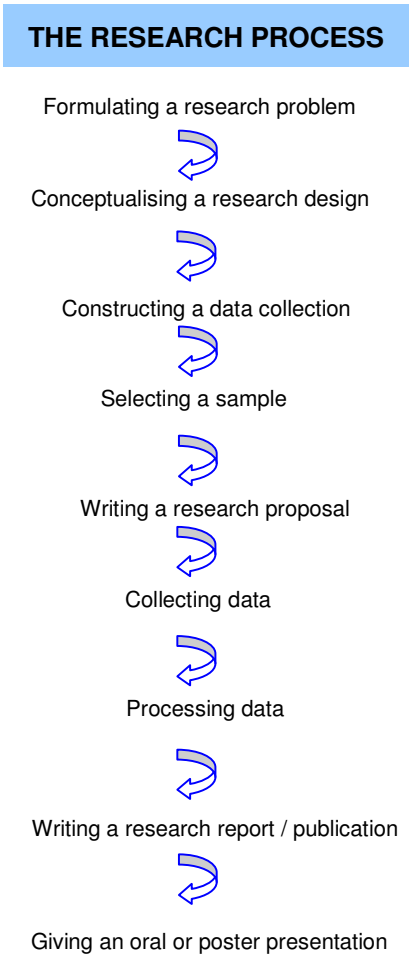
Table 2 provides the distinguishing features of each of the above three concepts. Further information can also be accessed using the following links:
www.nres.npsa.nhs.uk
www.rdforum.nhs.uk

Table 2: Distinguishing features of research, audit and service evaluation

DIFFERENTIATING CONCEPTS		
RESEARCH	**CLINICAL AUDIT**	**SERVICE EVALUATION**
Addresses clearly defined questions, aims and objectives. Qualitative: identifies/ explores themes following established methodology. Quantitative: designed to test a hypothesis.	Measures against a standard	Measures current service without reference to a standard
May involve randomisation	No randomisation	No randomisation
May involve allocation to intervention groups (quantitative) or uses a sampling framework underpinned by theoretical concepts (qualitative)	No allocation to intervention groups	No allocation to intervention groups
Results can be generalised (quantitative)or transferable (qualitative) to similar groups	Results are specific and local to a particular team, group, or service.	Results are specific and local to a particular team, group, or service.
May involve a completely new treatment or service	Will NEVER involve a completely new treatment or practice	Will NEVER involve a completely new treatment or practice
My involve the use of control groups	Will NEVER involve control groups	Will NEVER involve control groups
Must be registered with R&D and have management approval	Must be registered with Clinical Governance/Clinical Audit Team	Must be registered with Clinical Governance/Clinical Audit
REQUIRES REC REVIEW	**DOES NOT REQUIRE REC REVIEW**	**DOES NOT REQUIRE REC REVIEW**

The following diagram illustrates an overview of the different key elements of the research process.

Figure 1: The research process



Adapted from Kumar, R (1999) Research methodology: a step by step guide for beginners Sage Publications: London (page 17).

Planning and designing your study.

This is a major problem for individuals, especially for students. Ask yourself a question such as "Do I choose a topic related to my own or the university's interests or one that is relevant only to the area or speciality I work in?". Some individuals may also be in receipt of a studentship or other funded award or scholarship, which may already have identified a predefined topic for your project.

This section provides basic ideas to help you define a topic and the key research questions you need to ask, and the methods you might need to use to be able to seek the answers.

Turning your idea into a research question

Decide on an area of general interest, or a specific interest at work. Alternatively, are there any topics arising from recent audits or BWoSCC projects that you could progress as your own project? Then consider the following questions as these will form the basis of your research proposal and any applications you make for study approval.

a) Why does this area interest you?
b) Is your idea new or are you looking to verify / validate previous research?
c) What is the aim of your study / MSc project?
d) What is your hypothesis? (what you expect will or will not happen)
e) What support is there within your organisation that might provide advice or practical help?
f) How will patients, service users or colleagues benefit from your research?
g) Will you be involving patients or service users?
h) How long do you have to undertake your research project?
i) What resources might you require?
j) Do you need additional funding?
k) What ethical considerations might you need to account for?

** BUT

Please ensure your idea will fit into one of the BWoSCC key research themes:

- **Patient information and decision-making**
- **Quality of life and symptom control**
- **Advancing practice, nurse-led care and intervention**

Formulating objectives

Most research involves people, problems, programs, or phenomena. Think of your own area of work or speciality and what you do on a routine and non-routine basis. Ask yourself specific questions of interest in relation to those and think about it from the perspective of:

a. nurse
b. doctor
c. allied health professional
d. relative
e. colleague
f. manager
g. other multidisciplinary team members

Those questions will determine the methods and design of your research study. The following questions are provided as examples:

- How many patients/ clients do I encounter each day in my own ward/ clinic/ treatment room/ office?
- How effective is the service/ care my team or I provide?
- What are the strengths and weaknesses and/ or opportunities?
- How can I or my team improve this issue?
- What is the most effective intervention for a specific problem or treatment?
- What causes X or Y, and what effects so they have?
- What is the relationship between two or more phenomena?
- How can I measure the problem/ issue?
- Why do patients/ doctors/ staff etc behave in a certain way?
- Is the information I, or my team provide adequate? evidence-based? concise? clear?
- How satisfied are my patients/ clients/ colleagues?

Once you have the answers to these questions, you should then proceed to look for evidence in support of your topic and to explore the relevant literature.

Reviewing the literature

Before using the library, all staff must ensure they can access the online resources. All staff with their own login are not required to sign in at the enquiry desk. Others, such as newly employed staff may require access to the network for corporate induction/ policies and procedures. Whilst they are awaiting their personal login they can request library staff log them in. If you belong to this category, please show your staff ID to library staff who will instruct you what to do next. Special log in instructions for undergraduate students are available from library desk staff.

Other ways you can start the process is to:

- Visit your local NHS, university, and council library. Ask if there are any short introductory courses or one-to-one training available. Libraries may also have paper leaflets and 'how to' self-help guides on various searching techniques.
- Work out a search strategy to find all available evidence. Ensure you include textbooks, journals, abstracts, databases, reading lists etc. If necessary, discuss with your academic supervisor, mentor, and peers.
- Use NHS Scotland Knowledge Network (www.knowledge.scot.nhs.uk) and other internet search engines.

- Hand search bibliography and reference pages in journal articles and books for new, interesting, and relevant information.
- Read all available up to date literature. Make a template for entering and summarising your critique of each article you read. This helps you identify similarities and gaps of information etc.

An example of a critical appraisal template can be found in the Appendix 1 of this handbook. The example provided is suitable for appraising qualitative research. You may wish to modify the template to suit the appraisal of quantitative studies, which would need to contain more detailed sections to ensure a thorough scientific critique (such as statistical tests used, sample sizes etc).There is also some additional library guidance available for students preparing and writing an academic research thesis or dissertation. The following library information can also be accessed via Staffnet (Click Information services →Library, then follow links).

Postgraduate Nursing Researchers Information Resources Guide

Books

A selection of relevant books are held across the NHS Greater Glasgow and Clyde Libraries. Books can be sent to your nearest site for collection. To search the full NHS Greater Glasgow and Clyde Library Catalogue and/ or search for more recent publications you can do so online via:

http://www.glasgowlibraries.nhsscotland.com

http://www.nhsggc.org.uk/libraryservices

Alternatively, you can email us @: LibrarySubjectTeam@ggc.scot.nhs.uk

General Postgraduate Study

Author	Title	Year
Aveyard, H	Doing a literature review in health and social care: a practical guide	2010
De Brun, C	Searching skills toolkit: finding the evidence	2009
Fain, JA	Reading, understanding and applying nursing research	2009
Fraser. J	Creating effective conference abstracts and posters in biomedicine	2009
Girden, E	Evaluating research articles: from start to finish	2011
Lee, NJ.	Achieving your professional doctorate	2009
Offredy, M	Developing a healthcare research proposal	2010
Oliver, P.	Writing your thesis	2008
Wagner, E	Getting research published: an A to Z of publications strategy	2010
Williams, K	Getting critical	2009

Methodologies: General

Author	Title	Year
Biggs, H	Healthcare research ethics and the law: regulation, review, responsibility	2010
Bowling, A.	Research methods in health: investigating health and health services	2009
Burns, N.	The practice of nursing research: appraisal, synthesis and generation of evidence	2009
Depoy, E	Introduction to research: understanding and applying multiple strategies	2011
Dyson, S	Fundamental aspects of research for nursing	2010
Elwood, JM.	Critical appraisal of epidemiological studies and trials	2007
Fox, M.	Doing practitioner research	2007
Gerrish, K	The research process in nursing	2010
Hek, G	Making sense of research: an introduction for health and social care practitioners	2011
Hurley, W	Research methods: a framework for evidence based clinical practice	2011
Lobiondo-Wood, G	Nursing research: methods and critical appraisal for evidence based practice	2010
McLaughlin, H.	Service user research in health and social care	2009
Moule, P.	Nursing research: an introduction	2009
Neale, J.	Research methods for health and social care	2009
Oliver, P	The students guide to research ethics	2010
Polit, DF.	Nursing research: generating and assessing evidence for nursing practice	2008
RCN	User involvement in nursing research: RCN guidance	2007
Thomas, D	Designing and managing your research project: core knowledge for social and health researchers	2010
Thomas, G	Doing research: pocket study skills	2011
Wendler, D	The ethics of paediatric research	2010

Methodologies: Specific

Author	Title	Year
Andrew, S.	Mixed methods research for nursing and the health sciences	2009
Aveyard, H.	Doing a literature review in health and social care: a practical guide	2007
CRD:(Centre for reviews and dissemination)	Systematic reviews: CRD guidance for undertaking reviews in healthcare	2009
Corbin, J.	Basics of qualitative research: techniques and procedures for developing grounded theory	2008

Denscombe, M	Ground rules for social research: guidelines for good practice	2010
Forrester, M	Doing qualitative research in psychology	2010
Green, J.	Qualitative methods for health research	2009
Hackshaw, A	A concise guide to clinical trials	2009
Holloway, I.	Qualitative research in nursing and healthcare	2010
Khan, K	Systematic reviews to support evidence based practice; how to review and apply findings of healthcare research	2011
Koshy, E	Action research in healthcare	2011
Machin, D.	Sample size tables for clinical studies	2009
Machin, D.	Randomised clinical trials: design, practice and reporting	2010
Martin, V	Developing a narrative approach to healthcare research	2011
McNiff, J	Doing and writing action research	2009
McNiff, J	You and your action research project	2010
Streiner, DL.	Health measurement scales: a practical guide to their development and use	2008
Weeks, A	Lets do audit	2010
Williamson, G	Action research in nursing and healthcare	2012

Statistics & Epidemiology

Author	Title	Year
Aspelmeier, J	SPSS: a user friendly approach	2010
Bryman, A.	Quantitative data analysis with SPSS 14, 15, 16	2009
Freeman, JV.	How to display data	2008
Gibbs, G	Analyzing qualitative data	2009
Graham, A	Understanding statistics	2010
Marston, L	Introductory statistics for health and nursing using SPSS	2010
Peacock, J	Oxford handbook of medical statistics	2011
Polit, D	Statistics and data analysis for nursing research	2010
Saracci, P	Epidemiology' a very short introduction	2010
Wagner, W	Using SPSS for social statistics and research methods	2010

Journal articles

The following databases are available via the NHS Scotland Knowledge Library (using your ATHENS password) from any PC with Internet connection: (http://www.knowledge.scot.nhs.uk).

- OVID databases: including MEDLINE and Embase,
- The Cochrane Library
- EBSCO CINAHL: Nursing and allied health database, PsycInfo
- RefWorks: Bibliographic reference management software
- JBI Connect: from Joanna Briggs Institute

Recent articles mostly available from the Knowledge Network with your ATHENS password

- **Reading, writing and appraising**

Author	Title	Year
Doolan, D.M. & Froelicher, E.S.	Using an existing data set to answer new research questions: a methodological review. Research & Theory for Nursing Practice 23,3:203-215.	2009
Finfgeld-Connett, D.	Generalizability and transferability of meta-synthesis research findings. Journal of Advanced Nursing 66,2:246-254.	2010
Hand, H.	Reflections on preparing a poster for an RCN conference. Nurse Researcher 17,2:52-59.	2010

- **Methodologies (General)**

Author	Title	Year
Banner, D. & Grant, L.G	Getting involved in research. Canadian Journal of Cardiovascular Nursing 21,1:31-39.	2011
Clark, P.C., Dunbar, S.B., Aycock, D.M.et al.	Pros and woes of interdisciplinary collaboration with a national clinical trial. Journal of Professional Nursing 25,2:93-100.	2009
Clarke, K.A.	Uses of a research diary: learning reflectively, developing understanding and establishing transparency. Nurse Researcher 17,1:68-76.	2009
Freysteinson, W.M.	The ethical community consultation model as preparation for nursing research: a case study. Nursing Ethics 17,6:749-758.	2010
Higgins, I., Parker, V., Keatinge, D., et al	Doing clinical research: the challenges and benefits. Contemporary Nurse 35,2:171-181.	2010
Houghton, C.E., Casey, D., Shaw, D., et al	Ethical challenges in qualitative research: examples from practice. Nurse Researcher 18,1:15-25.	2010
Kostovich, C., Saban, K., Collins,E.	Becoming a nurse researcher: the importance of mentorship. Nursing Science Quarterly 23,4:281-286	2010
McGuinness, S. & Wilkinson, R	Nurse research and the law in competent adults. British Journal of Nursing 18,9:559-560.	2009
Palmer, J.A.	Nursing research: understanding the basics. Plastic Surgical Nursing 29,2:115-121.	2009
Pierce, L.L	Twelve steps for success in the nursing research journey. Journal of Continuing Education in Nursing 40,4:154-162	2009
Wainwright, D. & Sambrook, S	The ethics of data collection: unintended consequences?. Journal of Health Organization & Management 24,3:277-287.	2010
Welford, C., Murphy, K. & Casey, D.	Demystifying nursing research terminology. Part 1. Nurse Researcher 18,4:38-43.	2011
Wilson, C.B. & Clissett, P.	Involving older people in research: practical considerations when using the authenticity criteria in constructivist inquiry. Journal of Advanced Nursing 67,3:677-686.	2011

- **Methodologies (specific)**

Author	Title	Year
Anthony, S. & Jack, S.	Qualitative case study methodology in nursing research: an integrative review. Journal of Advanced Nursing 65,6:1171-1181.	2009
Balls, P.	Phenomenology in nursing research: methodology, interviewing and transcribing. Nursing times 105,32-33:30-33.	2009
Baumbusch, J.L.	Conducting critical ethnography in long-term residential care: experiences of a novice researcher in the field. Journal of Advanced Nursing 67,1:184-192.	2011
Borglin, G. & A Richards, D	Bias in experimental nursing research: Strategies to improve the quality and explanatory power of nursing science. International Journal of Nursing Studies 47,1:123-128	2010
Bradbury-Jones, C., Irvine, F. & Sambrook, S.	Phenomenology and participant feedback: convention or contention?. Nurse Researcher 17,2:25-33.	2010
Bradbury-Jones, C., Sambrook, S. and Irvine, F	The phenomenological focus group: an oxymoron?. Journal of Advanced Nursing 65,3:663-671.	2009
Casey, D. & Houghton, C.	Clarifying case study research: examples from practice. Nurse Researcher 17,3:41-51.	2010
Chen, H.Y. & Boore, J.R.	Using a synthesised technique for grounded theory in nursing research. Journal of Clinical Nursing 18,16:2251-2260.	2009
Christie, J., O'Halloran, P. & Stevenson, M.	Planning a cluster randomized controlled trial: methodological issues. Nursing Research 58,2:128-134.	2009
Davis, R.L.	Exploring possibilities: virtual reality in nursing research. Research & Theory for Nursing Practice 23,2:133-147.	2009
Ghezeljeh, T.N. & Emami, A.	Grounded theory: methodology and philosophical perspective. Nurse Researcher 17,1:15-23.	2009
Goodwin, V. & Happell, B.	Seeing both the forest and the trees: a process for tracking individual responses in focus group interviews. Nurse Researcher 17,1:62-67.	2009
Guise, V., Chambers, M., Valimaki, M., et al.	A mixed-mode approach to data collection: combining web and paper questionnaires to examine nurses' attitudes to mental illness. Journal of Advanced Nursing 66,7:1623-1632.	2010
Hagquist, C., Bruce, M. & Gustavsson, J.P.	Using the Rasch model in nursing research: an introduction and illustrative example. International Journal of Nursing Studies 46,3:380-393.	2009
Henly, S.J., Wyman, J.F. & Findorff, M.J.	Health and illness over time: the trajectory perspective in nursing science. Nursing Research 60,3 Suppl:S5-14.	2011
Hernandez, C.A.	Getting grounded: using Glaserian grounded theory to conduct nursing research. Canadian Journal of Nursing Research 42,1:150-163.	2010
Hunter, A., Murphy, K., Grealish, A., et al.	Navigating the grounded theory terrain. Part 1. Nurse Researcher 18,4:6-10.	2011

Author	Title	Year
Lash, A.A., Plonczynski, D.J. & Sehdev, A.	Trends in hypothesis testing and related variables in nursing research: a retrospective exploratory study. Nurse Researcher 18,3:38-44.	2011
MacDonald, S.E., Newburn-Cook, C.V.,Schopflocher, D., et al.	Addressing nonresponse bias in postal surveys. Public Health Nursing 26,1:95-105.	2009
Mack, R., Giarelli, E. & Bernhardt, B.A.	The adolescent research participant: strategies for productive and ethical interviewing. Journal of Pediatric Nursing 24,6:448-457.	2009
McConnell-Henry, T, James, A., Chapman, Y, et al.	Researching with people you know: issues in interviewing. Contemporary Nurse 34,1:2-9.	2009
Moore, J.	An exploration of the origin of classic grounded theory. Nurse Researcher 17,1:8-14.	2009
Polit, D.F & Gillespie, B.M.	The use of the intention-to-treat principle in nursing clinical trials. Nursing Research 58,6:391-399.	2009
Polit, D.F., Gillespie, B.M. & Griffin, R.	Deliberate ignorance: a systematic review of blinding in nursing clinical trials. hypothesis testing and related variables in nursing research: a retrospective exploratory study. Nurse Researcher 18,3:38-44.	2011
Pringle, J., Hendry, C. & McLafferty, E.	Phenomenological approaches: challenges and choices. Nurse Researcher 18,2:7-18.	2011
Roberts, T.J. & Ward, S.E.	Using latent transition analysis in nursing research to explore change over time. Nursing Research 60,1:73-79.	2011
Sadler, G.R, Lee, H.C, Lim, R.S.et al.	Recruitment of hard-to-reach population subgroups via adaptations of the snowball sampling strategy. Nursing & Health Sciences 12,3:369-374.	2010
Shaha, M., Wenzel, J. & Hill, E.E.	Planning and conducting focus group research with nurses. Nurse Researcher 18,2:77-87.	2011
Shin, J.H.	Application of repeated-measures analysis of variance and hierarchical linear model in nursing research. Nursing Research 58,3:211-217.	2009
Shin, J.H. & Scherer, Y.	Advantages and disadvantages of using MDS data in nursing research. Journal of Gerontological Nursing 35,1:7-17.	2009
Su, X., Azuero, A., Cho, J., et al.	An introduction to tree-structured modeling with application to quality of life data. Nursing Research 60,4:247-255.	2011
Vedelo, T.W. & Lomborg, K.	Reported challenges in nurse-led randomised controlled trials: an integrative review of the literature. Scandinavian Journal of Caring Sciences 25,1:194-200.	2011
Wu, H.L. & Volker, D.L.	The use of theory in qualitative approaches to research: application in end-of-life studies. Journal of Advanced Nursing 65,12:2719-2732.	2009

The following tools/ resources are available from **any PC on the NHS network** (via the Library Applications Website http://ascweb/library)

- ATLAS-ti: a qualitative data analysis tool
- SPSS: Statistical analysis
- Reference Manager: Bibliographic reference management software
- Mind Manager: Visual mind mapping tool

In addition, for Beatson WoSCC staff only, the middle PC in the library (Education Suite, on Level 0) has a direct access to SPSS software. Please see the librarian for assistance.

If you are a member of NHSGGC and Associated staff you can request books, journal articles, conference papers, reports and other documents which are not held in your local library's own collections. You will be asked if you have checked our catalogue and the Knowledge Network holdings first, and will be asked to sign and return a copyright declaration form for articles and book chapters - please do this as this is a legal requirement. Please use our Document Delivery and Inter-Library Loans Service at: http://www.gglss.scot.nhs.uk

We offer a range of updating services for NHSGGC and Associated staff. Our current awareness options include a range of bulletins on specific topics, contents pages from your favourite journals, regular email topic updates and the provision of reading lists to support in house courses, conferences and study days. More details are available from your local library or on the Library Network Website at http://www.nhsggc.org.uk/libraryservices

An expert literature search service is provided by library staff for NHSGGC and associated staff. If you have a question, we can help you find the right answer**.** If you need information for patient care, standards, guidelines, research, professional updating, or writing for publication, we can search a number of sources and provide you with a list of references, which can include journal articles, books and web sites, depending on your requirements.

Results for literature searches will normally be provided in 1-2 weeks depending on how thorough a search you require; enquiries can usually be answered more quickly and you should always advise us if you need results urgently. A search request can be made via your local Library or at http://gglss.scot.nhs.uk

Training & eLearning

The Library Network provides information skills training, trainer support, and participates in literacies support. The Library Network can also refer staff to learning opportunities provided by the Learning and Education Department. These services are available to all NHSGGC and Associated staff.

Examples of training provided include using the NHS Knowledge Network (www.knowledge.scot.nhs.uk), basic database searching, advanced database searching, using Refworks, accessing full text online journals and Critical Appraisal. **Training can also be provided on a one-to-one or group basis upon request.** For details of forthcoming training sessions please contact any of the following:

The NHSGGC Library Network website:
http://www.nhsggc.org.uk/libraryservices

The NHSGGC Library Network pages on Staffnet:
http://staffnet/Info+Centre/Library/Default.htm

Individual library contact numbers

Beatson West of Scotland Cancer Centre Library	Tel: 0141 301 7283
Gartnavel General Hospital Library	Tel: 0141 211 3013
Gartnavel Royal Hospital Library	Tel: 0141 211 3913
Glasgow Royal Infirmary Library	Tel: 0141 211 5975
Royal Alexandra Hospital Library	Tel: 0141 314 7178
Inverclyde Royal Hospital Library	Tel: 01475 504402
Southern General Library	Tel: 0141 201 2163
Stobhill ACH Library	Tel: 0141 355 1684
Vale of Leven Hospital Library	Tel: 01389 603843
Victoria ACH Library	Tel: 0141 347 8885
Western Infirmary Library	Tel: 0141 211 2472
Yorkhill Hospital Library	Tel: 0141 201 0794

If you need assistance with computer training, use of word documents and templates or other issues that are relevant to your study, please contact: the eHealth Trainer (BWoSCC) on 0141 301 7797. If from elsewhere, please ask your own organisation if there is an individual with a similar role whom you can contact.

Choosing the appropriate method and design

Once you have read and appraised the literature on your topic, you should have a good idea of any gaps that will help you identify your research question(s). Your research question will determine the design and the most appropriate method for your study, and if this will require a qualitative, quantitative or mixed (both) approach. As the majority of student (nursing) research however, tends to be qualitative, this handbook focuses mainly on related design, methodology, and analysis.

Research objective	Research design
• describe a phenomenon	descriptive
• explain why a relationship exists	explanatory
• test a phenomenon	experimental
• explore a relationship between phenomena	correlational
• predict a phenomenon	inferential

Qualitative Methods

- Qualitative researchers usually work inductively rather than deductively, as in experimental or quantitative research where a priori hypotheses are set and tested.
- Samples of participants are usually purposefully selected on grounds of convenience for example, rather than randomised as in experimental research
- In most qualitative studies, the central key problems are to identify what individuals do, experience, feel, behave etc and how structure and relationships influences the culture, situation, phenomenon or event (if it does).
- Interviews and various forms of observation are most commonly used methods of data collection.
- Data involves words, symbols and text (field notes, interview transcripts, diaries).
- Qualitative research often contains detailed descriptions of participants, as well as both the physical and social context within which data collection takes place (mostly in the naturalistic 'field'- the place where the phenomenon can be observed taking place, although this can also be observed in a lab-based setting).
- Qualitative studies frequently involve triangulation of data (different sources and / or different methods) to allow information to be crosschecked and establish validity of sources and data.
- Qualitative researchers need to be aware of their own perspectives, values, opinions, and biases. Any bias must be declared and controlled if results are to be accepted as truthful by others.

How to write a study proposal

Once you have decided on the topic, design and methods for your study, you will need to produce a written framework or outline of your project. This is called a research proposal. The fundamental requirement of any research project is a good research proposal. This document should define what your project is about, the aims and objectives, and methods of data collection and analyses that will be used- in other words, a concise summary. A research proposal is required for various reasons, including applications for:

- Funding
- University departmental ethics approval (degree requirements)
- In-house study approval
- NHS Research Ethics Committee approval
- NHS R&D Management approval

Your proposal forms an action plan and contractual agreement between the student and supervisor, student and university R&D officer, investigator (university) and NHS research ethics committee (or other funding source). Some key issues to consider are:

- Use a template where this is provided.

Different templates might be required for different organisations/ committees. This may require cutting and pasting information or adapting the length and content of information. Always check if you use the cut and paste facility that you read it to make sure it makes sense and answers the question fully as mistakes are often made here. Protocol templates for studies sponsored by Greater Glasgow and Clyde can be obtained from the R&D Central Office (GG&C).

- Keep it short.

Do not give more information than is necessary. Identify your key constructs as early as possible in the proposal and indicate its importance to theory or practice by providing a short, concise rationale of your study. Remember you can always include a copy of your full-length proposal/ protocol with your application form.

- Keep it simple

Ensure all jargon is written in simple language and lay man terms. If you use abbreviations or acronyms etc. ensure it is written in full the first time you use it. Thereafter, it is general practice to use the abbreviation.

What should be in a proposal?

- Full and short title
- A definition and/ or incidence of the problem
- Background information and a description of the problem
- Justification and rationale for conducting the study
- Aims of the study (primary and/ or secondary)

- The research question(s)
- Description of your study design and methods
- Sample (includes justifications for selection and size)
- Inclusion and exclusion criteria
- Potential risks and benefits
- Duration of participation
- Criteria for discontinuation
- Methods: how data will be collected
- Methods: how data will be analysed, including statistical information if appropriate
- How data will be stored and/ or destroyed
- Indemnity (NHS employed researchers covered for negligent harm, otherwise insurance required)
- Ethical considerations
- Confidentiality, anonymity and privacy
- Contact details
- Funding information (if relevant)
- How results will be disseminated
- References
- Appendices (consent forms, information sheets, cover letters, posters, observation templates, interview questions etc)
- Version number and date (all pages)

Where studies involve NHS patients or staff, you will be required to provide information about your study to enable potential participants to make an informed decision about whether or not to participate. Therefore you require a patient information sheet or, as it is often referred to, the PIS. You will also be required to prepare a consent form for participants who decide to take part in your study to sign. There are exceptions where a formal consent is not required and implied consent is enough. For example, returning a questionnaire can be taken as implied consent since if you did not return it, you chose not to take part. For most research however, this is a legal requirement and good clinical practice.

How to prepare a study PIS: participant information sheets
The information on this page is based upon the document 'Explaining Research', which can also be accessed from www.nres.npsa.nhs.uk/rec-community/guidance The length and content of the PIS should be dictated by the complexity and risk involved in your research study. Where appropriate, the information sheet could be divided into two parts.

Part One should allow the participant to decide whether the study is of interest to them; part two should provide further information. However, if your study is a simple qualitative design you may find that many of the suggested headings are inappropriate or irrelevant and could be presented in one part. Caution is advised when doing this: discuss with your supervisor to ensure you have not excluded any information that might cause concern upon ethics committee review.

PIS: Part one

This should provide brief, clear information on the essential elements of your study such as:

- condition or treatment under study
- voluntary nature of involvement
- what will happen during and after the trial
- any treatment that will be withheld or different to standard care
- participant's responsibilities
- potential risks
- inconvenience or restrictions
- advantages and disadvantages

PIS: Part two

This should contain additional information on other factors such as:

- confidentiality and data protection
- communication with the GP (where appropriate)
- indemnity and compensation
- how to complain about the conduct of the researcher(s)or management of the study
- how results will be disseminated or published

In qualitative research, as in traditional quantitative research, it is important to provide potential participants to your study with adequate and concise information to enable them to make a fully informed decision and provide consent. Information should be presented in an open, invitational style, using non-technical or jargon-free language. Choose a font style and size consistently throughout to make it easy to read. The following are examples of how the PIS and Consent Form should look. Please note these are examples only and will require modifications to fit the design/method of your own study. All documentation should display the study title at top of headed paper with contact details, logo etc. The current version number and date should be at the foot of the page.

Participant information sheet: Suggested headings and format

Title
Avoid a long-winded title. Keep it concise and user-friendly. Your title should be appropriate for the content and design of your study.

Introduction
Introduce yourself and say you are the CI carrying out the above research. The wording must be invitational such as *"we would like to invite you to take part in…"*

What is the study about?
Give a brief and concise summary of what the research is about. Avoid repetition.

What is the purpose of the research?
Say why you are carrying out the research. Avoid lengthy explanations- keep as brief as possible.

Why have I been invited?
You should explain briefly why and how the participant was chosen or selected and how many others will be in the study.

Do I have to take part?
Say 'No' to this. You should explain that it is completely voluntary and that should they decide during the research they wish to stop, then they are free to withdraw consent. Explain that all data gathered up to that point should either be kept (with consent) or destroyed if they wish.

What will happen if I agree to take part?
Explain what will be involved, i.e. interviews, questionnaires, for how long and where etc and whether interviews will be taped and anonymised quotes used etc. Also state that taking part will not affect current standard care etc.

Will my taking part in the study be kept confidential?
Say Yes to this. State who will have access to the information and how it will be kept private. State how information provided by the participant will be anonymised, coded and stored. In other words, stress anonymity and confidentiality.

Will my GP being informed that I am taking part? (only if patients are involved)
Yes – if we think it would be helpful although you would be asked to consent to this.

Will I receive payment or expenses?
If you intend to reimburse participants or provide incentives then this statement should be included and it should state the sum and explain that it is to cover out of pocket expenses.

Are there risks or benefits to taking part?
Explain any risks, discomfort, or inconvenience. If there is a likelihood that any aspect of the study may cause upset or distress, make sure you have contingency plans for dealing with this should it occur or be expected to occur (eg., access or referral to an independent person or counsellor) Where there is no intended clinical benefit, this should be stated clearly *"While the study will not help you directly, the information we get from the study will help improve the treatment or care of people with (condition etc)*

How do I complain?
To the researcher in the first instance *"If you have a concern about any aspect of this study, you should speak to the researchers who will do their best to answer your questions. If you remain unhappy and wish to make a formal complaint you can do this through the normal NHS complaints procedure".* Provide contact details to enable the person to do this.

What will happen to the results of the study?
Explain what is happening to the results. You may wish to give a copy etc if appropriate. Remember and mention the participant will not be able to be recognised personally from any quotes etc used in publications.

Who is funding the Research?
State who if this is appropriate

Who has reviewed the study?
Usually the name of the ethics committee, together with any similar in-house peer review committee (where appropriate) is given and you should state that a favourable opinion has been given etc. *"All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by _(title here)_ Research Ethics Committee"*

What do I do now?
Usually here it is stated that they sign a reply form saying they wish to take part and send back in a stamped addressed envelope or telephone the Research Assistant (contact details to be given), or whichever process is required for consent. State that a copy of the PIS and a signed copy of the consent will be returned to them for personal reference.

Who do I contact if I wish to complain?
Give details here about how the participants can complain. Usually someone independent in the first instance but if not resolved then the NHS Complaints System would apply when it is NHS research.

How can I find out more?
Give details of the research team where further advice can be sought (contact details to be included) or contact details of an appropriate individual for independent , impartial advice.

Insert contact address and telephone number here

Thank you for reading this information

Consent Form: Suggested headings and format

Study Number (if needed):
Patient Identification Number:

NHS
Greater Glasgow and Clyde
(insert own logo here)

CONSENT FORM

Title of Project:

Name of Researcher:

Please initial box

1. I confirm that I have read and understand the information sheet dated..xx/xx/xxxx..... (version.X) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from [company name], from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐

4. I agree to my GP being informed of my participation in the study ☐

5. I agree to take part in the above study. ☐

_____	_____	_____
Name of Patient	Date	Signature

_____	_____	_____
Name of Person taking consent	Date	Signature

When completed, 1 for patient; 1 for researcher site file; 1 (original) to be kept in medical notes

(Please use additional boxes where necessary for recording interviews etc, etc)**

Checklist

1. Have I identified and prioritised the clinical, psychological, social, and other problem(s), taking into account the patient's perspective?

2. Have I performed a sufficiently competent and complete examination to establish the likelihood of competing and influencing factors?

3. Have I considered additional problems and risk factors that may need opportunistic attention?

4. Have I, where necessary, sought evidence (from systematic reviews, guidelines, clinical trials, and other sources) pertaining to these problems.

5. Have I assessed and taken into account the completeness, quality, and strength of the evidence?

6. Have I applied valid and relevant evidence to this particular set of problems in a way that is both justified and sensible?

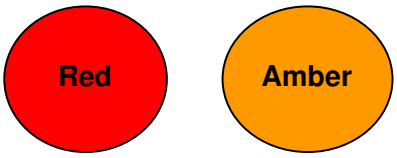
7. Have I presented the pros and cons and other information in a way that a lay person can understand?

8. Have I arranged review, recall, referral, or other further care as necessary?

9. Have I fulfilled the desired criteria as instructed to meet university, organisation, R&D, and NHS ethics requirements?

10. Have I secured a sponsor to indemnify my project?
    - For students the sponsor will be your University
    - For NHS research, the sponsor will be the NHS R&D Office.
    - For funded projects, the sponsor will be the Funder.

CHAPTER 2: NORMING



Approving the study and methodology

Knowing who to contact and when is often a source of confusion for individuals new to research, and can be particularly daunting for students. Within the Beatson WoSCC, there is a defined peer review process for reviewing research projects. Although this process is associated with the Clinical trials Unit (CTU) and is largely accessed for clinical trials, the process is the same for smaller studies. This should not be viewed negatively. On the contrary, this process ensures your study is subjected to a rigorous critique, and makes you think about your study in more depth. If there are any issues of concern not only will they be raised with you, but you may also be offered guidance and advice on how to improve or tighten up your study. This means that by the time you are at the stage of attending an ethics meeting you will be better prepared and can answer questions that may arise or are revisited.

In-house review and approval process

Once your proposal is completed, you may need to apply for organisational approval to proceed. In the BWoSCC, this may require submitting your study proposal to the In-House Trials Advisory Board (IHTAB) for peer review. If approved, this decision needs to be subsequently ratified by the Clinical Trials Executive Committee (CTEC). You must submit to CTEC before proceeding to any NHS REC and R&D.

IHTAB

This review acts as a support and screening mechanism for all new research to be conducted within the Beatson WoSCC that will involve active support and resources (such as statistical help) from the Clinical Trials Unit. You will be expected to attend this committee meeting to provide information about your study, answer any questions, and receive constructive feedback. Researchers are required to complete the 'outline proposal for a clinical trial' on the CTU portal. There are no formal meeting dates arranged for IHTAB meetings as these are convened as and when submissions are received. Please contact the clinical trials unit reception office for details of appropriate contact person to whom a submission should be sent. See appendix 3 for the current policy.

CTEC

For all other studies involving patients at the BWoSCC, including student research *(or if your study fits has been submitted and received approval from IHTAB)* , you must submit to CTEC to ratify your study, before proceeding to any NHS REC. You will not need to attend this meeting in person. The committee meets on a monthly basis and submissions must be made 2 weeks in advance of the meeting. Current dates can be accessed from the homepage of the Clinical Trials Unit portal. See appendix 4 for the current policy.

How do I do this?
Electronic forms and other specific information such as who to contact to book in your project for any of the above committees can be accessed in full from the CTU portal http://www.crukctuglasgow.org or by contacting the trials unit directly:

Cancer Research UK Clinical Trials Unit, Glasgow
Level 0
Beatson West of Scotland Cancer Centre
1053 Great Western Road
Glasgow G12 0YN

Tel: 0141 301 7174/ 7178 (internal extension -57174 / 57178)

NHS Research Ethics Committee review/approval process

Once you have received a letter confirming approval from IHTAB and/ or CTEC, you can proceed to have your study reviewed by an NHS Research Ethics Committee using the Integrated Research Application System (IRAS). This can be accessed from www.myresearchproject.org. Full instructions, support, and an online tutorial, are also provided to assist you on the IRAS online web pages.

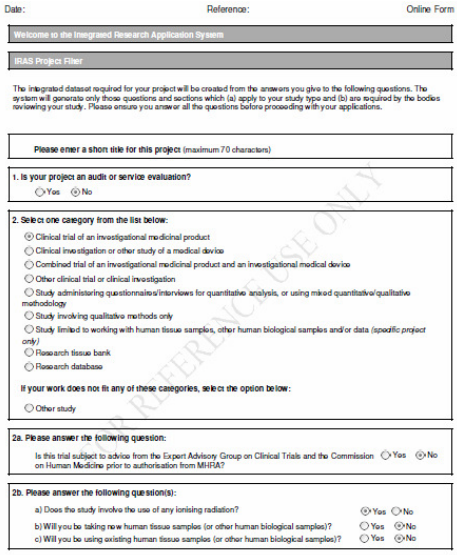
You may ask for your study to be reviewed by any REC in Scotland. There are four NHS RECs in the West of Scotland regional services (WOSRES), which can review most study types. The meeting dates of all NHS RECs are listed on the NRES website and contact details for the committee coordinator, can also be found here or refer to Appendix 5 for initial guidance.

How to use IRAS

Open the home page on www.myresearchproject.org.uk. If you have used the previous NRES form system you can use the same login and password. If you do not have a login you can request one from the login page.

1. The first screen is headed "My Projects". This screen will show all the projects you set up.
2. Click on "Create New Project". This takes you to the Project Filter page. Complete the project filter according to the type of application you wish to view. Clicking on some of the options will alter the questions in the project filter.
3. Completing the project filter (Figure 2) customises the form according to type of research project, disabling questions and sections that are not relevant. Therefore it is very important to answer the filter questions correctly.

Figure 2 : Project filter screenshot



Date: Reference: Online Form

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please enter a short title for this project (maximum 70 characters)

1. Is your project an audit or service evaluation?
○ Yes ◉ No

2. Select one category from the list below:
◉ Clinical trial of an investigational medicinal product
○ Clinical investigation or other study of a medical device
○ Combined trial of an investigational medicinal product and an investigational medical device
○ Other clinical trial or clinical investigation
○ Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
○ Study involving qualitative methods only
○ Study limited to working with human tissue samples, other human biological samples and/or data *(specific project only)*
○ Research tissue bank
○ Research database

If your work does not fit any of these categories, select the option below:
○ Other study

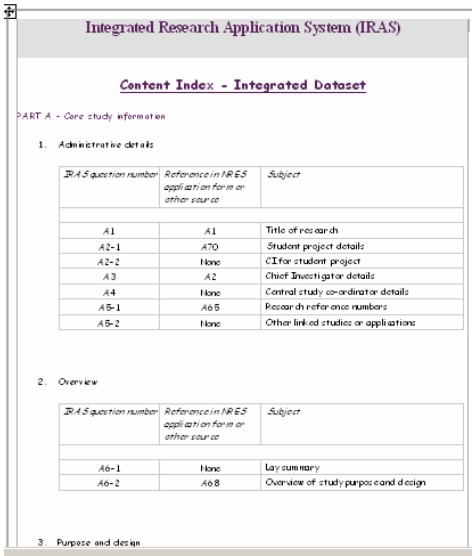
2a. Please answer the following question:
Is this trial subject to advice from the Expert Advisory Group on Clinical Trials and the Commission on Human Medicine prior to authorisation from MHRA? ○ Yes ◉ No

2b. Please answer the following question(s):
a) Does the study involve the use of any ionising radiation? ◉ Yes ○ No
b) Will you be taking new human tissue samples (or other human biological samples)? ○ Yes ◉ No
c) Will you be using existing human tissue samples (or other human biological samples)? ○ Yes ◉ No

4. Now click on "Navigate" at the bottom of the screen. You will see that the forms you need to submit (REC, R&D, MHRA etc) are listed on the left hand side. When you select any of these forms, the questions and sections enabled in IRAS for that form are displayed on the right hand side.

5. Complete the integrated dataset (Figure 3), as this will populate all the relevant forms for your project. Click on the link under Full Set of Project Data and then click on A1 in the navigation table on the right. You can now complete questions and move through the screens using the 'Next' buttons.

Figure 3: Integrated dataset screenshot



Integrated Research Application System (IRAS)

Content Index - Integrated Dataset

PART A - Core study information

1. Administrative details

IRAS question number	Reference in NRES application form or other source	Subject
A1	A1	Title of research
A2-1	A70	Student project details
A2-2	None	CI for student project
A3	A2	Chief Investigator details
A4	None	Central study co-ordinator details
A5-1	A65	Research reference numbers
A5-2	None	Other linked studies or applications

2. Overview

IRAS question number	Reference in NRES application form or other source	Subject
A6-1	None	Lay summary
A6-2	A68	Overview of study purpose and design

3. Purpose and design

6. If you start with one form and complete the answers in that form, then the same questions in other forms will be completed at the same time. You can access other forms and their navigation tables at any time by clicking on "Navigate". You can access question-specific guidance by clicking the button alongside a question.
7. For research involving the NHS, Site-Specific Information Forms must be created and completed for each site, in addition to the study-wide forms.

An online USER MANUAL is available for download from the IRAS online pages. If you require technical help with aspects of using the on-line form, you can email the IT Helpdesk at: helpdesk@infonetica.net.

Proportionate Review

The proportionate review service is designed to ensure an appropriate level of ethical review for low-risk studies and is currently being piloted. Where a study presents 'no material ethical issues' (involving minimal risk, burden or intrusion for participants), it can be reviewed and approved by a proportionate review sub-committee on behalf of the REC. Whereas a full REC meeting consists of up to 18 members, the sub-committee consists of 3 members (including one lay member). The aim is to review the application within 10 working days of receipt of a valid application, either at a meeting or by correspondence. The decision letter should be received within the 10-day timeline. However, the sub-committee can still refer the application to the full REC for consideration if it deems there are material ethical issues requiring further consideration. If this happens, the usual 60-day timescale would apply.

What are 'no material ethical issues'?

The following guide indicates suitability for proportionate review according to research type:

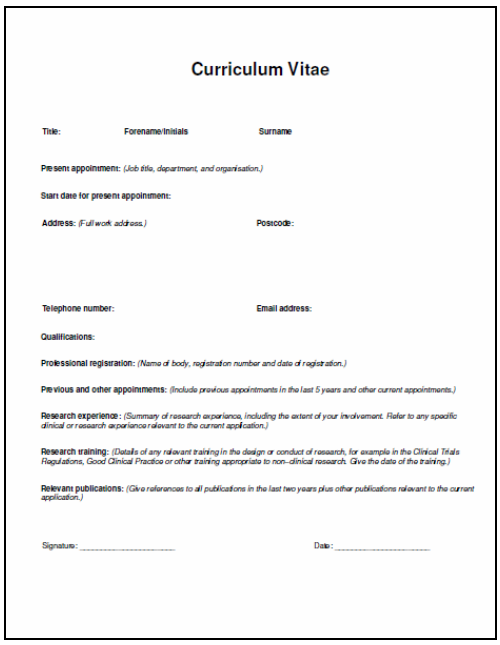
- *research using data or tissue that is anonymous to the researcher*
- *research using existing tissue samples already taken with consent for research*
- *research using 'extra tissue' (eg further blood taken at time of routine sampling or tissue taken at a clinically directed operation)*
- *questionnaire research that does NOT include highly sensitive areas or where accidental disclosure would NOT have serious consequences*
- *research surveying the safety or efficacy of established non-drug treatments, involving limited intervention and NO change to the patients' treatment*

You can view this tool on the NRES website. If you think your research project fits this criteria, tick the relevant box on the IRAS form and submit as normal.

Notes for Students

All applications student or otherwise should enclose a research protocol or equivalent document describing the objectives, design, methodology, statistical considerations (or other methods of data analysis) and organisation of your research study. Details of the student, educational course and academic supervisor should be provided at A2-1 in the IRAS application. A copy of a current CV for the CI (maximum 2 pages of A4) must be submitted with applications to the REC and R&D office(s). In the case of student research, a copy of the project proposal or assignment is also considered appropriate. It too should carry a date and version number in case it is necessary to make changes following review or during the project.

Figure 4: Curriculum Vitae Form



Curriculum Vitae

Title: **Forename/Initials** **Surname**

Present appointment: *(Job title, department, and organisation.)*

Start date for present appointment:

Address: *(Full work address.)* **Postcode:**

Telephone number: **Email address:**

Qualifications:

Professional registration: *(Name of body, registration number and date of registration.)*

Previous and other appointments: *(Include previous appointments in the last 5 years and other current appointments.)*

Research experience: *(Summary of research experience, including the extent of your involvement. Refer to any specific clinical or research experience relevant to the current application.)*

Research training: *(Details of any relevant training in the design or conduct of research, for example in the Clinical Trials Regulations, Good Clinical Practice or other training appropriate to non-clinical research. Give the date of the training.)*

Relevant publications: *(Give references to all publications in the last two years plus other publications relevant to the current application.)*

Signature: _____ Date: _____

- Students below doctoral level

If your project is to be undertaken as part of an undergraduate or Masters level award, answer No to Question 9a. As the student, you should complete the application, but your academic supervisor becomes the CI and therefore has to complete both the CI and supervisor declarations in Part D. The REC will invite the student to attend the meeting to answer questions about the study and will address all correspondence to the student (copied to the CI). (Supervisors are also encouraged to attend the meeting.) If a favourable opinion is given by the REC, it is expected that the student will actually undertake the research under supervision by the CI.

- Doctoral students

If your project is to be undertaken as part of a PhD or other doctorate, answer Yes to Question 9a. It is normally expected that a doctoral student undertaking a project will be named as the CI rather than the academic supervisor. However, in some cases it may be

more appropriate for a clinical supervisor to take on the role of CI for a project undertaken by a doctoral student, especially where the study in question may involve significant risk.

- Student participation in other studies

Where the student is participating in a project that is not purely educational, the CI may be another experienced researcher such as a health professional or academic researcher.

Declaration by academic supervisor

Under the Research Governance Framework, academic institutions sponsoring research within the NHS are responsible for ensuring that students are properly supported and supervised in the conduct of research. Your academic supervisor should sign the declaration in Part D3 of IRAS to provide assurance these requirements will be met.

Role of the sponsor

For any research that takes place in the NHS (Scotland) there must be a sponsor. The sponsor will normally be one of the organisations taking the lead for particular aspects of the arrangements for the study.

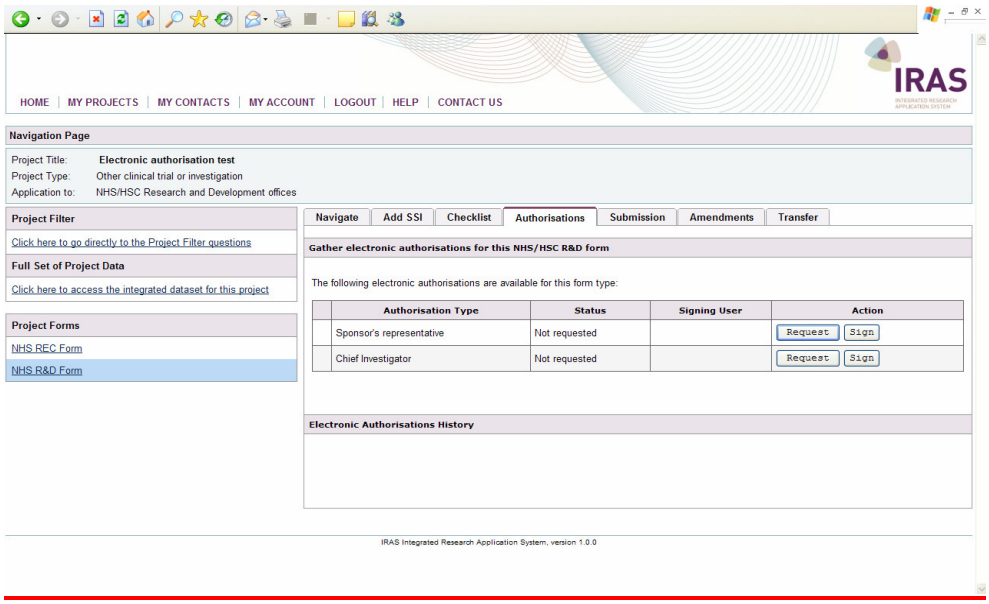
The sponsor may be the Chief Investigators' employing organisation, the lead organisation providing healthcare, or the main funding body. NHS GG&C can act as sponsor in a study where the CI is an NHS GG&C employee or in a study that involves NHS GG&C patients, staff, or resources. For more information on sponsorship, please contact your R&D Research Coordinator.

Electronic authorisations in IRAS

IRAS now offers the facility for electronic authorisations as an alternative to ink signatures on hard copies and allows Principal Investigators, experts, sponsors, educational supervisors, etc to "sign" declarations by giving an authorisation on a form generated through IRAS. This can then be transferred under secure conditions to the recipient (authoriser). Once a transfer is requested, IRAS will mail the recipient to notify them when a review of the project and the signature is required. R&D can accept electronic transfers in order for the coordinator to review forms and protocols prior to signing off your study as sponsor.

Applicants must obtain the relevant authorisations before selecting "Proceed to Submission". If you need to make any changes after authorisation, the authorisation becomes invalid; meaning any altered forms would not be accepted for submission.

Figure 5: Electronic Authorisation Screenshot



DOUBLE CHECK:

1. Has the IRAS form for your project signed off by:
   - Head of department (University or NHS)

   Responsible for signing off any study conducted in the relevant directorate. (For BWoSCC, this will be the Clinical Director)

   - Support department (Clinical)

   For BWoSCC nursing, and especially where this involves the researcher undertaking research with patients, this will be the lead nurse or deputy. For AHP, Pharmacy, Radiotherapy, or any other support department required please approach the relevant lead for the department for authorisation signature.

   - R&D department

   Academic coordinator signing as sponsor representative

   - Academic supervisor

   Responsible for supervising as part of academic qualification

If you are not an employee of GG&C NHS, you or your supervisor will need to apply for a research passport. This provides an honorary contract with GG&C NHS or a 'letter of access' if you have already have a NHS contract with another Health Board.

If you are an employee of GG&C but are also including NHS sites outside the GG&C area, you will need to apply to a research ethics meeting that deals with multi-site applications (MREC). Advice can be found on IRAS Online under 'guidance for applicants'.

NHS R&D offices –the SSI Form

The SSI (site-specific information) Form is a joint-purpose form and provides the R&D office with specific details of the resource involved in the research project at a specific site. Every study requires an SSI form to be completed, for multi-centre studies an SSI for each site can be generated within one project in IRAS. The documents in the checklist for the R&D Form must also be submitted in accordance with the instructions in the submission tab. The R&D Form (both PDF and XML copies) should be included in your application to the R&D office along with the SSI Form and all other supporting documentation as indicated in the checklist. Contact details for R&D offices are available from http://www.rdforum.nhs.uk or R&D GG&C website at www.nhsggc.org.uk/r&d.

For multi-centre research in Scotland, NHS Research Scotland (NRS permissions Coordinating Centre http://www.nhsgrampian.org/nrscc) provides coordination in obtaining NHS permission from the Health Boards involved. CIs should submit the R&D Form to the coordinating centre in accordance with the instructions provided in the R&D Form submission tab.

Make sure your form is correct and requires no further amendments. It is best to complete a checklist to ensure you have all the required and accurate documentation. Please take time to go through checklists (Table 3) and (Table 4) carefully.

NHS R&D management approval

All research conducted within the NHS must have R&D management approval. The R&D approval process ensures:

- an appropriate study sponsor is identified
- the scientific quality of the proposal (as required)
- there is a favourable ethical opinion from an appropriate REC
- appropriate regulatory authorisations are in place
- appropriate risk/benefit analysis
- provisions for appropriate insurance/indemnity
- financial and resource implications of the study are assessed
- all researchers have substantial or honorary NHS GG&C contracts
- all researchers are adequately qualified
- support department approval
- formal agreements or contracts with any external bodies (if appropriate) meet requirements of the Board.

Table 3: Checklist for REC Form

Document Title
Covering letter on headed paper
REC application (IRAS Parts A-D)(signed/authorised copy)
Site-Specific Information Form - only if study requires SSA and main REC is also the SSA REC for a non-NHS research site (signed/authorised copy)
Research protocol or project proposal (6 copies)
Summary CV for Chief Investigator (CI)
Summary CV for supervisor (student research)
Summary CV for student(signed/authorised copy)
Research participant information sheet (PIS)
Research participant consent form
Letters of invitation to participants
Only required if appropriate to design of your study:
Referees' or other scientific critique report (can be helpful)
Statement of indemnity arrangements
Letter from sponsor
GP/Consultant information sheets or letters
Letter from statistician
Letter from funder
Summary, synopsis or diagram (flowchart) of protocol in non-technical language
Interview schedules or topic guides for participants
Validated questionnaire
Non-validated questionnaire
Copies of advertisement material for research participants, e.g. posters, newspaper adverts, website. For video or audio cassettes, please also provide the printed script.
Instructions for use of medical device

Table 4: Checklist for NHS R&D / SSI-Site specific form

Document Title
R&D Application (IRAS Parts A-D) (signed/authorised copy)
Site-Specific Information Form (signed/authorised copy)
Summary CV for Chief Investigator (CI)(signed and dated)
Summary CV for Principal Investigator (PI) (signed and dated)
Research protocol
Research participant information sheet (PIS)
Research participant consent form
Letters of invitation to participant
GP/consultant information sheets or letters
Evidence of insurance or indemnity (non-NHS sponsors only)
Letter from statistician if appropriate
Letter from funder if appropriate
Referees' or other scientific critique report(s) (eg, IHTAB)

Summary, synopsis or diagram (flowchart) of protocol in non-technical language (can be very helpful to your submission)
Interview schedules or topic guides for participants
Validated questionnaire
Non-validated questionnaire
Copies of advertisement material for research participants, e.g. posters, newspaper adverts, website. For video or audio cassettes, please also provide the printed script.
Printed R&D form and SSI form
Documents required prior to final NHS permission (may be submitted after the initial application)
Written final confirmation from the organisation(s) acting as sponsor
REC favourable opinion letter and all correspondence
Confirmation of REC favourable opinion for any substantial amendments

Final submission using IRAS

Once you are satisfied all documentation is complete you should click on the "*Proceed to Submission*" option listed under 'Submission'. Your application history will now be saved in IRAS and will generate a submission or reference code, which will appear at the foot of each page of the form for reference. You will then be able to save and/or print the completed form for submission. **NB: selecting Proceed to Submission does not actually submit your application to the reviewing organisation**. If you need to amend the application subsequently, selecting Proceed to Submission will save a new version and generate another submission code. To print an application form for review *prior to submission*, use the Print option within the form or under the Save/Print tab."

Ensure you have also printed off the R&D and SSI forms for your R&D submission, which should be submitted to R&D in parallel with your Ethics submission. Since 1st September 2010, R&D will only accept electronic submissions (XML versions of R&D/ SSI forms).

IRAS will allocate a reference number for your application and will confirm in writing the subsequent process involved. All subsequent documentation should bear this reference as this becomes your personal study identifier. Remember to include appendices such as patient information sheet (PIS), consent Forms, GP letters, questionnaires, interview questions, as well as any advertisements such as posters, flyers etc. Finally, remember to include a copy of your study protocol/ proposal. Ensure each appendix has the correct version number and date displayed. Now you are ready to send your documentation to the NHS Ethics Committee and to the relevant R& D department (local R&D if one site involved, NHS National Coordinating Centre for multiple sites)

Booking in your study and attending a Research Ethics Committee Meeting (REC)

Research projects undertaken as part of a course of study must undergo the same review process as other research projects. Applications from students will be subjected to the same standard of ethical, management, and/or regulatory review as all other research proposals. Once you decide which Committee you wish to submit your application to (preferable local

WOSRES or if you have no real preference, the next available committee meeting, wherever that is located in the UK), you will need to complete the checklist, check there are no omissions and that you have all the necessary signatures. You must ensure that your application is ready to submit when you telephone to book a slot for ethical review. Only then should you contact the REC.

Once ready to submit, you should telephone either your local REC office (WOSRES 0141 211 1722/ 2123) or the Central Allocation System (CAS). Details are also on NRES online When you phone the WOSRES office direct the coordinators will advise of the next available meeting within the West of Scotland (0141 211 1722/2123). Complete applications must be with the WOSRES office two weeks before the meeting date. A printed copy of Scotland REC meeting dates can be found in the appendices of this handbook. However, since these are subject to change at any time, please confirm the meeting dates for each individual REC by checking the NRES online pages for updates.

REMEMBER: You should submit your application to the REC within four working days of making the booking. You will be asked a series of questions in relation to the study, so you should have the following documentation in front of you for the booking process.

- the completed and signed REC application form
- all other supporting documentation as outlined in the REC checklist. Paperwork should be one-sided, not stapled together, and all must have the same version number and date.

Please be advised academic supervisors are encouraged to attend the REC meeting in support of their students. Therefore, you should choose a meeting when both you and your academic supervisor will be available to attend. This can be beneficial for both you and the REC committee who are present on the day you attend. You will be offered the first available agenda slot within the UK. You may however, request review by a named committee, but if you choose this option the 60-day clock will start from the submission date of the REC and not the date of application receipt.

Attending the REC meeting

You may be asked to attend the meeting and will be given the date, time and location of this meeting. Individuals are usually fearful and anxious about this. Don' t be —think of it as an opportunity to show your knowledge of your study! If you are a student, your academic supervisor or co-investigator will be expected to accompany you to provide support for you and your study. The committee members will discuss your study prior to inviting you into the meeting room. You may be asked to clarify information about your study by answering any questions the committee deem relevant to their decision-making prior to issuing approval. You will rarely be given a decision on the day but will be informed in writing within the time stated. You will receive a letter stating one of three possible decisions:

- Favourable opinion
- Provisional opinion
- Unfavourable opinion

If your study was given an unfavourable opinion, precise reasons will be given for this. If a provisional approval is given, you will need to address the points raised or provide further information before amending your application appropriately. All amended documents accompanying your amendment must display the new version number and date together with evidence of tracked changes as requested before returning to the Committee for approval. Only once a favourable ethics opinion and R&D Management Approval has been granted can you start your study.

West Research and Development Office contacts

(All based at R&D Management Office ,1st Floor, Tennent Institute, Western Infirmary, G11 6NT)

Dr Nathaniel Brittain (R&D -Academic Co-ordinator) Tel: 0141 211 8544
Email: Nathaniel.brittain@ggc.scot.nhs.uk

Barbara Ross (Research Administrator) Tel: 0141 211 1880
Email: Barbara.Ross@ggc.scot.nhs.uk

Eileen McCafferty (Audit Facilitator) Tel: 0141 211 1947
Email: Eileen.McCafferty@ggc.scot.nhs.uk

Dr Judith Godden (WoSRES Scientific Officer/ Manager) Tel: 0141 211 2126
Email: Judith.Godden@ggc.scot.nhs.uk

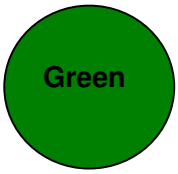
Reporting amendments to your study post-REC approval

If you need to extend the recruitment period, widen your sample by using different sites, change your Principal Investigator etc, you will need to apply to the REC for further approval. Examples of what constitutes substantial (major) and non-substantial (minor) amendments can be found at http://nres.nhs.uk/applications/after-ethical review/notification of amendments/

Study progress reports

You are required to complete and submit an annual progress report until the end of your study, at which time you will also be required to complete and end of study/ final report. Guidance on submitting these reports can be accessed from
http://www.nres.nhs.uk/applications/after-ethicalreview/endofstudy/

CHAPTER 3: STORMING



Doing the study — collecting data.

Now you should be almost ready to proceed with your study but before you go ahead, take time out to consider what you may still need to do, the practicalities involved, and make an action plan. This will act as a reference to guide you if you get lost in the process and will help you when it comes to writing up your study. At this stage a little extra time spent planning can serve you well in the long run!

Informing gatekeepers

Before you can begin to collect data you need to ensure that any relevant key personnel in your organisation (managers, data protection officers, doctors, colleagues etc) who are to participate in, or take responsibility for, your study are fully informed about your study and you have their approval to proceed. Remember, people you may have consulted in the early stages may have changed and be unaware of your proposed study. Following REC approval, once R&D has issued a management approval letter for your study, it will be necessary to approach these people to confirm and/ or re-negotiate (where necessary), the following:

- data collection times,
- access arrangements (clinical / non-clinical areas, medical notes etc)
- release time for staff taking part (if appropriate),
- use of facilities or equipment (if appropriate)

Practical issues to consider

- Before data collection, consider what problems or pitfalls might occur and try to have a contingency plan to deal with the expected and unexpected (i.e., if you are interrupted while observing others or during an interview, or if a participant were to become distressed etc).
- Ensure you have sufficient resources with you when collecting data in the research field. For example, if you are using an observation schedule or interviewing, make sure you have sufficient copies to record data, or spare tapes etc if using audio equipment.
- Book rooms for interviews in advance of data collection away from the ward area if possible. Make sure you have a sign for the door to inform others of your presence and to ensure privacy and avoid interruptions. If interviewing, it is good etiquette to have drinking water available for the researcher and participant.
- Remember to explain to participants what is expected from them immediately before you collect data.

Producing data trails

To ensure validity and reliability of your data, it is a good idea to keep a record of your research in the form of a diary of sorts, e.g., using a field diary, reflective diary or log book. Consider the following tips and think of other ways you can track or enhance your data. Ensure you take into account the moral and/or ethical implications and the code of conduct within Good Clinical Practice Guidelines.

- Keep a summary table to keep a log of participants, recording key information.
- Keeping a trail of your research helps with recall of events, influencing factors, environmental conditions and problems that arise prior to, and during, data collection.
- Some people find it useful to record staff and patient numbers and/ or make a diagram of the clinical layout prior to actual data collection as an 'aide-memoire' and to help recall.
- Take note of any questions that you had during the course of data collection. For example, why a certain event happened, or why a person behaved or acted in a particular manner etc.
- As soon as possible after interview or observation make note of how it went, noting any problems or questions that arose or anything of a similar nature that may be relevant.

Analysing quantitative data

1. Decide the best way to manage and analyse your data (SPSS, Excel)
2. Review data (survey or questionnaire) for completeness
3. Code data
4. Verify or cross-check data
5. Conduct data entry
6. Verify or cross check data entry
7. Analyse data (descriptive tests, or other advanced statistical tests)

Links for other useful information on designing and using questionnaires:

Walonick, David (1997-2004) Survival Statistics, can accessed from www.statpac.com

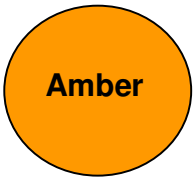
Bowers, D (1998) Further Statistics from Scratch-For Healthcare Professionals John Wiley &Sons: Chichester.

Boynton, Petra M (2004) Administering, analysing and reporting your questionnaire BMJ 328 pp 1372-13775.

Analysing qualititative data

1. Decide how best to manage and analyse your data
2. Computer assisted methods (NVivo, ATLAS-ti, WORD or similar)
3. Manual pen and paper methods
4. Review your data: listen to recordings, read transcripts and/ or field notes.
5. Code data
6. Identify themes and sub-themes
7. Repeat step 2.
8. Amend themes as necessary
9. Verify or cross-check data

CHAPTER 4: PERFORMING



Disseminating results.

Congratulations on completing the study. Although you have completed and submitted your thesis or dissertation, there is still some outstanding work to be done. You may be asked, expected, or in case of funding recipients obligated, to disseminate your results to the wider professional, academic and/ or clinical audience. This may take the form of reports, oral and/ or poster presentations, and written publications for peer-reviewed relevant journals.

Providing updates and end-of-study reports

It is compulsory to submit a yearly progress report and an end-of-study report (depending on the duration of your project), to the REC that approved your study. These can be generated through the project within the IRAS system. Guidance can be obtained by accessing this link: http://www.nres.nhs.uk/applications/after-ethicalreview/endofstudy. If you have not received a form to complete from the relevant organisational departments etc, then write and send your own report giving a concise summary of your progress and/ or results including:

- numbers you expected to recruit
- number of individuals actually recruited to the study
- numbers of individuals who have withdrawn
- any problems encountered
- brief summary of results etc

NB: For those who have received funding from the BWoSCC Cancer Education Initiative Fund (CEIF), a full report of your study and results should be provided to the Research Practitioner, Audrey Morrison. If you have self-funded or received external funding you are still encouraged to provide a report or a link to your thesis.

Writing for publication

Your manager or academic supervisor may have expressed an interest or advised you to publish your findings. If so, they may agree to act as lead or secondary author to enable your study to be published in a relevant peer-reviewed journal. Decide on the journal(s) that are appropriate to the subject theme(s) of your dissertation then look up the guidelines for authors intending to publish in that journal (normally at the front of the journal in printed format, and online). This provides guidance on font, style, word limit and use of tables, diagrams etc. Ensure you stick to the format given. Alternatively, ask your librarian for an electronic list of various journals' author guidelines.

Don't panic! At first it may seem an impossible task to reduce the content of your dissertation to suit the word limit prescribed by the journal in question. This is where your supervisor can be of great assistance. Also, the research practitioner as before, is available to help you if required. Look carefully at the journal in which you hope to publish. Look for articles that describe a similar setting, topic, or methodology as you used in your own study, and look at how they have structured the paper. Remember to think about the key themes and messages you wish to convey and how this can be done within the structure of the article. This can be a lengthy process from submitting your article and actual publication. Most journals will state their expected deadlines for article turnaround.

Making a poster presentation

Posters are used to convey the key messages and results of your research project. Whereas in an oral presentation you do this by talking and presenting supplementary images as supportive evidence, in a poster presentation all your communication must be presented to your audience as a visual display of static text and images.

Don't think a poster presentation is the easy option as most Conferences now expect the author to stand beside their poster and talk about it for five to ten minutes. This is usually performed at times when a group of conference attendees are shown round poster display boards by a conference facilitator. Either way, for both oral and poster presentations you will be allocated a specific time to answer questions and provide further clarification on your study.

How do I make a poster?

Firstly, refer to your Conference information to determine the space allowed for the poster display. This is normally set, typically given in specific size dimensions (cm, mm or A1, A2 etc). Secondly, you will need to consider how much text you will need for:

- Title
- Author
- Institution
- Headings
- Summary (like a brief abstract)
- Introduction
- Methodology
- Results
- Conclusions
- Images or Diagrams

Think about what key message you wish to convey and the people who will be attending the conference. This will hep you decide what level and depth of information you should provide. In other words, match the content to the knowledge and experience of conference attendees. What type of conference is it? Will it be attended by nurses, medics, and/ or academics? *** Key message: Be Selective with text, images, and results.**

Tips:

- Use colours sparingly and avoid colour clashes and vivid colours that are normally associated with conflict and confusion by the reader. Pastel or muted shades are therefore much better. Choose complimentary and contrasting colours for the colour background and foreground of the poster. Remember some of your audience may be colour-blind so it is best to avoid colours such as red on green.
- Keep to the one Font type. Use a font style that is easy on the eye such as Arial, or Verdana.
- Titles should be slightly larger than the body of text but not too large a contrast and in Sentence case rather than all upper case.
- A picture is worth a thousand words. One image such as a graph, diagram, or photograph may avoid need for larger sections of text that might be better used to focus on a key message or result. But remember to label the image.
- Only use clipart if it compliments the topic as it can distract rather than enhance your poster.
- Check your spelling for typos, punctuation, and grammatical errors.
- Think of the sequencing and placement of text and images as a news headline or magazine article. Play around a bit and decide how it looks on the eye. Imagine you are reading your poster for the first time. Does it flow? , make sense? are there any mistakes? Ask others for their opinion and advice on how to improve it.

If you are nervous about your ability contact your medical illustration or graphics department for advice and templates. Allow plenty time and do not leave this until last minute as they are always very busy and can have long lead-in times.

<u>When the day of the conference arrives</u>
Key tip: Be there early!

- Once you have registered, you are usually given special instructions on where the poster will be displayed and allocated a position or board number. Usually adhesive tape or tacks etc are provided but to play safe always take along some of your own (always helpful when one edge of your poster is acting stubborn and wont stay in place etc).
- Stand beside your poster between the allocated times for group questions (if this is the case) and at coffee breaks and lunch breaks if possible (once you have eaten too that is!).
- Remember no one is there to criticise you. Most people are really interested and keen to take topics of interest back to the workplace. Use this time to your advantage to:
- Take along printed A4 summary sheets of your study or poster together with any other relevant items (such as leaflets and business cards) and place beside your poster. This allows people to take away information about your study when you are not at the

poster stand. If really interested, you will find these people will contact you using the details (email/telephone) on your documentation.

- Network with the people at adjacent poster display boards! It passes time, helps relieve your anxiety and is good practice! Remember they are likely just as anxious as you!

GOOD LUCK!

So what should I do now?

Take a well-earned REST
and
CELEBRATE your achievement!

Appendix 1: Critical Appraisal Template (Example-Qualitative studies)

Title:				**Author:**
Source:				**Date:**
Keywords:				**Contact no.**
Other				**File source**
Questions	Yes	Can't tell	No	**Summary of paper**
1. Was there a clear question and did it match aims?				
2. Was an appropriate epistemological framework described / justified?				
3. Sample strategy defined and justified?				
4. Are methods to collect data appropriate?				
5. Were any quality control measures used, and if so, described?				
6. Was relationship between researcher & participant explicit?				
7. Are the results credible?				
8. Are explanations plausible and coherent?				
9. Were conclusions justified?				
10. Have alternative explanations been explored?				
11. Are findings transferable?				
12. Do you have any major concerns regarding this study?				
13. Ethical approval stated? Any concerns?				
14. Can the findings be related to practice?				
Study design/methods				
Main findings				
Limitations/ future recommendations				

Appendix 2: Contacts List

A list of current contacts is provided here for your reference. If you have any questions please refer to the most appropriate individual using the information provided.

NAME	TITLE/ROLE	TELEPHONE	EMAIL
Audrey Morrison BWoSCC	Research Practitioner	0141 301 7650	Audrey.morrison@ggc.scot.nhs.uk
Cathy Hutchison BWoSCC	Cancer Consultant Nurse	0141 301 7080	Cathy.hutchison@ggc.scot.nhs.uk
Nathaniel Brittain WIG	R&D: Academic Coordinator	0141 211 8544	nathaniel.brittain@ggc.scot.nhs.uk
Judith Godden WIG	Scientific Officer -WoSRES	0141 211 2126	Judith.godden@ggc.acot.nhs.uk
To be confirmed WIG	Research Ethics Manager	0141 211 6238	c/o Judith Godden –see above
Andrea Harkins BWoSCC/ CTU	Head of Trial Coordination	0141 301 7186	A.harkin@clinmed.gla.ac.uk
Grace Lindsay GRI	Research Lead Nurse	0141 232 1072	Grace.lindsay@ggc.scot.nhs.uk

Appendix 3: Cancer Research UK Clinical Trials/Research Unit Glasgow –

IHTAB Quality System: Policy on the Function of the In-House Trials Advisory Board (version 2-7th September 2012)

INTRODUCTION
This policy document describes the role, review activity, membership and organisation of the In-House Trials Advisory Board (IHTAB).

ROLE
IHTAB acts as a *peer review* for new research that will require CR-UK CTU input or support in its capacity as a CR-UK/NCRI Accredited CTU.

There are 2 levels of review that IHTAB can undertake:

1. **Full Scientific Review**
   Research that has not been developed within a NCRI Clinical Studies Group (CSG) must be submitted to IHTAB for a full scientific review. Proposals submitted for full review should be:
   - Submitted on the IHTAB Clinical Proposal Form and/or ASU Proposal Form (where possible)
   - In an early draft stage that allows the potential for update following IHTAB scientific critique
   - Tabled for discussion as a new proposal at an IHTAB meeting. This will be the case for most trials. However, if a clinical trial has been developed via the respective NCRI Clinical Study Group (CSG) framework, this will be considered to have received scientific peer review and can be submitted to IHTAB for endorsement only. If this is the case, IHTAB may request minor changes or updates to the proposal
   - Research being proposed within a CSG framework may be presented for full scientific review if this is desired by the proposer

2. **Endorsement**
   Research that has been developed and approved by a NCRI CSG can be submitted to IHTAB for endorsement only as this will be considered to have received scientific peer review.
   Proposals submitted for endorsement only:
   - Do not require to be submitted on an IHTAB proposal form but a summary of the research must be provided
   - Will be tabled for endorsement at the next available IHTAB meeting (meetings will not be arranged simply to endorse the research) or reviewed via e-mail circulation

MEMBERSHIP
The membership of IHTAB includes:

- Director of CR-UK CTU (Chair)
- Professor of Medical Oncology
- Professor of Translational Cancer Research
- Professor of Clinical Oncology
- ECMC Lead
- Head of the Analytical Services Unit
- Two representatives from the Beatson Laboratories/Beatson Institute
- Head of Trial Co-ordination
- Head of Biostatistics

- Research Clinical Nurse Specialist
- Consumer Research Panel (it is expected that 2 members of the CRP will be allocated to IHTAB)
- Another Clinical Researcher that is central to the research portfolio of the BWoSCC

The CR-UK CTU In-House Trial Administrator (IHTA) is responsible for:

- Receiving new proposals
- Setting meeting dates
- Circulating meeting documents
- Minuting of meetings
- Providing formal feedback regarding proposals to researchers

ORGANISATION
IHTAB meets as required when new research proposals for full scientific review require review. Meetings will not be organised simply to endorse proposals. Where there is a requirement to endorse a proposal in the absence of a meeting, the proposal will be submitted by e-mail for review and endorsement.

PROPOSAL REVIEW PROCESS

Proposals Requiring Full Scientific Review : Submitting Proposals
Researchers are required to complete the *outline proposal for a clinical trial* form (available on the CTU web portal page) and send to the IHTA. A minimum amount of detail regarding the trial must be given on the outline document including:

- The study title
- Objectives
- Trial design
- Rationale for performing the study
- What further studies are planned should the proposed study be positive
- Any clashes with existing studies
- Characteristics of study population including eligibility criteria
- Planned interventions
- Study investigations that differ from usual medical practice for the disease
- Endpoints, outcome measures and statistical design
- Pharmacokinetic/pharmacodynamic studies
- Translational studies
- Sponsor support or funding source

If the proposal includes laboratory studies then the *outline proposal for Analytical Services Unit (ASU) laboratory studies* form (available on the CTU web portal page) must be completed as part of the submission to IHTAB for review. The following information requires to be provided:
- Study title
- Stage of development/review of protocol
- The objective of laboratory studies
- Assays to be used
- Rationale for biological objectives

- Anticipated patient numbers and samples per patient and assays per sample
- Stage of Good Laboratory Practice (GLP) validation of each assay
- Plan for who will perform assay
- Sponsor support or funding resource

The IHTA then circulates the proposal to the IHTAB members and arranges an IHTAB meeting. The proposal author attends the IHTAB meeting and presents their research project to the board. The IHTAB review consists of a discussion of the scientific merits of the proposal and covers the following:

- A discussion of the trial idea with reference to the strategy and ongoing studies in this area (i.e. what else is happening in that particular tumour site both nationally and locally)
- Where the idea fits in with BWoSCC and Institute of Cancer Sciences research strategy
- Whether there is appropriate local expertise to undertake the project
- A thorough evaluation of the scientific merits of any laboratory/translational component and discussion regarding additional studies that may strengthen the project
- Advice on obtaining funding resources e.g. project grants and industry sponsorship
- Allocation of resources (of current staff/funding) with regard to feasibility and timelines of the project and taking into account current projected workloads
- Advice with protocol development
- Advice with statistical design of the project

Proposals Requiring Endorsement Only: Submitting Proposals

Researchers are required to submit a comprehensive summary of the proposal and send to the IHTA. The template IHTAB proposal forms can be used if preferred.

If a date for an IHTAB meeting has been organised, or if there are proposals pending full scientific review, the IHTA will circulate the proposal to the IHTAB members and table this for endorsement on the next IHTAB agenda. The proposal author is not required to attend the IHTAB meeting.

If there are no IHTAB meetings scheduled and no proposals pending full scientific review, the IHTA will circulate the proposal to the IHTAB members and request this is endorsed via e-mail review.

ALL PROPOSALS: Subsequent Actions

Whether the research has received full scientific review or endorsement, if this is approved by IHTAB the following actions will take place:

- The CTU will provide assistance with funding applications/portfolio adoption as necessary
- The CTU will provide assistance with protocol development (if the research proposal is to be run through the CTU). Protocols are written in a standardised format using the CTU protocol template
- Once a proposal is approved to be run through the CTU its progress towards opening is reported to IHTAB
- If the research is to be undertaken locally in the BWoSCC, the study must be submitted to CTEC for review before BWoSCC patients can be invited to participate.

- **Appendix 4: Cancer Research UK Clinical Trials/ Research Unit Glasgow**

Quality System: Policy on the Function of the Clinical Trials Executive Committee (CTEC) (version 2- 7th September 2012)

INTRODUCTION

This policy document describes the role, membership, review process and organisation of the Clinical Trials Executive Committee (CTEC). CTEC oversees the participating site activity of the Cancer Research UK (CR-UK) Clinical Trials Unit (CTU), West of Scotland Cancer Research Network (SCRN-W) and Clinical Research Unit (CRU).

Role

Any clinical research study (hereafter referred to as 'trials') involving patient contact at the Beatson West of Scotland Cancer Centre (BWoSCC) must be reviewed by the hospital's internal steering committee, the Clinical Trials Executive Committee (CTEC). This is the first step for approval of a study and takes place prior to any local regulatory submissions being processed. CTEC reviews all protocols (both trials co-ordinated by the CTU and trials where the BWoSCC is a participating trial site) that will make use of CTU and CRU resources. CTEC also reviews and approves all CTU quality documentation and standard operating procedures (SOPs). In addition, CTEC reviews any trial which is to open in the SCRN-W, irrespective of whether or not the BWoSCC is a proposed site. The committee also maintains oversight of all recruitment figures at BWOSCC and across the network.

Membership

The membership of CTEC (with voting rights) is as follows:

- Head of the CTU
- Clinical Director of the BWoSCC
- Professors of Medical/Radiation Oncology and Palliative Care
- Representatives from major tumour teams (lung, breast, GI, haematology and urology)
- Representatives of the team responsible for phase I trials
- Head of Radiology
- Senior Clinical Trial Co-ordinator
- Head of Biostatistics
- Clinical Research Unit Clinical Nurse Specialist
- IV Team Research Nurses
- SCRN-W Manager
- CRUK Laboratory Scientist
- Consumer Representatives
- Radiology Reviewer

Guests of CTEC (with no voting rights) are as follows:

- Clinical Trials Pharmacist
- NHS R&D Representative
- NHS GGC Deputy Director Bio Repository
- CTU Regulatory Administrator (RA)
- Principal Investigators or designees presenting trial protocols being considered for the meeting

The Head of the CTU chairs each meeting and the Senior Clinical Trial Co-ordinator (SCTC) minutes each meeting.

CTEC Approval Process

All trial protocols require to be reviewed and approved by CTEC. CTEC members represent the key activity areas of the BWoSCC. These areas include Trial Co-ordination, Pharmacy, Medical, Nursing, Statistics, Radiology, Cancer Research UK laboratories and the WOSCRN network.

CTEC members make the decision to approve/reject or refer back a protocol after considering the following:

- The scientific merits of the trial (including statistical considerations)
- How it relates to other trials running in the BWoSCC
- How it fits into the research strategy of BWoSCC
- Pharmacy issues
- Nursing staff issues
- CTU resource requirements
- Suitability for the Scottish Cancer Research Network (West)

For trials which have been developed via IHTAB, the scientific merits of the trial (including statistical considerations) will not be further reviewed at CTEC. Other aspects will still be reviewed, however. Each trial protocol receives an initial review prior to submission to the CTEC meeting. Comments made at this initial review are returned to the PI for consideration. Protocols for review are sent to the RA. The PI then completes the CTEC submission form and submits the protocol for CTEC approval. Two weeks prior to the CTEC meeting the protocols will be made available to CTEC members via the web portal. The PI or a representative will present the trial protocol for review at the CTEC meeting.

CTEC has four forms of approval rating, A, B, C and D:

- A-The protocol is approved by CTEC. The PI can start regulatory submission procedures with the assistance of the RA
- B-Protocol is approved subject to minor comments. Comments are returned to the PI for action. When all the issues raised at the meeting are resolved the Chairman can then approve the protocol outwith the CTEC meeting. Approval is then minuted at the subsequent CTEC meeting. Once approval is granted the PI can start regulatory submission procedures with the assistance of the RA
- C-The protocol is subject to major comments, comments are reviewed and action taken (if required) and resubmitted to CTEC for approval. Once approval is granted the PI can start regulatory submission procedures with the assistance of the RA
- D-Protocol has not been approved and cannot be resubmitted to CTEC

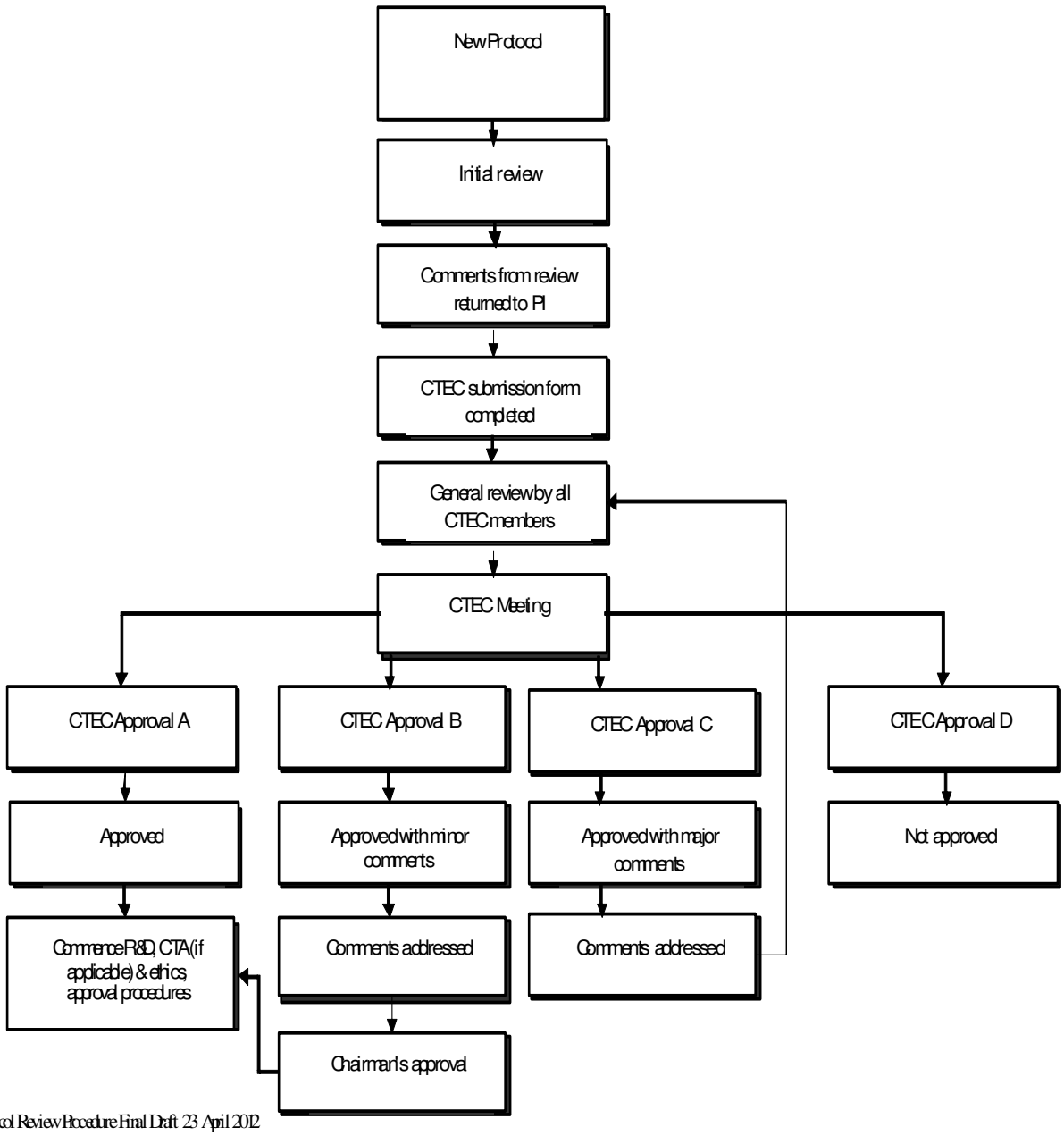
QUALITY DOCUMENT AND SOP REVIEW

CTU quality documents and SOPs are also reviewed by CTEC. Quality documents and SOPs are submitted to the RA 2 weeks prior to a CTEC meeting and accessed by CTEC members via the CTU web portal. Comments raised at the CTEC review are noted in the meeting minutes and incorporated into the documents and SOPs as requested.

Organisation

CTEC meets monthly. The SCTC issues minutes for each meeting, mentioning the documents (e.g. protocols, SOPs) that were reviewed and the opinion of CTEC. Approval is indicated by a record in the minutes of the meeting at which they were approved.

CTEC Protocol Review Procedure



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Appendix 5: REC Meeting Dates (NHS GG&C)

REC Committee	Meeting Dates All documentation must be sent to the coordinator **at least 2 weeks prior** to the meeting	REC Coordinator/ Contact Person
WoS REC 1 *Type III CTIMP Committee (accredited to review Clinical Trials of Investigational medicinal Products) plus Non-CTIMPs.*	**Western Infirmary** 1st Tuesday of the month Time 9:00 am	**to be confirmed** 0141 211 6238
WoS REC 3 Authorised to review all NON-CTIMP studies	**Gartnavel Royal Hospital** 1st Thursday of the month Time 2:00 pm	**Liz Jamieson** 0141 211 2123
WoS REC 4 Authorised to review all tissues bank studies plus all NON-CTIMP studies	**Glasgow Royal Infirmary** 1st Friday of the month Time 12:noon	**Evelyn Jackson** 0141 211 1722
WoS REC 5 Authorised to review all NON-CTIMP studies	**Lanarkshire Health Board- Hamilton** 3rd Wednesday of the month Time 2:00 pm	**Sharon Mcgregor** 0141 211 2102

WoSRES Scientific Officer: Dr Judith Godden 0141 211 2126

Committee Coordinators are assisted by 3 admin assistants:

Rose Gallacher 0141 211 1482
Sharon Jenner 0141 211 6270
Winifred McCartney 0141 211 6294