The ACORRN / SCoR Research Radiographer Starter Pack
For Therapeutic and Diagnostic Radiographers.

Version 2
December_09

NOTE: Some of the links in this document are now out of date. The SCoR does not endorse or take responsibility for any of the content contained on external websites.

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1. Aims

The purpose of this pack is not to offer comprehensive information, but to provide a useful aid and support mechanism for radiographers starting out in research. The pack has been compiled by a group of experienced research radiographers and focuses on areas they feel have been fundamental in their development.

The pack aims to offer advice on appropriate training and education needs, often in areas where initially you may think it is not required. It highlights the importance of the legal requirements required to participate in research as strongly encouraged by the regulatory bodies, and suggests ways of accessing further information.

At all times this pack should be used as an overview and guide to accessing further information. Legal requirements are constantly updated and changes made, it is essential that when participating in research you seek advice from the appropriate regulatory body and ensure you receive appropriate training.

Throughout this guide some terms are written in ***bold italics.*** These terms are further explained in the Glossary along with their URL's. Other relevant research terms are also listed in the glossary.

2. What is Research ?

Research is the process of answering questions and/or exploring phenomena using scientific methods: these methods may draw on the whole spectrum of systematic and critical enquiry. Research includes both ***quantitative*** and ***qualitative*** methodologies. Research activity ranges from high level, scientific generation of new evidence, to more every day utilisation of research findings to ensure that practice and patient-centred care is evidence based.

Research is intended to provide new knowledge and/or understanding. The methodology is designed so that the results will be of value to those facing similar problems or can be reproduced in similar circumstances and the findings are put in the public domain for critical examination to be accessed by those who would benefit from them. Note, research is different to ***audit*** and service evaluation, though they share similarities in that they are employed to answer specific questions. However research is designed to generate new knowledge and test hypothesis whereas ***audit*** and service evaluation test the application of current knowledge. The differences between these are discussed on page 27.

Research radiographers are involved with many aspects of research such as ***clinical research, pure research*** and ***health service evaluation***. Large aspects of their work are in the field of ***translational research*** which is specifically concerned with the application of ***basic research*** findings into innovative strategies, devices, products or services for the diagnosis, treatment or prevention of human disease or injury.

3. Research in the NHS

The nature of research is changing rapidly within the NHS and the UK as a whole. On 31 March 2006, the then Chancellor of the Exchequer, Gordon Brown, appointed Sir David Cooksey to lead a review to build agreement on the best institutional arrangements for the new single fund for health research. ***The Cooksey Review*** determined that further work was needed to ensure that publicly funded health research was carried out in the most effective and efficient way to facilitate rapid translation of research findings into health and economic benefits. To aid this, a new ***Office for Strategic Coordination of Health Research (OSCHR)*** was created that to take an overview of the budgetary division and research strategy of both the ***Medical Research Council (MRC)*** and the ***National Institute for Health Research (NIHR)*** to ensure the bridge between ***clinical research*** and translational research was following The ***Cooksey Review***. The Government launched a new national health research strategy *'**Best Research for Best***

Health' published in 2006 by the newly established ***United Kingdom Clinical Research Collaboration (UKCRC)*** which aims to bring together the major stakeholders that influence ***clinical research*** in the UK and particularly in the NHS. The Collaboration includes the main UK research funding bodies; academia; the NHS; regulatory bodies; the bioscience, healthcare and pharmaceutical industries; and patients.

Further information regarding the terms in ***bold italics*** above can be found in the Glossary, including URL's. It is recommended you visit these sites to gain a greater understanding of research in the NHS and how your role fits within this.

4. Legal Aspects of Research

Since 1997 the ***International Commission of Harmonization for Good Clinical Practice (ICH GCP)*** has standardised the clinical practice related to research. This is to ensure that good clinical practice is internationally established and is of a uniformly high standard. Since May 2004 the EU Directives, in addition to the Medicines for Human Use Act, have regulated much of the ICH GCP guidelines. In particular ethical committees have time lines for ***approval***, laboratory procedures are more tightly regulated and the consent procedure is governed.

GCP is an international quality standard for designing, conducting, recording and reporting trials that involve human subjects. ICH facilitates a mutual acceptance of clinical trial data from the US, Europe and Japan.

The Main principles of GCP remain a key aspect in research and summarised are as follows.

- The rights, safety and well being of trial subjects shall prevail over the interests of science and society
- Individuals involved in conducting a trial shall be qualified by education training and experience
- Trials should be scientifically sound and guided by a clear detailed protocol
- Trials should be conducted in compliance with the protocol having prior independent ***ethics*** approval
- Freely given ***informed consent*** should be obtained from every subject prior to participation
- Quality assurance and quality control are paramount

- ***Clinical trial***s shall be conducted in accordance with the ***Declaration of Helsinki***
- All trial information should be recorded, handled and stored in a way that can be accurately reported, interpreted and verified.
- Confidentiality of records must remain protected

The EU trial directive aims to protect the rights, safety and well being of trial participants, ensure the credibility of results and simplify and harmonise administrative provisions.

The Declaration of Helsinki is a statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects. “It is the duty of the physician in medical research to protect the life, health, privacy and dignity of the human subject”.
Current ***Medicine and Healthcare Products Regulatory Agency*** (MHRA) guidance stipulates that all staff working on ***clinical trial***s must update their understanding of GCP at least every 2 years.

Further information regarding the terms in ***bold italics*** above can be found in the Glossary, including URL’s. It is recommended you visit these sites to gain a greater understanding of the legal aspects of research.

5. Research in Radiography

Radiography is very much an emerging profession and although research carried out by radiographers is increasing the large body of knowledge required on which to base practice is still not established. It is important to formulate this evidence base and there are many topics of research just waiting to be investigated including established practice, innovative practice, radiation protection, service provision and of course patient care.

Radiographers are ideally placed to investigate a multitude of areas including; the use and development of equipment/protocols; testing the **efficacy** of diagnosing disorders with new protocols; the biology/physiology of diagnosing conditions; through to the implementation of new ways of working.

5a. What is the role of a research radiographer?

A research radiographers' role is to undertake or facilitate research, applying their knowledge of radiography to research activities.

Research radiographers can work in a variety of settings including clinical, academic, educational, management and business and can work both independently or as part of a team.

5b. What is the purpose of a research radiographer?

Many radiographers are actively involved in research at some time in their career, but this is often time-limited, driven by a specific project rather than as an on-going aspect of their work. There is a national need to encourage and promote greater on-going involvement in research by radiographers as evidenced by the ***Society and College of Radiographers*** (SCoR) 5 year research strategy and the ***Academic Clinical Oncology and Radiobiology Research Network*** (ACORRN) The advanced practice role of Research Radiographer has arisen to fulfil this need. As with other fields of advanced practice, the role title is applicable where the radiographers' duties require more in-depth subject knowledge. All radiographers, ideally, should have a research component to their role, the level of research activity increasing with advanced practice and consultant roles, but research radiographers will have specific expertise in the application of research methodologies.

5c. When is the term 'Research Radiographer' used?

The role title 'research radiographer' is a generic term applicable when research activities occupy the majority of the working time. To clarify, a role describes the part you play within your organisation as differentiated from your responsibilities which describes the obligations of a role.

Many radiographers may participate in research activities but the title 'research radiographer' is not applicable if this is not their major function. A radiographer may have more than one role within their department, for example someone working 2 days per week reviewing patients and 2 days a week undertaking research has the *role* of both a review radiographer and a research radiographer; someone working 4 days a week reviewing patients and 1 day per week undertaking research will have the role title 'Review Radiographer' and is *responsible* for review and research activities.

5d. What activities are considered as research?

There are many activities that a research radiographer may be required to undertake. A few are outlined below:

- Identifying future areas for research
- Reviewing relevant and previous literature/studies.
- Writing grant applications
- Finding and applying for funding
- Writing ***ethical*** approval applications
- Project management
- Accruing patients into trials
- Gaining ***informed consent***
- Giving study information to patients, carers, health professionals and others
- Collecting and or managing data for studies
- Creating and managing study databases
- Statistical analysis of study data
- Dissemination of research findings by publication or presentation
- Implementation of research findings into clinical practice
- Creating strategies for research programmes
- Teaching research methodologies
- Training for research practices
- Creating and managing research programmes
- Developing, implementing or evaluating the effectiveness of new techniques, treatments, equipment, or practices
- Managing research governance
- Creating and managing systems of work for research and research infrastructures
- Creating research documentation
- Reviewing research publications
- Adjudicating research proposals
- Adjudicating research dissertations and theses
- Supervising academic research activities
- Supervising clinical research activities

5e. Role specialisation for research radiographers

A research radiographer can specialise in many different aspects of research; sometimes the specialisation is demonstrated by different role titles, reflecting the main responsibilities.

The need for specialisation of roles will depend on the research structure within a department; sometimes a specific person takes on a single role, sometimes a

combination of roles. The role specialisations are outlined in greater detail in the table below:

Role specialisation	Main activities
Pure Research	Undertakes research projects - may include identifying research areas needed, project design, writing proposals, research governance, contributing to funding and ethical approval applications, project management, data collection, data analysis, dissemination and implementation of findings into practice
Trial Co-ordinator	Co-ordinates and administrates data collection and/or QA for projects - may include accruing patients, gaining consent, supplying information, data collection and database creation and management
Research assistant	Assists lead investigator in their research – may include data collection, creating research documentation, data management, and patient support
Technique development	Develops, implements or evaluates effectiveness of new techniques, treatments, equipment, or practices
Translational Research	Implements research findings into clinical practice – may include identifying and providing equipment, adapting process pathways, creating documentations, establishing training and competency assessment programmes, and feedback effectiveness of change
Research Manager	Manages the direction and workforce of a research programme – may include identifying research areas needed, creating strategies for research and establishing research programmes and structures, applying for funding and ethical approval, adjudicating research proposals, staff recruitment, project management, managing research governance, dissemination and implementation of findings into practice

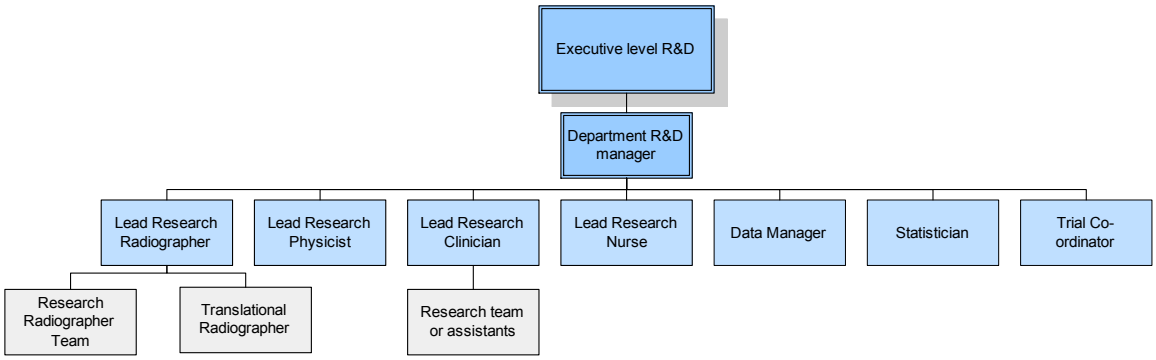
Research lecturer/ supervisor	Manages, educates and trains students in research methodologies and practices, supervises academic research activities, adjudicates research proposals, dissertations and theses, reviews research publications

5f. The role of research radiographer within a Multi-disciplinary Team (MDT)

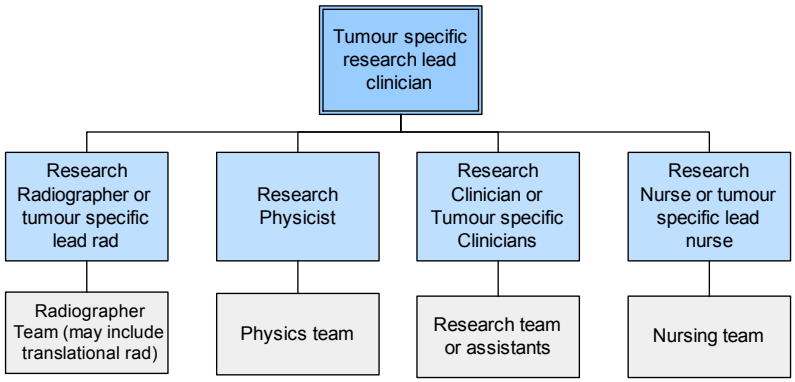
Some radiographers may have had sole responsibility for a research project when working for their professional qualification and some may undertake their own independent self-led projects during their career, but most ***clinical research*** will be conducted as part of a MDT. MDT working is important in the clinical setting as it is rare to find an area of investigation that does not impact on other staff members or professional groups; most projects will require the expertise of many disciplines and good communication is essential to prevent misunderstanding or duplication.

The research MDT may include many other disciplines, dependant primarily on the topic and placement of the study. Within the clinical setting this team often includes experienced radiographers, physicists, clinicians, managers and nurses and is responsible for managing the research process for the project (single, time-limited study) or programme (portfolio of studies contributing to a specific goal). For larger projects and programmes, a data manager, statistician and trial co-ordinator may also form part of the team. Your local research structure is likely to vary depending on need; it can be either led by a dedicated research team or be formed from multiple teams, or sometimes a combination of both. The team membership can be either from a specific department only or include staff from other services. All hospital-based research teams report to an executive level R&D directorate that sets the research governance for the hospital. When there is a collaboration between hospital and academic research teams the principle investigator is responsible for ensuring research governance is adhered to in accordance with local protocols. When getting started in research, it is recommended that you take time to establish how research governance works in your department.

Example of dedicated research team structure



Example of tumour specific research team structure



The radiographers' role within the MDT will vary according to their specialisation and level of skills and experience; this means they can act as either the research manager (or principal investigator) leading the project or programme, as the lead radiographer specialist for research, the trial co-ordinator, the lead for implementation into clinical practice or as an assistant collecting data.

5g. Studying diagnostic accuracy

Research radiographers may be involved in the study of ***diagnostic accuracy*** such as determining the effectiveness of a new test for population screening, or further development of an existing test or protocol to detect the target condition with greater accuracy. Unfortunately it is rarely feasible to examine the accuracy of a diagnostic test in a ***randomised controlled trial;****,* however it is useful instead to examine the accuracy of the new test/protocol against existing tests/protocols (often called the ***reference test*** or existing ***gold standard).***

Diagnostic accuracy may qualitatively describe the amount of agreement between the new test and existing gold standard, however the term also relates to clearly defined measurements of performance such as the number of true positives/true negatives/false positives and false negatives. Such figures then allow calculations to be made regarding the effectiveness of the new test, which must be at least as accurate as the gold standard and add more value if it is to be accepted into clinical practice, i.e. Be more accessible/cheaper/safer/or more reliable. For example there are currently many reviews and research studies comparing FAST ultrasound (Focused Assessment with Sonography for Trauma) and diagnostic peritoneal lavage (DPL) with the gold standard of CT scanning for the diagnosis of internal bleeding due to blunt abdominal trauma. In this instance, the advantage of FAST over CT is its accessibility, non use of ionising radiation, and cost. FAST is also non-invasive compared to DPL however the trade off is that FAST is slightly less accurate as CT or DPL. Never the less its ability to predict those with internal bleeding against those without is considered high enough for it to be of value as a diagnostic test. It adds to clinical practice by increasing speed of diagnosis without the need to move or invade the patient though in areas where the diagnosis may be equivocal then CT or DPL are further options.

5h. Diagnostic systematic reviews

As well as assessing the accuracy of one diagnostic test against another, the diagnostic research radiographer may be involved in ***diagnostic systematic reviews.*** A diagnostic systematic review is undertaken for the same reasons as a therapeutic systematic review, to produce estimates of test performance and impact based on all available evidence, to evaluate the quality of published studies, and to account for variation in findings between studies (Deeks 2001). Such an example might be the comparison of MRI, CT and Ultrasound in detecting liver metastasis. However diagnostic systematic reviews differ slightly in their use of statistics used to treat and summarise the material. Whiting et al (2003) (Whiting, Rutjes et al.2003) developed a tool for use in systematic reviews of diagnostic accuracy, other tools are also available.

5j. Recommendations for starting as a research radiographer

When starting out as a research radiographer, it is useful to clarify:

- What your role is
- What the local research structure is
- How you fit into it
- What your specific responsibilities are
- What authority you have
- Who you need to communicate with
- How often you need to communicate with others in the team.

In this way, radiographers can understand what is required of them for the role and know how to find help when they need it, avoiding the common problems of isolation associated with advanced practice working.

All radiographers should be encouraged to participate in research activities, starting out with data collection for a study. This instils experience of the research process, knowledge of research governance and helps develop an analytical clinical culture.

If unfamiliar with research, support can be found from the many books offering advice on how to get started (Boynton, 2005) This will not replace the support and help from face-to-face contact with other researchers but will give guidance and helpful hints. It is excellent to carry out research with radiologists or other health professionals as a way to gain expertise and knowledge but radiographers should strive to gain enough experience to initiate and carry out radiographer led research perhaps within a multi-professional group.

Suggested books can be found in the Appendix

6. Other Roles within Research

Although the research teams are of different sizes and compositions, the ***basic research*** delegation structure offers a generic model. Within the research environment key figures are appointed and termed as the following, in these roles they hold several responsibilities which must be upheld, a summary of these roles is documented and more detailed responsibilities can be accessed on the ICH website.

6a. Sponsor

An individual, company, institution, or organisation which takes responsibility for the initiation, management, and or financing of a ***clinical trial***, hence they hold responsibility for implementing and maintaining quality control and assurance, and ensuring the codes of practice are followed.

6b. Investigator

A person with the responsibilities and overall conduct of the ***clinical trial*** is known as the ***Chief Investigator****, (****CI****),* this is not site specific. However a person responsible for the conduct of the ***clinical trial*** at a particular site, is termed the ***Principal Investigator*** *(****PI****).* Any individual member of the ***clinical trial*** team designated and supervised by the investigator at a trial site to perform critical trial related procedures and/or to make important trial related decisions, this person is known as a ***Sub-Investigator***.

6c. Data Manager / Clinical Trials Administrator

Administrative duties such as ***case report form (CRF)*** completion or submitting ethics applications may be delegated to data managers or ***clinical trial*** administrators. Their role collectively is to assist the research nurses and investigators with all aspects of administration related to trials. Depending on the specific data manager /CTA role and team structure, this will include tasks such as: collecting patient notes, requesting scan results from other hospitals, ordering stationery, assisting with archiving, hosting monitors, completing ethics applications, scheduling trial activity, CRF completion, completing MHRA applications.

7. What is a Clinical Trial ?

A ***clinical trial*** is an experimental project that is designed to test therapies that may improve future treatments. The majority of ***clinical trial***s are concerned with the testing of drug therapy, but can also take into account other treatments, e.g. radiotherapy and surgical treatments. According to the National Institute of Health (NIH),***clinical trial***s are used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective. ***Clinical trial***s of experimental drug, treatment, device or behavioral intervention may proceed through four phases:

- ***Phase I clinical trial***s test a new biomedical intervention in a small group of people (e.g., 10+) for the first time to evaluate safety (e.g., to determine a safe dosage range and to identify side effects). The objective is to look for possible non-toxic schedules and usually it's the first time it is used in humans.
- ***Phase II clinical trial***s study the biomedical or behavioral intervention in a larger group of people to determine efficacy and to further evaluate its safety. The objective being to look for possible therapeutic effects.
- ***Phase III*** studies investigate the efficacy of the biomedical or behavioral intervention in large groups of human subjects by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects, and to collect information that will allow the intervention to be used safely. The objective is to compare treatments in a scientifically valid and ethically acceptable way by allocating treatments in a random way.
- ***Phase IV*** studies are conducted after the intervention has been marketed. These studies are designed to monitor effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.

7a. How is the size of a clinical trial determined?

Statistical tools are used to determine the number of patients needed to achieve the trial's principal objectives, but practical matters such as the availability of patients and resources must also be taken into account. The estimated time period for patients' accrual to any trial will depend on the frequency of any given disease. Common cancers could well be collected within one centre whereas less common cancers are likely to need to be accrued across multiple hospitals in order to achieve the required sample size.

If considering initiating a trial or study always seek the advice of a statistician before starting, this will ensure that the data gathered will be relevant to the trial objectives. The role of the statistician can not be underestimated, the main areas of involvement are determining sample size, overseeing methods of randomisation, advising on data collection tools and databases, assessing the impact of trial deviations, analysing trial data and results and assisting and preparing reports and publications.

7b. How is a patient randomised in a clinical trial?

Each patient who might be considered suitable for inclusion into a ***clinical trial*** undergoes the following sequence of events:-

- Diagnosis is confirmed
- Treatment required
- Patient is eligible for inclusion into the trial (according to the protocol)
- The patient has the trial explained to them and is given the Trial Information Leaflet
- The Patient now understands the principle of randomisation
- The Patient now understands the aims of the trial
- The Patient now understands their role within the trial
- Patient consent is obtained generally a legal requirement of 24 hours thinking time is required
- Patient formally entered into trial
- Treatment assigned at random via a computer programme, this is best done by a group offering an independent randomisation service
- Relevant on study forms are completed
- Treatment commences

Patient registration and randomisation must be achieved promptly so that there is no delay in the commencement of treatment.

7c. Follow up

Many trials are conducted to see if a treatment can prevent or delay disease recurrence and increase survival. Such studies usually require long term follow up data. Even when a trial is closed to patient entry (e.g.; when the required number of patients has been recruited) follow up continues.

7d. The Clinical Trial Process

The ***clinical trial*** process normally takes years to complete, and there are many things to do in each stage. These are summarised below:

STAGE	**Medicines and Healthcare products Regulatory Agency** (MHRA):	ETHICS	R&D	OTHER
SET-UP	• ***MHRA*** approval required	• Complete relevant sections of the ***NRES*** application form	• Apply to ***R&D*** and submit all relevant documents • R&D approval required	• ***ARSAC*** • Costings • Contracts • Insurance/ indemnity • Establish site files • Produce ***CRFs*** (only required if sponsor site)
DURING TRIAL	• sponsor to submit any amendments , and approved by the ***MHRA***	• sponsor advise the ethics committee of any amendments and seek approval of these amendments • File all amended documents as appropriate • Progress Reports (sponsor)	• Send details of all amendments to ***R&D***/ CTRG • Upon approval update site file and advise all members of the team of any new versions of documents	• Updating costings • Addendums to contracts • Update ***ARSAC*** licence if applicable • Maintaining site file • Version Control • ***Case Report Forms (CRF'S***)

CLOSURE	• End of Study Report submitted to ***MHRA.***	• End of Study Report submitted to ethics. • Final Progress Report submitted 12 months after study closure.	• Advise ***R&D*** when studies are closed to recruitment and also when data is locked for final analysis • Send copies of the End of Study Report and any related information to ***R&D*** when available	• Invoicing • Data Queries • Archiving

8. MHRA (Medicines and Healthcare Regulatory Agency)

Further information on the roles and responsibilities of the MHRA, plus how to apply for MHRA approval are in the glossary

8a. Study Set Up

A Clinical Trial Authorisation (CTA) from the MHRA is required for all clinical trials falling within the scope of the UK Regulations, which came into force on 1 May 2004.

8b. When is a Clinical Trials Authorisation required?

The Regulations *only* apply to trials of medicinal products, However medicinal products can apply to medical devices. Trials which do not involve a medicinal product, e.g. questionnaire studies or epidemiological studies are not covered by the Directive, and so an application to the MHRA does not need to be made. If in doubt, there is a section on the MHRA website entitled “Notice to Applicants” which includes an algorithm to help you decide whether a ***clinical trial*** requires an Authorisation, and if you are still unsure, the website also has a ***Clinical Trial***s Helpline where you can email and request an opinion from the MHRA of the status of the trial.

8c. Who should apply?

The application should be made by the sponsor or by someone authorised to submit the request on behalf of the sponsor. Usually, for commercial studies the pharmaceutical company who provide the trial drugs and sponsor the study will complete the application. For non-commercial sponsored trials it is the responsibility of the Principal Investigator.

8d. **What happens after the application is received?**

The CTA will be validated on receipt and an acknowledgement letter will be sent to the person submitting the application (and named in section C of the form). There are 2 scenarios at this stage:

1) The application is valid – the assessment period will begin and starts from the date of receipt of a valid application.
2) The application is not valid – the person making the application will be advised of what is missing/needs clarification etc. Nothing happens until the missing components are provided.

The initial assessment will be made within 30 days, with the day of receipt of the application by the ***Clinical Trial***s Unit being day 0.

There are 2 possible outcomes:

1) Acceptance (with or without conditions)
2) Grounds for non-acceptance

If there are grounds for non-acceptance the sponsor has at least 14 days (at least 30 days for gene therapy, somatic cell therapy or products containing genetically modified organisms) to submit an amended request for authorisation.

The amended request is assessed within a total of 60 days from receipt of the initial application (90 days for gene therapy products) and there are 2 possible outcome

1) Acceptance (with or without conditions)
2) Rejection

8e. Amendments- during trial

The MHRA must provide authorisation for amendments to documents that they received in the CTA application and originally authorised. The MHRA only need to be informed of

amendments to documents that they are not required to authorise. The following documentation should be sent with the amendment:

- A covering letter (details of what is required in this is on the website)
- A CT Amendment Form (available at the EudraCT website)
- An extract of the modified documents - showing the previous and new wording
- Supporting information including summaries of data (if applicable), possible consequences for patients already in the trial and possible consequences for the evaluation of the results.

The MHRA will notify you if you require ***approval*** for the amendments to be implemented. If you require ***approval***, this will be provided in a maximum of 35 days after submission of the amendments to MHRA.

8f. Study Closure

An “End of Study” report must be completed and sent to the MHRA. Further details and the form can be accessed from the EudraCT website. This form requests the following information:

- Name and address of the Sponsor’s (or sponsoring group’s) legal representative in the Member State
- Title of the trial
- EudraCT number
- Trial protocol code number
- Date of end of trial in the Member State concerned
- Date of end of complete trial in all participating centres in all countries within and outside the EU, when available

9. Other things to consider as part of the clinical trials process

9a. ARSAC Administration of Radioactive Substances Advisory Committee

Does the trial contain additional bone scans, PET scans or MUGA scans? If so, an ***ARSAC*** certificate will need to be obtained as part of trial set up.

9b. Trial Costings and Contracts

Prior to the study it is necessary to produce trial costings. How is the trial being funded? Detail any grants/funding from commercial organisations, DoH, other funds. It maybe that the trial is commercially funded however costs will still need to be calculated.

9c. Site Files

These should be established according to individual Trusts or university's ***Standard Operating Procedures*** (SOPs). The sponsor site, is required to hold a Trial Master File in addition to a site file. If the trial is a multi-site trial then participating site files for the other sites should be produced, and sent to the sites with guidance as to completion. When the trial is open to recruitment, it is important to maintain the site file. Throughout the study, all of these documents could potentially be amended and it is important to ensure the correct version is being used.

The site file generally includes the following documents

- Protocol and amendments
- Signed protocol
- Blank ***CRF***
- ***Informed consent*** and patient information sheets
- Signed informed consents
- Investigator brochure
- Financial agreement
- Insurance statement
- All correspondence to and from sponsor
- Archiving instructions
- Approvals and correspondence from ethics
- Laboratory procedures
- Personnel file with all participants C.V's and training
- Drug files such as handling procedures, randomisation codes, shipping records
- Patient details such as id log, Serious ***Adverse Event*** (SAE) reports.

10. Applying for hospital R&D Approval- study set up

Within most hospitals a policy of trust approval exists. All research conducted must be registered with, and approved by, the Trust's R&D department prior to any research activity commencing. This generally ensures the trust has the resources and finances to undertake such research and also the liability and insurance aspects of the trial are

covered. They are also invaluable in providing help and support for ***National Research Ethics Committee (NRES)*** submission should the study require such permission.

11. Research, Audit and Service Evaluation

<table>
<tr><td colspan="3">Research (R)</td><td>Clinical audit (A)</td><td>Service evaluation* (E)</td></tr>
<tr><td colspan="3">Definition: Attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods</td><td rowspan="2"></td><td rowspan="2"></td></tr>
<tr><td>Basic research</td><td>Applied research</td><td>Experimental Development (D)</td></tr>
</table>

Definition: Basic Research is experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundation of phenomena and observable facts, without any particular application or use in view.	**Definition:** Applied Research is also original investigation undertaken in order to acquire new knowledge, but directed primarily towards a specific practical	**Definition:** Experimental Development is systematic work, drawing on existing knowledge gained from research and/or practical experience, that is directed to producing new materials, products and devices; to installing new processes, systems and services; or to improving substantially those already produced or installed which will lead to an extension of knowledge.	**Definition:** An ***audit*** investigates whether something is being done and if not, why not	**Definition:** Evaluation focuses on assessing internal situation, such as collecting data about specific programs, with no intent to generalise the results to other settings and situations.
The attempt to derive generalisable new knowledge including studies that aim to generate hypotheses as well as studies that aim to test them.			Designed and conducted to produce information to inform delivery of best care.	Designed and conducted solely to define or judge current care.
Quantitative research – designed to test a hypothesis. Qualitative research – identifies/explores themes following established methodology.			Designed to answer the question: “Does this service reach a predetermined standard?”	Designed to answer the question: “What standard does this service achieve?”

Addresses clearly defined questions, aims and objectives. May establish new standards.	Measures against a standard.	Measures current service without reference to a standard.
Quantitative research - may involve evaluating or comparing interventions, particularly new ones. Qualitative research - usually involves studying how interventions and relationships are experienced.	Involves an intervention in use ONLY. (The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference.)	Involves an intervention in use ONLY. (The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference.)
Usually involves collecting data that are additional to those for routine care but may include data collected routinely. May involve treatments, samples or investigations additional to routine care.	Usually involves analysis of existing data but may include administration of simple interview or questionnaire.	Usually involves analysis of existing data but may include administration of simple interview or questionnaire.
Quantitative research - study design may involve allocating patients to intervention groups. Qualitative research uses a clearly defined sampling framework underpinned by conceptual or theoretical justifications.	No allocation to intervention groups: the health care professional and patient have chosen intervention before clinical ***audit***.	No allocation to intervention groups: the health care professional and patient have chosen intervention before service evaluation.
May involve randomisation	No randomisation	No randomisation
RESEARCH REQUIRES Research Ethics Committee (REC) REVIEW (review will determine ethical approval need - minor technical developments/changes do not usually need approval)	**AUDIT DOES NOT REQUIRE REC REVIEW**	**SERVICE EVALUATION DOES NOT REQUIRE REC REVIEW**

Definitions taken from NICE, NHS R&D Forum, NRES, CUH R&D. Any of these may raise ethical concerns under current guidance

* Technical, technique or treatment effectiveness evaluation falls under R&D

12. Ethics

All research needs to be reviewed by an ethics committee and permission must be sought from all NHS organisations if using NHS resources. If the research is to be conducted within a university or other department then refer to local protocols to determine from where ethical permission needs to obtained. Data collection MUST NOT begin until ethical approval has been gained.

The purpose of the ethics committee is to protect the safety, dignity and rights of humans or animals participating in research. The committee must comprise at least seven members from scientific and lay backgrounds. They have a maximum of 60 days from the date of receipt of an application to make a decision and 35 days to offer an opinion on amendments. Ethics submission and approval is required for all research which involves patients or human tissues. The previous table can give you guidance as to the necessity of ethics submission, but it is always best practice to enquire at your local R&D office or ethics committee for advice and guidance.

The committee will give ethical consideration to several aspects of a trial; these will include recruitment, study design, confidentiality, and informed consent. To achieve this, the committee require all paper work complete with version number, however as many members of ethical committees will not have specific expertise in your field of work, it's worth putting technical details into an appendix and writing the main proposal for a layperson audience.

A site specific assessment (SSA) is an assessment of the suitability of each research site and local Principal Investigator, further details about this process can be found on the NRES website.
www.nres.org.uk

12a. National Research Ethics Service (NRES) - ethical approval- Study Set Up
AS of April 2009 the NRES application has now been replaced by the ***Integrated Research Application System (IRAS)*** which was introduced into the UK in January 2008. The IRAS is a single system for applying for the permissions and approvals required to conduct research in the NHS. This new system is designed to streamline the process with one point of entry for applications and has comprehensive guidance.

12b. During Trial – Amendments

The ethics committee will need to know about all amendments to the trial; such as increase in patient numbers, changes to the protocol etc. It is important to ensure that the protocol and other supporting information such as recruitment posters and information leaflets. have a version number and a date, and that these details are updated each time the protocol is amended. Ethics will need copies of the updated documents, in addition to the Notification of Amendment form. This can be found on the NRES website. The ethics committee will then either acknowledge the amendment or approve/ reject the amendment

12c. During the Trial- Annual Reports

All ***clinical trial***s need to submit annual reports to NRES. The sponsor or the ***chief investigator*** site will complete this. A template for this is on the website.

12d. Study Closure

When the study closes to recruitment, the NRES need to be notified. There are instructions for this on the website. Again, only the sponsor site or the ***chief investigator*** must complete. In all other situations, this information will be for the site file.

In addition, when the study closes to recruitment, NRES will need to be informed. They will want to know how many patients were recruited and when exactly the study closed to recruitment.

13. Consent

The process of consent is complicated however it is critical in the field of research. The consent process and legal requirements vary for certain groups of patients such as minors or those with mental incapacity. It is essential that those who work in this field are familiar and regularly updated with changes in legislation. The following information is by no means comprehensive but aims to highlight key points.

Informed consent is defined as “the process by which a subject voluntarily confirms his/ her willingness to participate in a particular ***clinical trial***, after having been informed of all aspects of the trial that are relevant to the subjects decision to participate” ICH 1.28

Prior to the start of any study the ethical committee must have approved the consent process and documentation for a particular study. The length of time given to the patient

to consider the study varies and must be stipulated in the documents however the standard minimum time is 24 hours (excluding emergency treatment research) though longer (1 week() is usually preferred by ethics committees. Consent throughout a study is continuous and the patient holds the right to withdraw at any time.

When patients are being recruited into studies they should be informed of all aspects in language that is easily understood and they should not be bribed or coerced in any way. Consent must be obtained prior to any participation in a trial.

When consent has been obtained the patient should print, sign and date their name on the consent form, the practitioner taking consent must then do the same. International Commission of Harmonisation for Good Clinical Practice. (ICH-GCP) states the subject must be given a copy of consent and the original filed in the file notes, however better practice would also see a copy held in the patient notes.

The ***principal investigator*** retains the overall responsibility for the consent process at all times, they can perform the process alone or may delegate to a medically qualified co-investigator. If you undertake consent ensure you check that you are covered for indemnity by your employer. Radiographers can consent if they are the CI or PI or the study does not involve medical intervention such as Quality of life studies. It is vital you ensure you know your role and scope of practice.

The ICH-GCP recommends 20 elements of informed consent that are required which can be accessed via their website (see glossary), and informed consent guidelines are also available on the NRES website (see glossary). The college of Radiographers have also published guidelines on obtaining consent for imaging and treatment, of which many of the same principles of informed consent for research apply. (8).

Recommended Reading

General Medical Council (2008) Consent: Patients and doctors making decisions together

14. How to Access Trial Information and National Study Results

Information pertaining to UK radiotherapy trials may be accessed through the ***National Cancer Research Network (NCRN***) database by searching the radiotherapy section or by individual tumour study group trials. The NCRN database (www.ncrn.org.uk) lists all the national ***clinical trial***s that are in set-up, open to recruitment or closed. The number of radiotherapy trials listed will vary. They cover several tumour sites and a description of each trial may be accessed with information regarding the recruitment to date, date of closure, entry criteria, ***chief investigator*** and study contact. Copies of the protocol are available to healthcare professionals via e-mail or by links to the trial office.

Studies funded by, or of interest to the NHS and performed up to September 2007 are registered on the ***National Research Register*** database (see glossary for URL)
Since September 2007, the introduction of the ***United Kingdom Clinical Research Network (UKCRN)*** has shifted the responsibility for registering eligible research from NHS organisations to the researcher and the appropriate research network. The method of collecting this information is specific to each network but the total collection forms the UKCRN Portfolio Database which is an open access database of current ***clinical trial***s.

The national trials quality assurance team has a useful website www.rttrialsqa.org.uk which lists the current radiotherapy ***clinical trial***s and the necessary quality assurance programme for the individual trials.

The National Institute for Health Research has some good advice on how to negotiate ethics, and research governance. In addition, it is the place to gain up to date information on the current NHS research infrastructure.

15. Identifying and Dissemination of Research Knowledge and Information

15a. Literature searches.

Most literature searches are now undertaken electronically using a number of databases, though it is still important to be aware of 'grey literature' (literature that isn't published or indexed on any database) and checking the reference list of any relevant journal articles you may be using is also a useful way of ensuring you have all the relevant literature on your subject.

To enable access to databases institutions, either university or hospital or both, provide the user with a password. ***Athens*** and ***Ovid*** are examples of password authentication systems to access on-line resources and databases.

It is strongly recommended that you visit your subject librarian before commencing any database search as the list below is not exhaustive and other databases more pertinent to your topic may exist. Additionally, there are various search strategies by which you need to be familiar before embarking, such as ***MeSH (Medical Subject Headings)*** *terms*.

Useful databases:

Database	**Content**	**Access**
Pub-Med	General	Free
Med-line	General	Password
CINAHL	Nursing and allied health	Password
Cochrane	Evidence based, reviews	Free
HILO	Health Information for London Online- allows access to databases from any computer via ***Athens*** password	Password
Embase	Biomedical database	Accessed with ***Athens*** username and password

ISI Web of Knowledge (incorporates ISI Web of Science)	A collection of databases for health and social care.	Access needs institutional subscription
AMED	Allied and Complementary Medicine Database	Accessed with ***Athens*** username and password
EBSCO	An interface that allows a number of different databases to be searched at the same time	Access needs institutional subscription

There are a number of free online tutorials which take you through the process of searching databases for relevant literature. A couple of which are listed below.

Useful links:
http://www.imperial.ac.uk/library/pdf/NHS_Athens_improving.pdf (Accessed 11.09.09)
http://www.nlm.nih.gov/bsd/disted/pubmedtutorial/ (Accessed 11.09.09)

15b. Abstract writing

What is an abstract?
An abstract is a concise summary of the details of an article/presentation/poster. It should include the main points and conclusions. If a study has been performed it provides an overview of what the study is about and how it was conducted. It should be written in a readable style rather than in note form.

The importance of an abstract
When performing a database search an abstract is often the only detail individuals may see to convince them that the article is worth reading.

Abstract construction
Abstracts are usually structured under the following headings:

- Introduction

- Method and Materials
- Results
- Conclusions

Useful tips:

- Ensure the word limit is adhered to. This may differ between publications/ presentations.
- Include keywords/phrases in your abstract. Electronic searches are often run using these.
- Remember to include complete author list

15c. Poster Presentations

A poster is a concise presentation of work in a visual format. Do not be tempted to reproduce the abstract in large size. Use images imaginatively with minimal wording. A medical poster template can be downloaded within Microsoft Office PowerPoint.

Poster construction

A standard poster format is usually followed.

- Title
- Summary
- Introduction
- Methodology
- Results
- Conclusion
- Further work

Planning the poster is crucial and practical considerations to take into account include:

- Size requirement for the poster
- The limited space available to convey information
- The target audience
- The overall visual appearance of the poster
- Readability of text at a distance

The visual appearance of a poster is often a personal decision

. **15d. Oral presentations**

There are 2 distinct areas to address for an oral presentation:

- Slide preparation
- Presentation of slides to an audience

Slide preparation

- The talk should be pitched at an appropriate level for the target audience
- Organise the content into a coherent structure such as introduction/background, methodology, results and conclusion with suggestions for further work if necessary.
- Do not be tempted to place too much information on your slides (Less is More!), they are there as an adjunct to your speech and your verbal presentation.
- The content should highlight what you are going to tell the audience, then tell them and finally summarise what you have told them

Slide presentation

- Introduce yourself to the chair before the session begins
- Demonstrate an ability to communicate clearly to an audience
- Be aware of body language
- Smooth delivery
- Address the audience making eye contact during delivery
- Keep to time, if chair signals time is running short finish quickly
- Show an ability to answer questions
- Acknowledge funding and help

Useful Tips

- Practice. Get colleagues to listen and provide feedback. Also get lay members to listen (friends etc) who will be able to advise you no your style of delivery even if they don't understand your topic area.
- Practice timing. Record yourself giving the presentation and play it back to hear where you need to slow down or whether any information you give is confusing.
- Check technical equipment and be familiar with it's use

Useful links:

http://www.med.yale.edu/library/education/effective.pdf

http://www.med.yale.edu/library/education/yaletips.pdf

http://lorien.ncl.ac.uk/ming/Dept/Tips/present/comms.htm

16. Gaining Funding

Applying for and securing project funding is not easy even for experienced researchers. Competition is often high and funding bodies have limited budgets so proposals need to be high quality and value for money. Therefore, it is recommended that those new to research join established research teams on other research projects to gain experience and develop a research reputation before attempting to go it alone. It may also be worth looking for funding bodies that target novice researchers or those who are in the early stages of a research career. These funding bodies often have a remit to broaden research activity and in order to capacity build they may look positively on less experienced researchers offering support in order to nurture a research environment. For example, the ***Society and College of Radiographers*** has a funding stream that will support smaller projects.

A full list of funding opportunities can be found on the Research and Development website www.RDinfo.org.uk (accessed 11.09.09). When identifying possible funders remember to ensure your project reflects the priorities of the funding body as well as priorities of professional bodies, or government agencies. When completing funding applications it is important to follow guidelines stipulated by the funding body, failure to do so may jeopardise the success of the application.
Funding bodies generally use some form of peer review so it is important to find out how the application will be assessed the box below lists the criteria used by the College of Radiographers to assess funding applications.

The CoR Funding Assessment Criteria

- **Potential to advance the profession**
- **Closeness of fit with candidates career**
- **Methodology including an assessment of the following:**

1. **Appropriateness of the method**
2. **Considerations of data analysis proposed**
3. **Ethical implications**
4. **Procedures for testing reliability and validity (or trustworthiness and credibility).**

- **Value for money**
- **How the proposed study fits with CoR research priorities**
- **Potential for follow on work**
- **Dissemination strategy proposed**
- **Level of institutional support.**

Other major sources of funding are available through the ***National Institute for Health Research (NIHR).*** A number of different programmes of research are available through the NIHR the funding streams particularly relevant to radiographers include:

- Research for Patient Benefit
- Service Delivery and Organisation Programme
- Research Capacity Development Programme
- Health Technology Assessment Programme

For more details about the NIHR programmes you should access the NIHR web site (See glossary).

17. Research Training

You may feel that you need some training before you embark on a research project of your own or maybe you are thinking about a research career. Research training maybe provided in undergraduate and postgraduate courses in the form of single modules covering a broad perspective of research designs. These single modules are usually viewed as an introduction to research methods and further research training may be needed to develop specialist skills. Universities usually offer a range of taught modules or single day events for Continuous Professional Development (CPD) purposes. In the UK the RDInfo web site lists formal taught research courses as well as short courses on a range of research topics. In addition, practitioners should look out for local workshops or study days run by NHS ***Research Development and Support Units (RDSU)*** (see glossary) these are often free to attend.

Those wanting more formal training may want to consider a Masters course in research methodology or a Master of Science degree by thesis, Master of Philosophy (MPhil) or a Doctorate. The Doctor of Philosophy (PhD) qualification usually requires a period of

study of a range of research methodologies relevant to the chosen thesis topic. In addition, the newer Professional Doctorate qualifications include a formal programme of research training; both options allow individuals subsequently to give greater intellectual input to research studies rather than remaining simply as data collectors, interviewers or recruiters of research participants.

Looking at a recent review of training needs for research radiographers in the UK areas identified for further training and education were;

- Good clinical practice (***ICH-GCP***)
- Scientific report writing
- Statistics
- Human tissue bill
- ***Clinical trial***s directive
- Ethics
- Grant writing
- Research methodology
- Informed consent

This knowledge may help direct you when thinking about the additional knowledge you may require in this role.

- Further useful information on training and education can be accessed on the ACORRN website (see glossary)and the Society and College of Radiographer's (SCoR) website (see glossary). It may also be worth contacting your local NHS ***RSDU***, or local cancer research network as they will usually run free or inexpensive courses on topics such as research methods and data analysis. In addition they can usually provide statistical support often free of charge. Use your local R&D department as they are supportive of AHP researchers and will encourage with local support and expertise.

18. Helpful hints

- If you have them access the research nurses within your trust, they have been participating in research a long time and generally have already established good pathways into education and training and what is on offer locally.

- Record and document everything, you can never have too much information even if you only use a fraction of it, you can never go back and get that information again.
- Establish a log book for everyday – including contacts, phone numbers, problems with for example postal services. Always useful to provide evidence later if you have to explain events and actions taken.
- It is not good practice to be a lone researcher – seek out a mentor who is an experienced researcher and learn with them. This is further enhanced if you can be integrated to a multi-disciplinary research group.
- Negotiate dedicated time for research, it should not be fitted in around other things
- Contact the Society and College of Radiographers who have a dedicated research representative who will be able to guide and assist you.

- Establish your own filing system, both for hard copies and electronic copies of documents/ideas/minutes/results/references etc

Acknowledgements

Sarah Ashton, Lisa Dixon, Christine Camacho, Katie Doyle, Angela Ball
R&D department
The Christie NHS Foundation Trust, Manchester.

Ric Swindell,
Statistician
The Christie NHS Foundation Trust, Manchester.

Rachel Harris
Professional Officer for Research
Society and College of Radiographers

Nicola Stones, Gillian Heap
ACORRN

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