West Yorkshire
Research and Development

The general practice guide to research

Contents

West Yorkshire
Research and Development

Thinking about getting involved in research?

Why get involved in research?

Getting involved in research can be easier than you think.

Health professionals have reported many benefits of getting involved in research (Royal College of Physicians, 2016), including:

- It is intellectually stimulating
- I am contributing to my field/improving patient care
- It brings more variety to my job
- It allows me to develop/use a wider set of skills
- It makes me a better doctor
- I can pursue a special interest more deeply
- It is collaborative/collegial
- It enhances my CV or publications record
- It is a way to distinguish myself amongst my peers
- It will help me to get onto the career path I want
- It is recognised and rewarded by my employer
- It is something many of my peers do
- It is financially rewarding

"Patients in research-active institutions have better outcomes than those in other institutions, and are more likely to benefit from earlier access to new treatments, technologies and approaches."

Research for all – Building a research-active medical workforce 2016, Royal College of Physicians

Ways to get involved

- Recruiting patients to a study (this could be as little as putting up a poster in your waiting room, or making a call to the research team when you meet with a patient who meets the eligibility criteria for a particular study)
- Carrying out research activity at your site (which covers a wide range of activities, including consenting patients, completing questionnaires (staff or patients), carrying out medical procedures etc.)

Other ways to get involved

- You can also input into areas where you would like to see research take place, or feed specific ideas into organisations like the James Lind Alliance http://www.jla.nihr.ac.uk/priority-setting-partnerships/ or the NIHR (National Institute for Health Research) http://www.nets.nihr.ac.uk/identifying-research/help-us-shape-research.
- If you have been involved in any research we would be delighted to hear your story to encourage others to take part. If you would like to share your experiences please contact research@bradford.nhs.uk.
- Or of course if you want to lead your own study we can advise on this; see the section on **Developing your own study** (p7)

Getting involved

At any given time there are many studies out there which may fit your interests, may be looking for sites, and may be able to offer your practice financial or other benefits for taking part. But how?

You may be approached by a researcher or see an Expression of Interest notice or other advert.

But should you get involved?

As a starting point, you will probably want to think about:

- Does the study interest us and have a benefit for our patient population?
- Has the study been appropriately financed? i.e. will our time and facilities be financially covered?
- Does our practice/professional indemnity cover the research?
- What resources does the study require and do we have these available: e.g. staff, skills, facilities?
- How much time will the study take? For which staff members? Can we spare the capacity? Are the appropriate staff willing to be involved?
- What arrangements would need to be put in place for the study to take place?
- How many patients does the study team wish to recruit? Do we have sufficient patient population? Does our patient population have the demographics/conditions the study team is looking for?
- Is there any special equipment required for the study? Do we have the required equipment?
- Does the study require access to the clinical system – are they set up to use the clinical system that we use (some studies may only be able to work with SystmOne data, or EMIS data)?
- If the study team is asking to access our facilities/patients/systems, do we accept this? Please note that they will need a Letter of Access issued by the CCG to access practices – this must be shown to the practice before they can access your site, and demonstrates that they have had pre-employment checks, DBS checks where appropriate and are suitably qualified.
- Has the study team sufficiently considered how our patients' data and/or samples will be handled and transported? Does this comply with our data protection requirements?
- If there is a study treatment involved, does this cost more than standard treatment? If so, has the CCG agreed to pay the excess? The study team must have a letter from your CCG stating that they agree to cover this cost.
- Have there been any amendments to the study? Practices should make sure they review these as they can mean significant changes to what was originally proposed in the study documentation.

What next?

To find out about studies taking place in your area and looking for practices to take part, please contact research@bradford.nhs.uk. Have a look at the open studies list on our website – however there may be studies in the pipeline which we can tell you about so please get in touch if you'd like to discuss opportunities. We also have a questionnaire to allow us to collect information about areas your practice would be interested in researching, so that we can match you up to relevant studies. If this is of interest please complete the questionnaire in the **Appendix 1** and return it to research@bradford.nhs.uk.

If you've already found a study, or if a study has approached you, what next?

To find out about the study and exactly what activity the team would like to carry out, reading the **protocol** should give the essential information. This should tell you what exactly will be asked of you and your patients, so you can decide if you want to be involved. This is entirely voluntary. It could be as little as performing a database search or could be actually conducting a research activity at your site. You can also gain important information from other study documents – in particular the Statement of Activities and Schedule of Events. The HRA approval letter shows that the study has gone through an approval process and is deemed to be ethical, well thought-out and financially sound.

Then see our **document guide** for an explanation of what documents you need and a checklist to make sure you have everything.

When you have seen these documents, your practice must decide whether to take part. Once you have considered the implications of carrying out the study, if you have any questions please do not hesitate to contact us for advice research@bradford.nhs.uk. If you are happy to proceed you need to officially agree to take part, confirming your practice has capacity and capability to take part. A practice can always decline to participate, and an individual can also choose whether or not to participate.

The practice's capacity and capability is usually confirmed by 'signing off' the Statement of Activities (SOA) or practice-level agreement/contract. Please note the SOA is usually completed by the research team and then signed off by the practice. A hard-copy wet-ink signature is not required; the practice fills in the name of signatory and date and the form can just be emailed to confirm. The exact details of these documents are to be negotiated between the researchers and the practice.

The purpose of this document is to confirm whether your practice has the capacity and capability to conduct the research, so you should read it carefully to check what is planned to take place.

Now take a look at our "**starting a new study**" guide.

Developing your own study

If you are interested in an area of research but there is no existing study, there are a number of options.

Academics are often looking for suggestions of areas which would be important to practitioners working with particular health conditions, or to commissioners. If you have an idea and would like to pair with a local academic, or perhaps just suggest this to them, we have a number of contacts in local schools of medicine, healthcare, nursing and pharmacy. Please get in touch if you would like us to make an introduction.

You can also suggest study ideas/areas to organisations like the James Lind Alliance who work to develop priority areas for research in health. See www.jla.nihr.ac.uk for details.

Taking research to the next stage and developing your own research proposal is also a possibility and we are happy to advise and support you in working up an idea, submitting applications and working together with other practices. We can also highlight potential pitfalls and help you to work through them, so please get in touch via research@bradford.nhs.uk. In addition there is support available from organisations including CRN (the Clinical Research Network) and the RDS (Research Design Service), both part of the National Institute for Health Research.

We also fund small scale research proposals via Research Capability Funding and can help with applying for larger grants. Contact the team for help or advice research@bradford.nhs.uk.

Already involved in research?

Existing studies

If you are already involved in a research study, that's great!

Our Research Delivery Officer can provide help with study facilitation at the practice including help with recruitment techniques and search strategies to be used on practice based clinical systems in response to research queries and can also provide additional support with mail outs if required.

We are also happy to conduct a quick review if at any point you are not sure about what paperwork you are supposed to have, if you are at all concerned about what the study team is doing in your practice, or if you are not sure what you should be keeping in your site file. You can also see the lists in the appendices to this guide but if you would find it helpful we are happy to talk to you or have a look at the study documents or your site file.

Don't forget there may be documents you need to keep after your participation in the study has ended, so please check with us or the study team if you are not sure what you need to keep and for how long.

Key things to remember

Maintaining a site file

You should have received a site file when you started the study containing the key documents for the study.

Remember to keep the file in a safe place accessible to people who may need to refer to it. As well as all the documents you will need to use throughout the study, this is where the study team contact details and procedures for reporting any serious adverse events should be kept.

Any consent forms should also be kept in hard copy and securely.

Any time there is an amendment to the study you should be informed and given any amended documents. These should always be updated into the study file.

Any changes to staff need to be updated onto the delegation log and signed by the staff member and principal investigator.

GCP

GCP (Good Clinical Practice) training is aimed at practice staff who may be involved in research projects, to make sure they are prepared for carrying out the duties involved in a research study. For CTIMP (Clinical Trial of an Investigational Medicinal Product) studies it is a requirement, and it is a good idea for any staff involved in research. The training is provided for free by the National Institute for Health Research (NIHR) and can be completed online or in a face to face workshop lasting 1 day.

Letters of access

Anyone who accesses your site to conduct research must show you a letter of access which confirms the CCG has completed checks to ensure they are appropriately qualified and trained. Please note the end date on the letter – they may need to show you updated letters as the study goes on.

During and after the study

What you need to do during and after the study will vary between studies, but be aware that a study may be audited by the MHRA (Medicines and Healthcare products Regulatory Agency) for a number of years after the end of the study.

Support from WY R&D, other help

The WY R&D team is here to support you and to encourage participation in research, so we are always happy to answer any questions you may have. Please get in touch on research@bradford.nhs.uk.

Research team contact details

Development

Stella Johnson	01274 237309	stella.johnson@bradford.nhs.uk

Governance

Rebecca Harper	01274 237690	rebecca.harper@bradford.nhs.uk
Rose Dewey	01274 256115	rosemary.dewey@bradford.nhs.uk

Delivery

Emma Neil	01274 237416	emma.neil@bradford.nhs.uk

Engagement

Gemma Doran	01274 237727	gemma.doran@bradford.nhs.uk

Head of service

Paul Carder	01274 237406	paul.carder@bradford.nhs.uk

Next up...

When you want to move onto another study, see our "**starting a new study**" guide on page 14.

Taking part in a study

Starting a new study

So you've already considered the implications and decided to get involved. What next?

Things to consider when starting a new study

You'll need to get all of the study documentation. See our **document guide** for a description of the different documents you may get, although these do vary study by study.

The most important documents at this stage are the study **protocol**, **Statement of Activities** and **Schedule of Events**. These will give you an overview of the study and what exactly is being asked of your practice.

The study may not have full **HRA approval** at this stage, but must have approval before starting any research activity – this includes recruiting any patients. You must see a copy of the HRA approval letter (make sure this is not the Initial Assessment Letter which is only the start of the acceptance process).

It is always the practice's decision whether or not to participate, as well as the individual's decision whether they choose to participate themselves.

You will need to decide whether the study is suitable for your practice and make an assessment of capacity and capability, i.e. do you have the staff, resources, equipment, systems to participate and can you manage to provide the staff required and for the duration of the study? Consider whether your indemnity will cover the research. You need to make sure you understand what is being provided by the study team and what the practice would need to provide – ask the study team to confirm if anything is not clear.

For some studies, the HRA may decide that no formal confirmation of capacity and capability is needed. You should check the HRA letter to find out what you need to do, which is usually:

Confirmation of Capacity and Capability

This describes whether formal confirmation of capacity and capability is expected from participating NHS Organisations in England.
Participating NHS organisations in England that are PIC sites and Recruiting sites will be expected to formally confirm their capacity and capability to host this research. ● Following issue of this letter, participating NHS organisations in England may now confirm to the sponsor their capacity and capability to host this research, when ready to do so. How capacity and capability will be confirmed is detailed in the *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* section of the appendix.

OR

Confirmation of Capacity and Capability

This describes whether formal confirmation of capacity and capability is expected from participating NHS Organisations in England.

The HRA has determined that participating NHS organisation in England are not expected to formally confirm their capacity and capability to host this research.

- The HRA has informed the relevant research management offices that you intend to undertake the research at their organisation. However, you should still support and liaise with these organisations as necessary.
- Following issue of the Letter of HRA Approval the sponsor may commence the study at these organisations when it is ready to do so.

Confirmation will be either through completing the name and date on the statement of activities and returning it by email (no wet ink signature is required) or by signing the agreement. If the study wants to use an agreement which is not the standard model agreement you may want to get legal advice on what you are being asked to sign.

Where no formal confirmation is required you may confirm by completing the Statement of Activities or by email. This can help to speed up the process of getting the study started.

Document guide

To find out about the study and exactly what activity the team would like to carry out, reading the **protocol** should give the essential information. This should tell you what exactly will be asked of you and your patients, so you can decide if you want to be involved. This is entirely voluntary. It could be as little as performing a database search or could be actually conducting research at your site.

Protocol

A document that describes the objective(s), design, methodology, statistical considerations and organisation of a trial. The term protocol refers to the protocol, successive versions of the protocol and protocol amendments.

NIHR Clinical Trials Toolkit

Before a study can go ahead at a practice, there are a number of things you will need to see as a practice to make sure the researchers have gone through the proper checks. We have put together a pre-study checklist (see Appendix 2) which may help you to know what documents you need to see.

You may be asked to sign a contract, which will usually be a standard format (the Department of Health advises that researchers use their standard template). Alternatively, the study team may want to use a **Statement of Activities** in place of a contract (see http://www.hra.nhs.uk/resources/hra-approval-applicant-guidance/statement-activities-hra-approval/). If you are asked to sign any other contract you may wish to ask for legal advice.

After reviewing the content of the study and gaining an understanding of what your practice is being asked to do, there are a few things you need to check before a study can go ahead. All documents need to be stored in the study site file which is held on site throughout the study for reference purposes. Documents should be updated whenever there is an amendment so that people working on the study can check whether the current documents are in use.

Documents you will need to have sight of before agreeing to the study (see also pre-study checklist)

There are extensive checks carried out for all studies, to make sure they are ethical, feasible, well-planned, have consulted with the necessary groups including patient groups, and to make sure the staff involved are suitable.

HRA (Health Research Authority) approval – the HRA issues a letter confirming that the study has been accepted from a governance point of view. Make sure that you see a copy of the approval letter, not just the initial assessment letter. In some rare cases there may not be an HRA letter, but if you are not sure whether you should have an HRA letter or not please contact us.

REC (research ethics committee) approval – the HRA letter will refer to the REC approval letter where applicable. This confirms that ethics checks have been carried out. Ethical approval is not needed for staff-only studies or for some other types of study. If you are not sure please contact us research@bradford.nhs.uk.

Statement of Activities and Schedule of Events – for non-commercial studies only, this explains what exactly will take place at your practice (if you agree), financial considerations and data arrangements. Practices must sign the Statement of Activities to agree that they have assessed and arranged their capacity and capability and are ready to proceed. For commercial studies an **agreement** or contract will be in place which practices should sign to agree to take part. Non-commercial studies can also use an agreement if they choose.

Advisory email regarding Capacity and Capability. The WY R&D team has an overview of research taking place in primary care and will retain a copy of the document set for all studies. We will be able to advise your practice on whether there are any issues regarding capacity and capability, any overlaps with other studies, or any over-use of a particular patient population. The study team should share this email with participating practices, who can then check whether the WY R&D team has identified any issues.

Letter of Access – if anyone is coming into your practice who is not a member of your practice staff, even if they are an NHS employee, they will need to show you a Letter of Access. This is issued by the WY R&D Team to confirm that the person is suitably trained and checked to carry out the planned research.

Local documents – the document pack should include the current version of the protocol, any patient information sheets, consent forms and any other documents to be used at your site.

Excess Treatment Cost agreement – if the study treatment costs more than standard NHS care, this has to be funded. For commercial studies the commercial funder pays this. Otherwise the difference may be paid for by the CCG. This means the study team has to apply to the CCG to ask them to fund the cost and the CCG will issue a letter to the study team to confirm – this has to happen before the study starts. If you are not sure whether an Excess Treatment Cost is involved please contact us research@bradford.nhs.uk. If a study takes place without the CCG agreeing to pay any excess treatment cost, the practice could become liable for this cost.

Other documents to be held in the site file (see also site file checklist)

Delegation log – This is a very important part of the site file as the Principal Investigator (responsible for research at the site) will delegate other members of staff to undertake particular duties. If these duties are not outlined in the delegation log the members of staff are not authorised to undertake them. It is also important to keep the delegation log up to date and sign when there is an end to the role (both the member of staff and the PI needs to sign).

Training log – This relates to the training required to carry out the study, which may be part of the Site Initiation Visit. Members of the team will be taught how they are expected to conduct the study visits, how to record them and how to report any adverse events. The specific activities depend on the study type.

Screening log – Where screening is a necessary part of the study, the Sponsor will provide a log to practices where they should record patients screened.

CVs of all involved staff – All staff should complete a research CV which includes details of their training and qualifications to undertake the research. This will confirm to anyone monitoring the study that they are appropriately qualified.

Standard operating procedures (SOPs) – these are the procedures involved in running the study including procedures for reporting adverse events.

Contact details for the study team.

Current versions of all study documents, which may include: Patient invitation letter, Patient information sheet, Consent form (template), Case report form. These are important to make sure the practice is using the latest up to date versions of these documents.

Case Report Forms (CRFs) are where information is recorded at the study visits. They can be paper or electronic. The CRFs are an essential part of the study data and it is important that they are completed accurately.

Taking part in a study

Study teams will usually hold a Site Initiation Visit to 'kick off' the study at your practice. Practice staff should attend if they are conducting any elements of the research. The visit will usually include training for staff on what they need to do. It gives staff the opportunity to ask any questions. You should receive a site file which should be held at your site and updated any time there is a change to the study.

The Principal Investigator is responsible for all research activity taking place at the site. If someone else is to carry out a particular duty, for example a healthcare assistant may take blood samples, this should be documented to say that the Principal Investigator delegates that duty to the healthcare assistant. A full delegation log listing out all delegated duties should be held in the site file and signed by the Principal Investigator and delegates.

In the new HRA system, when a practice takes part in a study their lead GP will normally take on the role of Principal Investigator (PI). This means they take responsibility for the conduct of the research at that site.

CVs for any staff undertaking research at the site should also be held in the site file. The CV should include relevant qualifications and training including dates, so that monitors can check that the people undertaking research activity are appropriately qualified.

Copies of all the latest versions of study documents – e.g. consent forms, patient information sheets, protocol, should also be kept in the site file.

Signed consent forms should be held securely. Usually these are in paper version and the originals must be retained.

At the Site Initiation Visit, you should be given a process for reporting adverse events or issues, and a contact in the research team for any queries. You will be given training and any forms (case report forms – CRFs), either paper or electronic, which are to be completed as part of the study. These will be where things like activities and measurements taken at any study visit will be recorded.

You will also receive information about whether and how you will be financially recompensed for your work on the study. Your practice will usually need to invoice either the study team or the Clinical Research Network (CRN) to receive payment.

Monitoring the study

Finally, at all times during the study and for a period afterwards, your practice may be monitored to ensure the quality of the research. This could be done by the Sponsor or various regulatory bodies, e.g. the MHRA (Medicines and Healthcare Products Regulatory Agency). Monitors may ask to see your practice's site file so it should always be up to date. Study sponsors can access patient records to ensure that the information being collected matches up to that held in the medical record.

The CCG can also audit the study to make sure everything is being done correctly by the study team and at the practice. The practice has to follow the study procedures and keep the necessary records, whilst also maintaining its statutory responsibility for things like data protection. The Principal Investigator (PI) for a study, usually a GP at your practice, is responsible for research activity taking place at your site, and for the study team to whom they have delegated certain tasks.

Monitoring by the Sponsor will check and confirm that the processes outlined in the study protocol are being followed correctly. The Sponsor is ultimately responsible for study conduct and will be checking to make sure the team at your site is following procedures correctly. They may check against medical records to determine whether the right information is being recorded and will also check to make sure the site file is up to date.

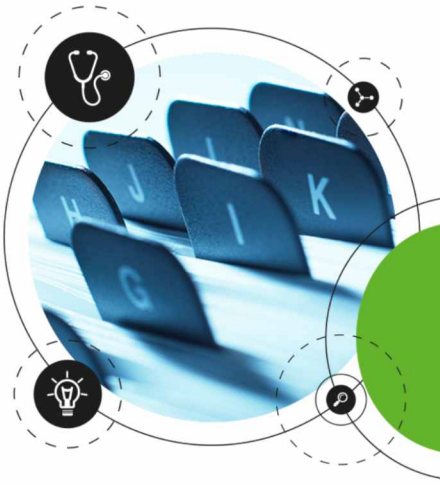
Regulatory authorities such as the MHRA will check for compliance with all relevant legislation and guidance.

It is important to grant access to bodies who require access to your site for monitoring purposes. If you are not sure who to grant access to please contact us for advice or speak to your contact at the Sponsor. For CTIMPs (Clinical Trials of Investigational Medicinal Products) this is a legal requirement and for all studies it is an expectation.

After the study

Your practice should retain the site file and consent forms after the study for an agreed period of time (agreed with the research team). If the people working on the study move on, the study information should be transferred to another member of staff. If you are not sure how long to keep the file for, contact the study team who should be able to advise.

Appendices



Appendix 1: Research interest questionnaire

This form should be completed by the GP/Nurse research lead, to provide basic information about interest in specific types of proposed studies.

NAME OF SITE: _____

TOPICS:

Please tick any topic(s) that are of interest:

- **Asthma** ☐
- **Coughs and colds** ☐
- **COPD** ☐
- **Diabetes** ☐
- **Elderly care** ☐
- **Heart problems** ☐
- **Infant care** ☐
- **Mental health** ☐
- **Other:** ☐

If 'Other', please state: _____

NURSE-LED:

Please tick yes for interest in nurse-led studies only; no, for those studies not nurse-led, or tick to indicate no preference:

Yes	No	No preference
☐	☐	☐

QUALITATIVE/QUANTITATIVE:

Please tick to indicate a preference of qualitative or quantitative research studies, or no preference:

Yes	No	No preference
☐	☐	☐

DATABASE SCREEN:

Please tick to indicate interest in database screen studies:

Yes	No	No preference
☐	☐	☐

TESTS:

Please tick below to indicate which test(s) would **not** be acceptable:

BMI	☐
Blood pressure	☐
Blood test	☐
Cholesterol	☐
DNA swab	☐
Stool sample	☐
Urine sample	☐
Weight	☐

Other: Please state: _____

_____

Thank you for taking the time to complete this questionnaire

Appendix 2: Pre-study checklist

When a study approaches your practice, they need to have the following before they can start the research. They may approach you before this but cannot start the research until you have seen:

- ☐ Letter of HRA approval
- ☐ Letter of REC approval if the research involves patients

Then, either

- ☐ The HRA approval letter may state that practices are not required to confirm capacity and capability.

If not, you will need to see:

- ☐ Statement of Activities and Schedule of Events – which the practice will need to sign to confirm they have capacity and capability to undertake the research.

OR

- ☐ Model agreement which the practice will need to sign to take part in the study.

AND

- ☐ An advisory email issued by the West Yorkshire R&D Team which should be forwarded to your practice by the sponsor or research team

If the study involves a treatment which is additional to or more expensive than standard care treatment, you will also need:

- ☐ A letter of agreement from the CCG stating the Excess Treatment Costs are agreed for this study.

If members of the study team will be accessing the practice to conduct any research

- ☐ Letter of Access issued by the CCG and stating the correct CCG in the body of the letter.

Appendix 3: Site file checklist

The study team should provide you with a **study site file** which should include as a minimum:

- [ ] Governance documents (e.g. HRA and REC approval letters, any specialist approvals for example MHRA approval for drug studies)
- [ ] Study protocol
- [ ] Delegation log – completed with names and signatures of each member of staff involved in the study, and start/end dates of their roles
- [ ] Training log
- [ ] Screening log
- [ ] CVs of all involved staff
- [ ] Standard operating procedures (SOPs) including procedure for reporting adverse events
- [ ] Contact details for the study team
- [ ] Current versions of all study documents, which may include: Patient invitation letter, Patient information sheet, Consent form (template), Case report form

You will need a **secure place to store signed consent forms** as paper copies must be retained.

The study team will also conduct a **Site Initiation Visit** where practice staff who will be involved in the study will learn about the study, what they need to do and procedures for reporting etc.

Any **members of staff** who will conduct any research activity (this includes taking consent, sending out letters, taking samples, issuing medication, and many more – please ask if you are not sure) **need to provide their CVs and sign the delegation log** – which is also signed for each member of staff by the Principal Investigator.

The site file needs to be kept up to date so if anything changes – any amendments to the study, any changes to the research team, new people getting involved or people being removed from the delegation log, this needs to be updated to the site file.

Appendix 4: Research jargon buster

Also see document guide

Research roles

It can be difficult to understand the different terms within a research study. Please see below for some common role names:

Chief investigator – In the case of a CTIMP: a) In relation to a clinical trial conducted at a single trial site, the Investigator for that site; or b) In relation to a clinical trial conducted at more than one trial site, the authorised health professional, whether or not he is an Investigator at any particular site, who takes primary responsibility for the conduct of the trial. For research other than CTIMPs: The person who takes overall responsibility for the design, conduct and reporting of a study if it is at one site; or if the study involves researchers at more than one site, the person who takes primary responsibility for the design conduct and reporting of the study whether or not that person is an Investigator at any particular site.

Principal investigator – For CTIMPs, the authorised health professional responsible for the conduct of that trial at a trial site, and if the trial is conducted by a team of authorised health professionals at a trial site, the Investigator is the leader responsible for that team.

For research other than CTIMPs: The person responsible, individually or a leader of the researchers at a site, for the conduct of a study at that site.

Delegate – person to whom the investigator has delegated significant trial related duties.

Sponsor – The individual, or organisation (or group of individuals or organisations) that takes on responsibility for confirming that there are proper arrangements in place to initiate, manage and monitor, and finance a study. Responsibilities are defined by the Research Governance Frameworks and by the Clinical Trials Regulations.

For CTIMPs, the sponsor (or their legal representative) must be named on the Clinical Trial Authorisation. The sponsor may delegate functions as necessary to comply with the Clinical Trials Regulations, for example to the Chief Investigator or Clinical Trials Unit.

Other terms

Control group – a group of patients who are usually not receiving the study intervention for comparison with the case group.

Randomisation – the practice of allocating patients at random to receive one treatment or other, or no treatment. It is essential that a process is followed to ensure that the allocation is truly random, often done by computer.

Blinding – the practice of making sure that the treatment is concealed where possible. This should reduce bias, which could occur if someone feels better because they know they have received a particular treatment.

Double blinding – ensures that neither the patient nor the health professional knows what treatment is being given, to reduce potential bias on both sides.

Inclusion/exclusion criteria – the list of criteria which make patients eligible to take part in a study, also called **eligibility criteria**. Again it is important that these are followed as there may be safety reasons not to include certain people, or it may make the study findings invalid if a patient is included who doesn't fit the criteria.

Informed consent – it is a vital part of research that patients (or sometimes their representative) give voluntary and informed consent. They are usually given a patient information sheet and the opportunity to talk the study through with a researcher or other professional before signing a form to given written consent.

Investigator brochure or **Summary of product characteristics** – a document detailing the full medical profile of a drug being studied.

Amendment – after receiving approval from the HRA, any changes to the study have to be submitted and approved as amendments.

Monitoring/audit – the process of checking and making sure that research is being conducted correctly and in accordance with the protocol and all agreed documents. Both the sponsor and the CCG may conduct their own monitoring.

Site file – a physical file containing all documents relevant to the study conduct at the site. This varies by study but for guidance please see our document guide.

Abbreviations

GCP – Good Clinical Practice. Training in conducting research, available for free from the NIHR. This is essential for all staff working on CTIMPs and advisable for anyone involved in research projects.

NIHR – National Institute for Health Research. The body which funds and supports research across the NHS.

HRA – Health Research Authority. The body responsible for governance - they approve studies and amendments taking place in the NHS.

REC – Research Ethics Committee. Groups which also review any studies involving patients for ethical considerations.

PIS – Patient/participant Information Sheet. The document which should contain all information relevant to a patient/participant who will take part in a study.

PIC – Participant Identification Centre. Sites which only identify participants to take part in a study. They may also invite patients but do not take consent or conduct any research activity.

PPI – Patient and public involvement. Research studies are encouraged to involve patients and the public as much as possible in designing and carrying out the study – to ensure that patients' views are taken into account.

ICF – Informed consent form. The form where the participant or his/her delegate signs to indicate consent to participate in the study (in some instances verbal consent may be permissible if outlined in the protocol).

MHRA – Medicines and Health Products Regulatory Authority. This body is involved in drug studies and must authorise any drugs being used in trials.

CTIMP – Clinical Trial of an Investigational Medicinal Product. A clinical trial that is within the scope of the UK Medicines for Human Use (Clinical Trials) Regulations 2004. An investigation in human subjects, other than a non-interventional trial, intended: a) to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more medicinal products, b) to identify any adverse reactions, or c) to study absorption, distribution, metabolism and excretion, with the object of ascertaining the safety and/or efficacy of those products.

IMP – Investigational Medicinal Product. A study drug.

Contact details

Development
Stella Johnson 01274 237309
stella.johnson@bradford.nhs.uk

Governance
Rebecca Harper 01274 237690
rebecca.harper@bradford.nhs.uk

Rose Dewey 01274 256115
rosemary.dewey@bradford.nhs.uk

Delivery
Emma Neil 01274 237416
emma.neil@bradford.nhs.uk

Engagement
Gemma Doran 01274 237727
gemma.doran@bradford.nhs.uk

Head of service
Paul Carder 01274 237406
paul.carder@bradford.nhs.uk

Team inbox research@bradford.nhs.uk