Research Radiographer

Starter Pack

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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 currently active on the ACORRN Research Radiographer working party 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 and which are now 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 information. Legal requirements are constantly updated and changes made, it is essential that when participating in research you seek further information and advice from the appropriate regulatory body, and ensure you receive appropriate training.
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 [1]. Research includes both quantitative and qualitative methodologies. Research activity ranges from high level, scientific generation of new evidence, to more everyday utilisation of research findings to ensure that practice and patient-centred care is evidence based [2]

It 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 and are accessed by those who would benefit from them.[3]

Research radiographers are involved with many aspects of research, large aspects of their work can be in the field of Translational research this 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.

Legal Aspects of Research

Since 1997 the International Commission of Harmonization for Good Clinical Practice (ICH GCP) has standardised the clinical practice related to clinical 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 are summarised 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 trials 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
- A trial must have ethical approval

The EU trial directive aims to protect the rights, safety and well being of trial participants, ensure the credibility of results and to 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”. [4]
Current MHRA guidance stipulates that all staff working on clinical trials must update their understanding of GCP at least every 2 years.

For further information about the legal aspects of research visit:

www.cirp.org/library/ethics/helsinki
www.ich.org
www.ukcrn.org.uk/index/training.html

NRES guidance on approval for research involving ionising radiation
Version 2, September 2008 via www.nres.npsa.nhs.uk
WWW.myresearchproject.org.uk
The Role of the Research Radiographer

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.

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 (SCoR res strategy, Acorn gap analysis). The advanced practice role, 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 roles, but research radiographers will have specific expertise in the application of research methodologies.

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. 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

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1 To clarify, a role describes the part you play within your organisation as differentiated from responsibilities which describe the obligations of the role.
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.)

**What activities are considered as research?**

There are many activities that fall into the category of research. A few are outlined below:

- Identifying research areas needed
- Writing grant application or finding funding for research
- Writing ethical approval applications
- Project management
- Accruing patients into trials
- Consenting patients for studies
- Giving study information to patients, carers, health professionals and others
- Collecting 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 or carrying out audit of practice and changes to practice
- Creating strategies for research programmes
- Teaching research methodologies
- Training for research practices
- Creating and managing research programmes
• Developing, implementing or evaluating 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

**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. A few of these are:

• Pure research (often called Research Radiographer)
• Trial co-ordination
• Research assistant
• Technique development
• Translational
• Research manager
• Research lecturer/supervisor

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:
<table>
<thead>
<tr>
<th>Role specialisation</th>
<th>Main activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pure Research</td>
<td>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</td>
</tr>
<tr>
<td>Trial Co-ordinator</td>
<td>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</td>
</tr>
<tr>
<td>Research assistant</td>
<td>Assists lead investigator in their research – may include data collection, creating research documentation, data management, and patient support</td>
</tr>
<tr>
<td>Technique development</td>
<td>Develops, implements or evaluates effectiveness of new techniques, treatments, equipment, or practices</td>
</tr>
<tr>
<td>Translational</td>
<td>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</td>
</tr>
<tr>
<td>Research Manager</td>
<td>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</td>
</tr>
<tr>
<td>Research lecturer/supervisor</td>
<td>Manages, educates and trains students in research methodologies and practices, supervises academic research activities, adjudicates research proposals, dissertations and theses, reviews research publications</td>
</tr>
</tbody>
</table>
Role of Research Radiographer within Multi-disciplinary Team (MDT)

Most radiographers will 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 subject matter expertise of many disciplines and good communication is essential to prevent misunderstanding or duplication.

R&D structure within clinical setting

The research MDT 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 tumour specific 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 getting started in research, it is recommended that you take time to establish how the research mechanism works in your department.
The radiographers’ role within the MDT will vary according to their research role 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.
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 do you have
- Who you need to communicate with
- How often.

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 the need for research governance and helps develop an analytical clinical culture.

Diagnostic Radiographers in Research

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, therefore there are many topics of research just waiting to be investigated, these include established practice, innovative practice, radiation protection, service provision and of course patient care.
Quantitative and qualitative research methods can be used, but it is the qualitative data, although time-consuming to collect and analyse which will give the rich valuable patient experience that we as professionals do not have.

Radiographers are ideally placed to engage with patients to investigate their treatment and care. This patient-centred approach to research has been advocated by the UK Government under its Patient Public Involvement (PPI) Agenda. This engagement is essential as patients are the ones who experience our service, no matter what we think it is like—they have found out by experience and we must listen and learn from them how we can improve our practice or service to them. If you wish to know more relating to involving patients in research the website http://www.involve.org.uk/home will be useful, and also contains other valuable links.

If unfamiliar with research, support can be found from the many books out there, 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. In fact it is an excellent 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. Radiography is a degree profession, therefore this must be the ultimate goal. Suggested books list can be found in the Appendix.
Other Roles within Research

Although the research teams are of different sizes and compositions, the basic research delegation structure (page 12) 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 however further far more detailed responsibilities which can be accessed on the ICH website.

**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.

**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*.

**Data Manager / Clinical Trials Administrator (CTA)**

Administrative duties such as CRF completion or submitting ethics applications may be delegated to data managers or CTA's. 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.
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 trials 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 NIH, Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective. Clinical trials of experimental drug, treatment, device or behavioral intervention may proceed through four phases:

- **Phase I** clinical trials 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 trials 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 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.
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.

How is a patient randomised to a particular 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.

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.

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.

For further information about cancer research please visit:
www.cancerresearchuk.org
www.bacr.org.uk

For further information about cancer clinical trials, go to:
www.ncrn.org.uk
www.icr.ac.uk
www.eortc.be
www.mrc.ac.uk
www.ncri.org.uk
www.cancer.gov
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:

<table>
<thead>
<tr>
<th>STAGE</th>
<th>Medicines and Healthcare products Regulatory Agency (MHRA):</th>
<th>ETHICS</th>
<th>R&amp;D</th>
<th>OTHER</th>
</tr>
</thead>
<tbody>
<tr>
<td>SET-UP</td>
<td>• MHRA approval required</td>
<td>• Complete relevant sections of the NRES application form</td>
<td>• Apply to R&amp;D and submit all relevant documents</td>
<td>• ARSAC</td>
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<td></td>
<td></td>
<td>• MREC and LREC approval required</td>
<td>• R&amp;D approval required</td>
<td>• Costings</td>
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<tr>
<td></td>
<td></td>
<td>• Apply to R&amp;D and submit all relevant documents</td>
<td>• ARSAC</td>
<td>• Contracts</td>
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<tr>
<td></td>
<td></td>
<td>• R&amp;D approval required</td>
<td>• Costings</td>
<td>• Insurance/indemnity</td>
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<td></td>
<td></td>
<td>• ARSAC</td>
<td>• Contracts</td>
<td>• Establish site files</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Costings</td>
<td>• Insurance/indemnity</td>
<td>• Produce CRFs (only required if sponsor site)</td>
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<tr>
<td></td>
<td></td>
<td>• Contracts</td>
<td>• Costings</td>
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<td>• Insurance/indemnity</td>
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<td></td>
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<td>• Establish site files</td>
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<td></td>
<td></td>
<td>• Produce CRFs (only required if sponsor site)</td>
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<td>• Invoicing</td>
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<td></td>
<td>• Data Queries</td>
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<td></td>
<td></td>
<td>• Archiving</td>
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<tr>
<td>DURING TRAIL</td>
<td>• sponsor to submit any amendments, and approved by the MHRA</td>
<td>• sponsor advise the ethics committee of any amendments and seek approval of these amendments</td>
<td>• Send details of all amendments to R&amp;D/CTRG</td>
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<td></td>
<td></td>
<td>• File all amended documents as appropriate</td>
<td>• Upon approval update site file and advise all members of the team of any new versions of documents</td>
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<tr>
<td></td>
<td></td>
<td>• Progress Reports (sponsor)</td>
<td>• Update ARSAC licence if applicable</td>
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<td></td>
<td></td>
<td></td>
<td>• Maintaining site file</td>
<td></td>
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<td></td>
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<td></td>
<td>• Version Control</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>• CRFs</td>
<td></td>
</tr>
<tr>
<td>CLOSURE</td>
<td>• End of Study Report submitted to MHRA.</td>
<td>• End of Study Report submitted to ethics.</td>
<td>• Advise R&amp;D when studies are closed to recruitment and also when data is locked for final analysis</td>
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<tr>
<td></td>
<td></td>
<td>• Final Progress Report submitted 12 months after study closure.</td>
<td>• Send copies of the End of Study Report and any related information to R&amp;D when available</td>
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<td>• Invoicing</td>
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<td>• Archiving</td>
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</table>

A useful website for setting up clinical trials is:
- www.ct-toolkit.ac.uk
- WWW.myresearchproject.org.uk
MHRA (Medicines and Healthcare Regulatory Agency)

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.

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 Trials Helpline where you can email and request an opinion from the MHRA of the status of the trial.

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.
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 Trials 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 outcomes:

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

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

**Links**

[http://eudract.emea.europa.eu/](http://eudract.emea.europa.eu/) - EudraCT home page which has links to getting EudraCT number, application form, substantial amendment form, end of trial form.


**Other things to consider as part of the clinical trials process**

**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.

**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.

**Site Files**  
These should be established according to individual Trust 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 cvs and training
- Drug files such as handling procedures, randomisation codes, shipping records
- Patient details such as id log, sae reports.
# Research, Audit and Service Evaluation

<table>
<thead>
<tr>
<th>Research (R)</th>
<th>Clinical audit (A)</th>
<th>Service evaluation* (E)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition:</strong> Attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods.</td>
<td><strong>Definition:</strong> An audit investigates whether something is being done and if not, why not.</td>
<td><strong>Definition:</strong> 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.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Basic research</th>
<th>Applied research</th>
<th>Experimental Development (D)</th>
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<tbody>
<tr>
<td><strong>Definition:</strong> 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.</td>
<td><strong>Definition:</strong> Applied Research is also original investigation undertaken in order to acquire new knowledge, but directed primarily towards a specific practical.</td>
<td><strong>Definition:</strong> 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.</td>
</tr>
</tbody>
</table>

The attempt to derive generalisable new knowledge including studies that aim to generate hypotheses as well as studies that aim to test them.

Quantitative research – designed to test a hypothesis. Qualitative research – identifies/explores themes following established methodology.

Designed and conducted to produce information to inform delivery of best care.

Designed to answer the question: “Does this service reach a predetermined standard?”

Designed and conducted solely to define or judge current care.

Designed to answer the question: “What standard does this service achieve?”
<table>
<thead>
<tr>
<th>Addresses clearly defined questions, aims and objectives.</th>
<th>Measures against a standard.</th>
<th>Measures current service without reference to a standard.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quantitative research - may involve evaluating or comparing interventions, particularly new ones. Qualitative research - usually involves studying how interventions and relationships are experienced.</td>
<td>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.)</td>
<td>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.)</td>
</tr>
<tr>
<td>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.</td>
<td>Usually involves analysis of existing data but may include administration of simple interview or questionnaire.</td>
<td>Usually involves analysis of existing data but may include administration of simple interview or questionnaire.</td>
</tr>
<tr>
<td>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.</td>
<td>No allocation to intervention groups: the health care professional and patient have chosen intervention before clinical audit.</td>
<td>No allocation to intervention groups: the health care professional and patient have chosen intervention before service evaluation.</td>
</tr>
<tr>
<td>May involve randomisation</td>
<td>No randomisation</td>
<td>No randomisation</td>
</tr>
</tbody>
</table>

**RESEARCH REQUIRES 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
Ethics
All research needs to be reviewed by an ethics committee and permission must be sought from all NHS organisations where research will be conducted. The purpose of the ethics committee is to protect the safety, dignity and rights of individuals 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. The previous table can give you guidance as to the necessity of ethics submission, but it is always the best practice to enquire at your local office 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.

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

NRES forms- ethical approval- Study Set Up
The completing the NRES form is part of the Ethics procedure. The lead site for a study would complete parts A and B, as well as part C, participating sites, we would only need to complete the part C. The NRES forms are completed through the website.

www.nres.org.uk
After sections A and B are completed:

- The form needs to be sent for approval. You can apply to any ethics committee in the country, whichever is geographically most convenient, or whichever has the nearest meeting date. A full list of these are available on the NRES website.
- A number of other documents need to be sent to NRES, such as Patient Information Sheets (PIS) and Informed Consent Forms (ICF).
- The study will have to go to an ethical meeting
- Remember to keep a signed copy of the form for your records.

**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 content of the PIS/ICF, Protocol Updates etc. It is important to ensure that the protocol etc. has a version number and a date, and that these details are updated each time the protocol is amended. Ethics will need to be sent 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

**During the Trial- Annual Reports**

All clinical trials 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.

**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, LREC will need to be informed. They will want to know how many patients were recruited and when exactly the study closed to recruitment.
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. 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. 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. A nurse or radiographer should not be sole signatory on consent, this is due to not being medically qualified, and not covered by normal professional indemnity. However there are exclusions to this rule where 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 recommends 20 elements of informed consent that are required which can be accessed via their website ICH 4.8.10, and informed consent guidelines are also available on the NRES website. Further information can also be found in the College of Radiographers document (8).

Recommended Reading

General Medical Council (2008) Consent: Patients and doctors making decisions together
How to Access Trial Information and National Study Results

Information pertaining to UK radiotherapy trials may be accessed through the 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 trials that are in set-up, open to recruitment or closed. The number of radiotherapy trials listed will vary they cover several tumour sites, 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.

The national trials quality assurance team has a useful website at www.rttrialsqa.org.uk which lists the current trials and the necessary quality assurance programme for the individual trials.
Identifying and Dissemination of Research Knowledge and Information

Literature searches

Resources

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

Useful databases:

<table>
<thead>
<tr>
<th>Database</th>
<th>Content</th>
<th>Access</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pub-Med</td>
<td>General</td>
<td>Free</td>
</tr>
<tr>
<td>Med-line</td>
<td>General</td>
<td>Password</td>
</tr>
<tr>
<td>CINAHL</td>
<td>Nursing and allied health</td>
<td>Password</td>
</tr>
<tr>
<td>Cochrane</td>
<td>Evidence based, reviews</td>
<td>Free</td>
</tr>
<tr>
<td>HILO</td>
<td>Health Information for London Online- allows access to databases from any computer via Athens password</td>
<td>Password</td>
</tr>
</tbody>
</table>

Useful links:

Journal searches
The following is a non-exhaustive list of radiotherapy related journals that may be of value:

Radiotherapy and Oncology
http://www.sciencedirect.com/science/journal/01678140

International Journal of Radiation Oncology*Biology*Physics
http://www.sciencedirect.com/science/journal/03603016

British Journal of Radiology
http://bjr.birjournals.org/
Clinical Oncology
http://www.sciencedirect.com/science/journal/09366555

Physics in Medicine and Biology
http://www.iop.org/EJ/journal/PMB

Medical Dosimetry
http://www.sciencedirect.com/science/journal/09583947

Journal of Radiotherapy in Practice
http://journals.cambridge.org/action/displayJournal?jid=JRP

Radiography
http://www.sciencedirect.com/science/journal/10788174
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 listing
**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. The link below provides some advice on constructing posters:

[http://lorien.ncl.ac.uk/ming/Dept/Tips/present/posters.htm](http://lorien.ncl.ac.uk/ming/Dept/Tips/present/posters.htm)
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
- 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
- Practice timing
- 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
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 doctoral projects as well as small projects. A full list of funding opportunities can be found on the research and development website www.RDinfo.org.uk. 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.

<table>
<thead>
<tr>
<th>The CoR Funding Assessment Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Potential to advance the profession</td>
</tr>
<tr>
<td>• Closeness of fit with candidates career</td>
</tr>
<tr>
<td>• Methodology including an assessment of the following:</td>
</tr>
<tr>
<td>1. Appropriateness of the method</td>
</tr>
<tr>
<td>2. Considerations of data analysis proposed</td>
</tr>
<tr>
<td>3. Ethical implications</td>
</tr>
<tr>
<td>4. Procedures for testing reliability and validity (or Trustworthiness and credibility).</td>
</tr>
<tr>
<td>• Value for money</td>
</tr>
<tr>
<td>• How the proposed study fits with CoR research priorities</td>
</tr>
<tr>
<td>• Potential for follow on work</td>
</tr>
<tr>
<td>• Dissemination strategy proposed</td>
</tr>
<tr>
<td>• Level of Institutional support.</td>
</tr>
</tbody>
</table>
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 (http://www.nihr.ac.uk/programmes_research_programmes.aspx).

**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 Research Design Services (see http://www.national-rdsu.org.uk/).

Those wanting more formal training may want to consider Masters courses 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\textsuperscript{[6]} 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 [7], areas identified for further training and education were;

- Good clinical practice (ICHGCP)
- Scientific report writing
- Statistics
- Human tissue bill
- Clinical trials 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 Acorn website www.acorn.org or the Society website www.sor.org. It may also be worth while contacting your local NHS Research and Development Department, or local cancer research network they will usually run inexpensive but useful courses on topics such as research methods, and data analysis. In addition they can usually provide statistical support free of charge. Use your local R&D department generally they are supportive of AHP researchers and will encourage with local support and expertise.
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 who have a dedicated research representative, they will be able to guide and assist you.
Glossary of Research Terms

A

Abstract:
A brief description of completed or proposed study; in research journals, usually located at the beginning of the journal paper or the submission for a conference presentation.

ACORRN Academic Clinical Oncology and Radiobiology Research Network

Adverse Reaction (ADR):
A reaction to a study drug which is harmful and unintended and which occurs at a dose normally used for the prophylaxis, diagnosis or treatment of disease or the modification of physiological function.

Adverse Event (AE):
Any adverse change in health or "side-effect" that occurs in a person during a clinical trial or within a pre-specified period after dosing is complete.

Approval:
(In relation to institutional review boards). The affirmation decision of the IRB (i.e., ethics committee, MHRA, R&D) that the clinical trial has been reviewed and may be conducted at the institution site within the constraints set forth by the IRB, the institution, good clinical practice (GCP), and the applicable regulatory requirements.

ARSAC:
Administration of Radioactive Substances Advisory Committee (ARSAC).

ASTRO
American Society for Therapeutic Radiology and Oncology

Audit:
(Of a clinical trial). A systematic and independent examination of trial related activities and documents to determine whether the evaluated trial related activities were conducted, and the data were recorded, analysed and accurately reported according to the protocol, sponsor’s standard operating procedures (SOP’s), good clinical practice (GCP) and the applicable regulatory requirements.

Audit Trail:
Documentation that allows reconstruction of the course of events.
Baseline Assessment:
Assessment of the subjects as they enter a trial and before they receive any treatment.

Basic research:
Research designed to extend the body of knowledge in a discipline for the sake of knowledge or theory construction, rather than for solving an immediate problem.

Blind Study:
Single blind study - One in which the subject is unaware of what trial product they are taking.
Double blind study - Patient and doctor are unaware of trial product they are taking.
Treble blind trial - Patient, doctor and statistician are unaware of trial product.

Case Report Form (CRF):
A printed or electronic document designed to record all protocol required information to be reported to the sponsor on each trial subject.

Clinical research:
Research designed to generate knowledge to guide clinical practice.

Clinical Research Associate (CRA):
Person employed by the sponsor, or by a contract research organisation acting on a sponsor’s behalf, who monitors the progress of the investigator’s sites participating in a clinical study.

Clinical Research Organisation (CRO):
A company that is running the trial on behalf of the sponsor.

Clinical Research Manager:
Person who handles most of the administrative responsibilities of a clinical trial, acts as liaison between investigative site and sponsor, and reviews all data and records before a monitor’s visit.

Clinical Trial:
Systemic study of a test article (treatment, drug, device) in one or more human subjects.

CTUs:
Clinical Trial Units

Controlled Study:
A study in which a test article is compared with treatment that has known effects.
Co-ordinating (Chief) Investigator:
An investigator assigned the responsibility for the co-ordination of investigators at different centres participating in a multicentre trial.

COREC:
Central Organisation of Research Ethics Committees. Now known as NRES.

CSDG:
Clinical Studies Development Group

CTIMP:
Clinical trials of investigational medicinal products. These trials may fall within the scope of the Medicines for Human Use (Clinical Trials) Regulations 2004. If the trial does fall under the regulations, there are a number of additional requirements that must be met before the trial begins.

Data and Safety Monitoring Board (DSMB):
Researchers – ideally independent of the trials they monitor – who periodically review the data from clinical studies.

Data Monitoring:
Process by which case report forms are examined for completeness, consistency and accuracy.

Declaration of Helsinki:
A set of recommendations or basic principles that guide medical doctors in the conduct of biomedical research involving human subjects. It was originally adopted by the 18th World Medical Assembly (Helsinki, Finland; 1964).

Demographic Data:
Characteristics of subjects or study populations which include such information as age, sex, family history of the disease or condition for which they are being treated, and other characteristics relevant to the study in which they are participating.

Double Blind Study:
A study in which neither the subject(s) nor the investigator(s) know what treatment a subject is receiving.

ECMCs:
Experimental Cancer Medicines Centres

Effectiveness:
The desired measure of a drug’s influence on a disease condition as proved by substantial evidence from adequate and controlled investigations.
Efficacy:
A product’s ability to produce beneficial effects on the course of duration of a disease.

EORTC:
European Organisation for Research and Treatment of Cancer

EPSRC:
Engineering and physical Sciences Research Council

ESTRO
European Society for Therapeutic Radiology and Oncology

Ethics:
A system of moral values that is concerned with the degree to which research procedures adhere to professional, legal, and social obligations to the study participants.

EudraCT:
A database of all clinical trials. It has been established in accordance with Directive 2001/20/EC. All trials involving CTIMPs need a EudraCT number, which is obtained as part of the MHRA application

Evidence Based Practice:
Practice that uses research findings as a basis for clinicians’ decisions, actions and interactions with patients.

Exclusion Criteria:
A list of criteria, any one of which excludes a potential subject from participation in a study.

Final Report:
Complete, comprehensive description of a completed trial that describes the experimental materials and statistical design. It also presents and evaluates the trial results and statistical analyses.

Focus Group interview:
An interview with a group of individuals assembled to answer and discuss questions on a given topic.

Food and Drug Administration (FDA):
The USA regulatory authority charged with, among other responsibilities, granting IND and NDA approvals. US equivalent to the MHRA.
**G**

Good Clinical Practice (GCP):
A standard for the design, conduct, performance, monitoring, auditing, recording analyses, and the reporting of clinical trials that provides assurance that the data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial subjects are protected.

**H**

Health services or systems research
Improvement of the efficiency and effectiveness of health professionals and the health care system through changes to practice and policy.

**I**

IMP:
See Investigational Product

IDMC:
Independent Data Monitoring and Ethics Committee

Informed Consent:
A process by which a subject voluntarily confirms his/her willingness to participate in a particular trial after having been informed of all aspects of the trial that are relevant to the subject’s decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.

Institutional Review Board (IRB):
An independent body constituted of medical, scientific, non scientific members, whose responsibility it is to ensure the protection of the rights, safety and well being of human subjects involved in a trial. They are responsible for approving and providing continuing review of the protocol and methods and material to be used in obtaining and documenting informed consent of trial subjects. For example; ethics committees.

Investigational Product:
A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorisation when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

Investigator:
A person responsible for the conduct of the clinical trial at a trial site.

Investigator’s Brochure (IB):
A compilation of the clinical and non clinical data on the investigational product.
IOG:
Improving outcomes guidance

L

LREC:
Local Research Ethics Committee.

M

Medicines and Healthcare products Regulatory Agency (MHRA):
The United Kingdom regulatory authority that approves or rejects Clinical trial protocol applications.

Meta-analysis:
A statistical process for pooling data from many clinical trials and summarising it through formal statistical means.

Monitoring:
The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, standard operating procedures (SOP's), good clinical practice (GCP) and the applicable regulatory requirements.

MREC:
Main Research Ethics Committee.

Multicentre Trial:
A clinical trial conducted according to a single protocol, but at more than one site, and therefore carried out by more than one investigator. Synonym: multicentre study.

N

NCRN:
National Cancer Research Network. It provides the NHS with the infrastructure to support cancer clinical trials in England.

New Drug Application (NDA):
An application to FDA for a license to market a new drug in the United States.

NIHR:
National Institute for Health Research

NPRI:
National prevention research initiative. UK wide initiative made up of government bodies, research councils and major medical charities that are working together to encourage and support research into disease prevention.
NRES:
National Research Ethics Service. Provides leadership for the research ethics committees of the UK (whether MREC or LREC). Formerly known as COREC.

NTRAC:
National Translational Cancer Research Network superseded by ECMCs

Nuremburg Code:

Open Study:
A trial in which subjects and investigators know which product each subject is receiving; opposite of double blind study.

Outcome research:
Research designed to document the effectiveness of health care services and the end results of patient care.

Pharmacodynamics (PD):
The branch of pharmacology that studies reactions between drugs and living structures, including the processes of bodily responses to the pharmacological, biochemical, physiological and therapeutic effects.

Pharmacoeconomics:
Branch of economics that applies cost-benefit, cost utility, cost-minimisation, and cost-effectiveness analyses to compare the economics of different pharmaceutical products or to compare drug therapy to other treatments.

Pharmacogenetics (PG):
The study of genetic variation that gives rise to differing response to drugs.

Pharmacokinetics (PK):
The study of the processes of bodily absorption, distribution, metabolism, and excretion (ADME) of compounds or medicines.

Pharmacovigilance:
Term used for adverse event monitoring and reporting in some countries.

Placebo:
A pharmaceutical preparation that contains no active agent. In blinded trials, it is generally made to look just like the active agent.

Principal Investigator: PI
In a multicentre study; the lead investigator responsible for each individual site.
Prospective Study:
Investigation in which a group of subjects is recruited and monitored in accordance with criteria described in a protocol.

PPI Patient and Public involvement:
Involving patients and public in research is an increasingly important part of NHS R&D and is indeed a key requirement of research governance. Department of Health policy over recent years has increasingly emphasised the importance of involving patients and the public in all aspects of their health care, including research.

Protocol:
A document that describes the objective(s), design methodology, statistical considerations, and organisation of a trial. A protocol also usually gives the background and rationale for a trial.

Protocol Amendment:
A written description of a change(s) to or a formal clarification of a protocol.

Q
QL:
Quality of life

QALYS:
Quality-Adjusted Life-Years

QART:
Quality Assurance in Radiotherapy

Qualitative research:
The investigation of phenomena, typically in an in depth and holistic fashion, through collection of rich narrative materials using flexible research design.

Quantitative research:
The study of phenomena that lends itself to precise measurement and quantification, often involving rigorous and controlled design such as questionnaire survey.

R
Randomisation:
The process of assigning trials subjects to a treatment or control group using an element of chance to determine the assignments in order to reduce bias.
Recruitment Period:
Time period during which investigators must complete enrolment of their quota of subjects for a trial.

Recruitment Target:
Number of subjects that must be recruited into a study to meet the requirements of the study protocol.

Research Governance:
The rules and procedures set out to ensure researchers are accountable for their actions, and that organisations accept their responsibilities for the research they sponsor and host.

Serious Adverse Event (SAE):
Any untoward medical occurrence that at any dose: results in death, is life threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect.

Site Files:
Where trial documentation should be filed

Source Data/ Source Documents:
Original documents, data and records, such as hospital records, clinical and office charts, laboratory notes, memoranda, subject’s diaries, pharmacy dispensation records, evaluation checklists, etc. i.e., patient notes.

Sponsor:
An individual, company, institution or organisation which takes responsibility for the initiation, management and/or financing of a clinical trial.

Standard Operating Procedures (SOP’s)
Detailed written instructions to achieve uniformity of the performance of a specific function.

Statistical Significance:
Level at which an investigator can conclude that observed differences are not due to chance alone.

Statistical test:
An analytical procedure which allows a researcher to determine the probability that obtained results from a samples reflect true populations as defined in the trial/study null-hypothesis and alternative hypothesis.
Sub-Investigator:
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.

Subject/ Trial Subject:
An individual who participates in a clinical trial, either as recipient of the investigation product(s) or as a control.

Subject Identification Code:
A unique identifier assigned by the investigator to each trial subject to protect the subject’s identity and used in lieu of the subject’s name when the investigator reports adverse events and/or other trial related data.

Serious Unexpected Serious Adverse Reaction (SUSAR):
An adverse reaction to a CTIMP, the nature of severity of which is not consistent with the applicable product information.

T
Translational research:
that that 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;

U
UKCRN:
UK Clinical Research Network.

UKCRC
UK clinical research collaboration. The aims of the group are to develop a coordinated approach to improving public health research environment.

V
Validation of data:
Procedure carried out to ensure that the data contained in the final clinical trial report match original observations.

W
Washout Period:
Period of time without active treatment, usually scheduled before the beginning of the placebo and active treatment arms. This can refer to a required period of withdrawal from treatment before active treatment starts.
References

   January 2003


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