



Core Competency Demonstration Form

1. IS THERE SUPPORT WITHIN THE PRACTICE FOR RESEARCH ACTIVITY?

1.1 Are all the partners* agreeable to research activity taking place within the practice?

Please record how the practice meets this criterion: _____

*If the practice is not a partnership, to answer this question you will need to obtain the support of the appropriate person or organisation.

2. DOES THE PRACTICE HAVE IDENTIFIED SPACE AND FACILITIES TO HOST RESEARCH?

The following will need to be available regardless of the nature of the research study:

When the practice takes part in research:

2.1. Secure storage for records and files will be required.

Can the practice provide appropriate lockable storage for research records/files that is separate from other practice record storage?

Please record here how the practice would demonstrate this: _____

2.2. A password security system is necessary for accessing electronically held research data.

Can the practice put this in place?

Please record here how the practice would demonstrate this: _____



2.3. Electronically held research data must be regularly backed up and an arrangement in place for the back up copy to be held off site.

Is the practice Research Lead aware of this requirement?

Please record here how the practice would demonstrate this: _____

2.4. Practice staff time will be required to support research activity.

Has the practice discussed how it will provide this staff support and identified which members of staff might be involved?

Please record here how the practice would demonstrate this: _____

CLINICAL TRIAL QUESTIONS –skip to section 3 if the practice does not want to take part in clinical trials

2.5. Storage/archive facilities are normally necessary to hold records of completed studies.

Is the practice aware that it might need to provide this?

Please record here how the practice would demonstrate this: _____

2.6. Lockable storage will need to be provided for any pharmaceuticals which may form part of a study.

Can the practice provide this?

Please record here how the practice would demonstrate this: _____



2.7. A lockable fridge will need to be provided for storing some pharmaceuticals that may form part of a study.

Can the practice provide this?

Please record here how the practice would demonstrate this: _____

2.8. Visiting trial monitors, external researchers recruiting patients etc may need access to a room in the practice.

Can this be made available?

Please record here how the practice would demonstrate this: _____

2.9. Computer access is often required for external research staff.

Can access be provided to a terminal linked to the practice clinical system?

Please record here how the practice would demonstrate this: _____

2.10. Meetings between practice staff and external researchers often occur in clinical trials.

Can the practice provide a suitable meeting room?

Please record here how the practice would demonstrate this: _____

2.11. Some trials require the use of particular types of equipment

Can the practice show it has a practice procedure for ensuring that the proper equipment will be available to meet the needs of trials in which it intends to participate and that it is in proper working order?

Please record here how the practice would demonstrate this: _____



3. CAN SEARCHES OF THE PRACTICE DATABASE BE CARRIED OUT?

3.1. Does the practice review the quality of its clinical information system and discuss how to maintain a high standard of quality?

Please record here how the practice would demonstrate this: _____

3.2 Are there members of practice staff who know how to use the search facilities to identify groups of patients with specific characteristics?

Please record here how the practice would demonstrate this: _____

Research Governance PART I

4. DO YOU KNOW WHAT IS REQUIRED OF YOUR PRACTICE AND INDIVIDUAL MEMBERS OF STAFF WITH REFERENCE TO RESEARCH GOVERNANCE?

When the practice takes part in research:

4.1. All practice staff should understand that practices must not engage in research involving NHS patients which has not received ethical and NHS research governance approval.

Can the practice demonstrate that staff are aware of this?

Please record here how the practice would demonstrate this: _____

4.2. Complete records need to be maintained for all research studies in which your practice is involved. Has the practice a system to ensure that complete records will be maintained? If not, is one being put into place?

Please record here how the practice would demonstrate this: _____



4.3. All research studies must have a Research Sponsor.

Is the Research Lead aware that they must ascertain who the Sponsor is (and the Research Lead must be aware of their role) before the practice agrees to participate in a research study?

Please record here how the practice would demonstrate this: _____

4.4. The practice will need a system to identify the income and expenditure relating to different research projects.

Can the practice do this?

Please record here how the practice would demonstrate this: _____

CLINICAL TRIAL QUESTIONS – skip to section 5 if the practice does not want to take part in clinical trials

4.5. Practices participating in clinical trials need to be aware of the Clinical Trials Regulations and how these affect them.

Can the practice demonstrate its awareness of the Clinical Trials Regulations?

Please record here how the practice would demonstrate this: _____

Research Governance PART II

5. ARE YOU AWARE OF THE RESPONSIBILTIES YOU HAVE TO YOUR PATIENTS AND STAFF IF THEY ARE PARTICIPATING IN RESEARCH STUDIES?

5.1. The practice's Data Protection registration must include any research activity in which the practice is involved.

Is your Data Protection registration up to date, does it cover collection and storage of research data (and data analysis if this also takes place in the practice), and do you know the name of your Data Controller?



Please record here how the practice would demonstrate this: _____

When the practice takes part in research:

5.2. The practice staff will already be aware of the guidance relating to the access and use of patient records and confidentiality of patient information. If they become involved in research studies, they need to be aware of how this guidance relates to use of information for research.

Is the Research Lead aware of his/her responsibility to ensure that staff are familiar with the relevant aspects of this guidance?

Please record here how the practice would demonstrate this: _____

5.3. Practice staff who will be involved in recruitment for research studies need to be competent in obtaining “informed consent”. Patients need to be fully aware that should they decline to participate in a study, this will not affect their care or relationship with the practice in any way.

Is the Research Lead aware of his/her responsibility to ensure that staff involved in recruitment understand, and are competent in obtaining, informed consent?

Please record here how the practice would demonstrate this: _____

5.4. Patients need to be aware if a practice is involved in research. This should be adequately publicised (e.g. on practice notice boards, in patient information leaflets and/or on the practice web site).

Is the Research Lead confident that this is, or will be, done?

Please record here how the practice would demonstrate this: _____

5.5. When deciding whether or not your practice should participate in a study, consideration should be given to the sum of money being offered to the practice. This should reflect the time that will be taken and the work to be done in the practice. The practice should not accept an amount that could be seen as offering an improper inducement to recruit patients into a study or to retain them once recruited.



Is the Research Lead confident that they understand the issue of improper inducement and would be supported by the practice in refusing participation in any studies which involved such inducement?

Please record here how the practice would demonstrate this: _____

5.6. All research studies must minimise and carry indemnity for risk to patients. Staff must be aware of the difference between negligent harm and non-negligent harm. The practice Health and Safety policy needs to adequately cover the practice’s research activities.

Is the Research Lead aware that they must make themselves aware of any risk to patients before the practice participates in a study and ensure that such risks are minimised and adequate indemnity is in place?

Please record here how the practice would demonstrate this: _____

CLINICAL TRIAL QUESTIONS – these questions should only be answered if the practice wants to take part in clinical trials

5.7. An adverse event might occur during the course of a trial.

Can the practice demonstrate how it would react to such an occurrence?

Please record here how the practice would demonstrate this: _____

5.8. Occasionally, it may be necessary when participating in a clinical trial involving an intervention together with a placebo, to break the code (e.g. double blind pharmaceutical trials). Practices need to have in place a system to ensure that all staff, including the Out-Of-Hours and other services, who may need to know how to break the code, are able to do so.

Can the practice demonstrate how it will ensure this can happen?

Please record here how the practice would demonstrate this: _____
