RESEARCH READY HANDBOOK

Online self-accreditation for community pharmacy

Competence, Confidence, Compliance
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FOREWORD

The Royal Pharmaceutical Society Research Ready programme aims to build knowledge about what is required and what is recommended to take part in existing research\(^1\) studies, such as those on the National Institute for Health Research’s portfolio.

The Research Ready programme is designed to support pharmacy teams who are about to take part in or considering taking part in a specific research project. Research Ready is underpinned by the Department of Health’s Research Governance Framework for Health and Social Care (available on the Health Research Authority website) which sets out the broad principle of good research governance and is key to ensuring that health and social care research is conducted to high scientific ethical standards.

This programme is also aimed at pharmacists or technicians who will be ‘site investigators’ in a project designed by someone else.

This document describes the core elements of the Research Ready programme to aid those looking to become accredited. We have set out a series of questions to highlight what community pharmacy teams need to consider - and what you will need to have in place - before you take part in research. The document signposts teams to sources of information that will help them comply with specific requirements and develop good practice in relation to their participation in research.

The document is aimed at the individual within the community pharmacy who will take on the role of Research Lead within the Research Ready Community Pharmacy. The Research Lead must be a registered pharmacist or technician and be willing to take professional responsibility for completing the assessment. More information on the ‘Roles and Responsibilities of the Research Lead’ can be found on the RPS website.

There are five key sections to this document:
1. Research support
2. Research space and resources
3. Patient medication record
4. Governance and ethical review
5. Responsibilities to patients, public and staff

You must be able to commit to all the statements (highlighted in the text boxes in the document) in order to receive Research Ready accreditation. The exception to this is section 3 (see notes for that section). If you do not register interest at the beginning to participate in clinical trials, you will not be expected to meet the additional criteria detailed in section 6.

If your community pharmacy can meet all the requirements outlined in the five sections of this document then please complete the online assessment tool to become a ‘Research Ready’ Community Pharmacy. The data will be held by the Royal Pharmaceutical Society and will be shared with the research networks of the National Institute for Health Research to support and enable your involvement in existing studies.

\(^1\) “Research can be defined as the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods. This includes studies that aim to generate hypotheses as well as studies that aim to test them”. This includes “Research concerned with the protection and promotion of public health, research undertaken in or by the Department of Health, its non-Departmental Public Bodies and the NHS, and research undertaken by or within social care agencies. It includes clinical and non-clinical research; research undertaken by NHS or social care staff using the resources of health and social care organisations; and any research undertaken by industry, charities, research councils and universities within the health and social care systems that might have an impact on the quality of those services”. [Ref. Research Governance Framework for Health and Social Care.]
The RPS's Research Ready team will use the data to advise research councils, medical research charities and universities about interested pharmacy sites. You will then receive invitations to take part in studies (via the RPS or NIHR), but you are not under obligation to take part. You should make decisions on a study-by-study basis.

If you are interested in developing your own research projects, learning more about research or would like further one-to-one support please do not hesitate to get in touch. We have a range of tools, events and workshops that can help your research journey.

For further information, please contact:

Royal Pharmaceutical Society Research
Email: researchready@rpharms.com
Tel: RPS Support 0845 257 2570
INTRODUCTION

Research Ready is an online self-accreditation tool which enables community pharmacies involved in or considering becoming involved in research or research support activities to demonstrate their commitment to research excellence.

Research Ready asks pharmacies to commit that resources, staffing and consent arrangements are in place and covers five core areas which are aligned with latest research governance frameworks.

This Handbook will provide information on each of the questions asked in the online self-assessment to ensure you are able to answer the questions and confirm the necessary requirements for self-accreditation.

**Appendix 1** of this Handbook provides a summary of all the requirements for Research Ready and can be used as a checklist prior to completing the online self-assessment.

Before you complete the Research Ready accreditation you should follow steps one to five of the ‘Six Steps to Research Ready Accreditation’ summarised below.

Note that it is important that the Research Lead for the pharmacy completes the Good Clinical Practice training before starting the assessment as they will be asked to provide the date of their certificate of completion during the Research Ready assessment.

<table>
<thead>
<tr>
<th>Step</th>
<th>Task</th>
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<tbody>
<tr>
<td>1</td>
<td>Read through this Research Ready guidance including Appendix 1: Summary/checklist</td>
</tr>
<tr>
<td>2</td>
<td>Determine who will be the Research Lead in the pharmacy (this must be a pharmacist or pharmacy technician)</td>
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<tr>
<td>3</td>
<td>Decide whether you want to take part in health research (e.g. audit or service evaluations) and/or clinical trials</td>
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<tr>
<td>4</td>
<td>Discuss Research ready accreditation with your superintendent/owner and the pharmacy team</td>
</tr>
<tr>
<td>5</td>
<td>Complete Good Clinical Practice (GCP) training (this must be completed before starting the online assessment as you will be asked to confirm the date of your certificate)</td>
</tr>
<tr>
<td>6</td>
<td>Complete the online self-accreditation tool and submit to RPS</td>
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**NOTE**

It is important that, before starting the assessment, the Research Lead for the pharmacy has:

- gained consent from the superintendent/owner of the company for the pharmacy to engage in research activity; and
- completed the Good Clinical Practice training (as they will be asked to provide the date of their certificate of completion during the Research Ready assessment).
RESEARCH READY ONLINE ASSESSMENT

**Registration details**

The online self-assessment should be completed by the designated Research Lead for the community pharmacy who must be a registered pharmacist or pharmacy technician.

The initial four questions ask for the contact details of the Research Lead including their GPhC/PSNI registration number.

The Research Lead is then asked to confirm whether they are applying for accreditation, or re-accreditation, or informing RPS of a change in details. (Note that accreditation lasts for three years, after which the accreditation needs to be renewed.)

**Choosing the type/s of study in which to participate**

The next question asks whether the pharmacy wishes to participate in:

- Health research, or
- Health research and clinical trials.

Health research includes audit, service evaluation and other clinical or service research projects. They do not usually, but might, include the administration of a treatment to a patient. Common health research activities involving community pharmacy include: displaying poster material, sign-posting possible participants to studies, recruiting participants to studies.

Clinical trials are usually set up to test the effectiveness of a medicine, be it a new medicine coming to market, or an established medicine being used for a different and new purpose. It can also test the relative effectiveness of different medicines in the same therapeutic class.

Whether you choose to be involved in health research or clinical trials you will be fully supported in the processes around research by the RPS.

The [RPS Research and Evaluation Hub](#) provides an introduction to research and evaluation which includes an overview of the different types of studies including clinical trials.

If a pharmacy wishes to participate in clinical trials, in addition to health research, there are additional requirements for Research Ready accreditation – see section 6.

**Assessment questions**

Once the type of study (i.e. health research or health research and clinical trials) has been selected your will be directed to answer questions under five key sections to this document:

1. Research support
2. Research space and resources
3. Patient medication record
4. Governance and ethical review
5. Responsibilities to patients, public and staff.

Details of the questions, together with guidance on the requirement, can be found in this Handbook.

NB: It’s useful to keep a copy of this guidance handy when working through the online assessment. Individual sections can be collapsed to make navigation easier.
1. Research support

1.1 Superintendent pharmacist or company owner support

The superintendent pharmacist or company owner is supportive of research activity taking place within the pharmacy.

- There is a section with information specifically for superintendent pharmacists and/or company owners or management teams on the RPS website. Please ask them to read this.

- Please print off the proforma and pass it to the superintendent pharmacist or owner for signing. You will need to keep a completed and signed copy of the file for your records; this is written and signed confirmation that the superintendent/owner is supportive of research activity taking place in the pharmacy and has delegated responsibility to the Research Lead to take decisions regarding the pharmacy’s involvement in research.

- We do not expect all pharmacy staff in the pharmacy to be actively involved in research. However, it is important that staff who do wish to be actively involved are supported by colleagues and management. Such a culture will aid development of research awareness within a pharmacy and promote understanding of why research is important for improved patient care and service delivery.

- It is important that the pharmacy team makes the decision about whether or not to take part in a piece of research. The company may feel strongly that a particular project is good for the profession, but only the pharmacy team can gauge how a project will fit with their workload. The Research Lead in the pharmacy must have the casting vote in whether a project goes ahead.

- The pharmacy team should be briefed on the pharmacy’s commitment to becoming Research Ready and what this means. There is a PowerPoint presentation available on the RPS website that explains the background to Research Ready, and gives an outline of the concept. Please share this with colleagues.

2. Research space and resources

The pharmacy has identified space and resources to host research as detailed below.

2.1 Secure storage

Secure storage for project records and files will be provided.

If the project involves paper records:

- The pharmacy can provide appropriate storage for research records/files that is only accessible to staff who are involved with the project.

- The pharmacy can arrange long-term secure storage of project data for the period specified by the research team.
Storage of paper records
- A drawer in a lockable steel cabinet or similar that can hold A4 folders is suitable for this purpose. The cabinet should be kept in an area of the pharmacy where public access is denied or unusual. Keeping the key in the cabinet lock itself or in the desk drawer next to the cabinet is not secure. A record should be in place of who has access to research files (electronic and hard copy) on a study-by-study basis.

Retention of paper records
- Records for completed health research studies have to be kept for an extended period of time. This may be 5-7 years. For clinical trials, it is not unusual to have to keep the records for 15 years, and can be up to 25 years for trials involving children. The pharmacy should consider how it would archive records from completed studies.
- Secure storage can be arranged with an external provider, once the trial/project has finished, but it must be possible for the records to be accessed within a reasonable time period if needed. Fees for such storage should be considered within the remuneration for a project.
- Records kept on the premises must be protected from long-term deterioration due to environmental factors, or indeed from inadvertent disposal by staff.
- The key to archive cabinets must be carefully stored and similarly protected from damage or loss.
- There must also be a system - that will survive changes in staff, or even ownership - to show what records are being kept, for how long, and where.
- Controlled destruction should take place after the prescribed storage period has ended.

If the project involves electronic records:
- A password security system will be put in place for accessing electronic research data.
- Research data held in the electronic patient medication record (PMR) as well as additional research data held outside the PMR must have password protection that should be restricted to named team members, for example:
  - Any electronic research file held on a shared drive.
  - Any patient identifiable lists (patients either mailed for a study or recruited to a study) used specifically for the research.
- A risk assessment of the storage facilities should be undertaken.
- Electronically held research data will be regularly backed up, with an arrangement in place for secure storage of the back-up copy.
- Existing systems in place for the PMR should be transferable to research data held electronically. It is worth noting that some electronic storage facilities, like Dropbox, may be located on servers outside the UK and this would not be acceptable for the storage of NHS or research records.

2.2 Pharmacy staff time

Pharmacy staff time will be provided to support research activity.

- The pharmacy team has discussed how it will provide this staff support and identified which members of staff will be involved. This includes someone in the pharmacy who will be responsible for project administration (liaison with external researchers, monitoring progress, receiving and acting upon changes to project protocols).
• The pharmacy will need to be aware of the resources (time, staffing, training etc) necessary to support its research activity. It will be necessary to identify the staff who will be contributing to research activity, the amount of their time that will be required and any necessary ‘back-fill’ of their time. This might be identified on a study-by-study basis; the contracts of current staff may include dedicated research time or a number of research dedicated staff may already be employed by the pharmacy.

• There is a significant amount of admin time needed for certain clinical trials: a member of staff would have to stay on top of updates to the protocol, for example. The trial team may need to visit the pharmacy out-of-hours to discuss progress: staff resource should be anticipated for such visits.

• Contracts should be in place that include staff dedicated research time; and/or, a written statement (on a study-by-study basis) should be in place detailing staff involvement and time commitment (and associated payment/reimbursement details).

2.3 Consultation space

A private consultation space will be provided to support research activity.

• There is a consultation room within the pharmacy where conversations can happen with study participants.

• Prospective participants must always have the option to have a conversation in a private area (which cannot be overheard from outside), and so a consultation room is necessary to take part in research and trial activity. Different types of facilities in consultation rooms may allow a pharmacy to take part in a range of projects: for example, having a hand washbasin or examination couch may extend the number of projects possible to conduct in the pharmacy, but a basic room is sufficient to be accredited. A pharmacy may indeed decide that it is worth upgrading its consultation facilities to take part in a specific project.

2.4 Internet access

The pharmacy staff have access to the Internet.

• Staff members have access to the Internet in order to input data to web-based collection systems and to consult up-to-date guidance documents about research and trials.

• Access to the Internet will enable staff to have access to up-to-date guidance about research and trials (such as electronic case report forms [eCRF]² and interactive web response systems [IWRS]³). Some studies may require data to be entered into a web-based system.

²The term eCRF stands for Electronic Case Report Form data entry. A CRF is a paper questionnaire used in clinical trials. The CRF is used by investigators, project coordinators, data managers etc. to collect, review and organise data from each working site. Over time the CRF can go from one handwritten page to hundreds of pages. With electronically captured data gathered over a period of weeks or months, eCRF allows the data to be centralised, organised and accessible within a global platform mostly known as “e-Platform”.

³Interactive Web Response Systems (IWRS) use a standard web browser and email service, allowing study administrators and investigators to securely interact with the study database, making study deployment fast and easy.
We understand that some companies have a ‘white list’ of permitted sites that are determined centrally. Some studies may require data to be entered into a web-based system. Gaining permissions can take some time, so you must ensure these requests are submitted as soon as possible.

See Section 6.1 for additional requirements for pharmacies involved in clinical trials regarding research space and resources.

3. Patient medication record

This section is non-essential for research ready accreditation. However, if you intend to use the Patient Medication record (PMR) for research purposes then you must complete the following questions.

Basic searches of the patient medication record (PMR) can be carried out.

The ability to explore PMR systems to generate lists of people with certain characteristics or medicines/conditions is very variable. We would not exclude a pharmacy from Research Ready if they weren’t able to do these searches, but it could limit the type of studies in which they could get involved. In general practice, projects often involve searching the patient records to find people who fit certain criteria (e.g. age, condition) and then the staff send out invitation letters to all those people who fit the criteria. This can be done at a time that suits the practice, slotted into its workload. In pharmacies where we couldn’t do these searches, all the recruitment would have to be when patients presented in the pharmacy.

3.1 PMR data quality

The pharmacy staff will review the quality (completeness, accuracy) of the information they put into the PMR system, and will regularly discuss how to maintain a high standard of quality.

- It is really important that information entered into the PMR is complete and accurate. It is very straightforward to do for the labelling details, but may be more difficult for fields like age/date of birth and postcode. Pharmacy has a wealth of data within its PMR that we can use to benefit patients. Making sure that records are complete and accurate, with ongoing discussion among staff who input data to the PMR, will ensure that this information is reliable, and of the highest quality.
- Pharmacies may wish to develop a SOP for adding new records if they do not already have one.
- It is important now to start informing patients that their stored PMR data might be used for research purposes.
- The RPS has published guidance on using electronic health records, including the summary care record, and the principles therein about accuracy of patient data may be useful.
3.2 Searching the PMR

The pharmacy has identified members of pharmacy staff who know how to use the search facilities to identify groups of patients with specific characteristics.

- Again, this may or may not be possible in your pharmacy. You will get the chance, at the end of this process, to tell us if you can do these advanced searches. Some systems have the ability to tag patients, and/or set up a ‘pop-up box’ to flash during dispensing.

4. Governance and ethical review

The Research Lead knows what is required of his/her pharmacy and individual members of staff with reference to research governance.

In addition to the Research Lead being in receipt of valid Good Clinical Practice (GCP) training (see 4.5) staff involved in research, should receive training in the purpose of research governance and ethical review.

When the pharmacy is considering participation in a study, or when a study is active in the pharmacy, research matters should be a regular agenda item at pharmacy meetings.

The Health Research Authority website includes a section on research legislation and governance which ‘pulls together all the legislation governing health research’.

4.1 Ethical approval

The Research Lead understands that different types of projects need different levels of ethical approval, and will confirm that each project (be it audit, evaluation or research) has achieved the appropriate approvals before agreeing to take part.

- Audit and service evaluation projects do not need NHS ethical approval, although any that are done by universities should have their own institutional approval. Student projects from universities – which are now often audits or evaluations - should also have this university approval.

- Research projects involving NHS patients need ethical approval by a Local Research Ethics Committee, and the study lead should provide you with the NHS Research Ethics letter stating where and when it got its approval. You can put this in the project file.

- Pharmacy customers are considered NHS patients if the project is about NHS services e.g. getting prescriptions or having MURs. They may not be considered NHS customers if they are accessing non-NHS services, such as buying an over-the-counter medicine or accessing a weight loss programme that is not NHS-funded. If the project does not have ethical approval, you are justified in asking why not.
4.2 Sponsor role

The Research Lead is aware that he/she must ascertain who the Sponsor is, and the Sponsor’s role in the project, before the pharmacy agrees to participate in a research study.

- The term ‘Sponsor’ can be confusing, but they are very important to the research. A Research Sponsor needs to be identified for studies that involve human participants, their tissues or data. This is an individual or organisation that takes on responsibility for confirming there are proper arrangements in place to initiate, manage, monitor and finance a study. Sponsors must also ensure that appropriate indemnity is in place before research begins.

- The sponsor of a non-commercial study is not usually the funder, but the employer of the research project team. Thus it is often a University or hospital Trust. The sponsor is generally the body that indemnifies (holds the insurance for) the project.

- The sponsor of a commercial trial will often be the company seeking to market the medicine.

4.3 Records

Complete records need to be maintained for all research studies in which the pharmacy is involved. The pharmacy has a system to ensure that complete records (protocols, approvals etc.) will be maintained in a project file.

- These records will include, in addition to data that has been collected, copies of protocols, ethics and governance approval, patient information sheets, signed patient consent forms, etc.

- A complete project file (electronic or paper format) for each study being hosted should be kept in the pharmacy (readily accessible to the external research team), including (but not limited to):

  - A copy of the NHS (or University/institutional) Research Ethics Committee letter stating that the study has been given a favourable opinion, including a list of approved versions of study documents (with version numbers attached to the letter) to ensure correct materials (including promotion materials) are used in the pharmacy.

  - A copy of the Health Research Authority (or Health and Care Research Wales or NHS Research Scotland) approval letter for research in NHS organisations.

  - Financial data relating to studies hosted and contracts held.

- As for project data, a back-up copy of this file should be kept.

4.4 Income and expenditure

The pharmacy will have a system to identify the research income and expenditure relating to different studies.
• You could demonstrate this by showing how the pharmacy already does this or how it would do this. If your pharmacy is in receipt of study funding, your funder will expect financial reports on the income and expenditure related to different studies. You could demonstrate how your pharmacy meets this criterion by writing down whether the pharmacy accounts are audited or scrutinised and who does this for you. When deciding whether or not your pharmacy should participate in a study, consideration should be given to the sum of money being offered to the pharmacy. A robust accounting system will show whether the remuneration is covering the resources needed for the study.

• Where a pharmacy company participates in a research study (which may involve multiple sites), the head office will probably maintain this system but the individual pharmacy will be expected to keep track of research activity for monitoring and invoicing purposes.

4.5 Good clinical practice (GCP) training

The research lead will have completed GCP training, which will be updated at regular intervals. Other participating staff will receive study-specific training and extracts from GCP training (or consistent with GCP training) applicable to the tasks they undertake (e.g. record keeping).

• A key requirement for anyone involved in the conduct of clinical research is Good Clinical Practice (GCP) training. GCP is the standard and guidelines to which all research is conducted.

• Details of GCP training and resources can be found on the NIHR website. GCP training can be accessed through workshops or online. Courses specific to pharmacy are starting to become available. Links to upcoming face-to-face GCP courses are available on the RPS website.

• There is no official guidance on how frequently the updating ‘at regular intervals’ might be. However, for Research Ready accreditation, the date of completion of any GCP training must be within the last two years.

• Studies often incorporate elements of GCP training for support staff into their own training events. The Research Lead should think through what other staff might need to know for a specific project, and may contact the study investigator, local Clinical Research Network contact, or the Society’s Research Ready team for advice.

4.6 Good clinical practice (GCP) certificate date

Date of completion of GCP training (introduction or refresher course).

• The date of the Research Lead GCP training certificate must be within the last two years to be valid for Research Ready accreditation.

See Section 6.2 for additional requirements for pharmacies involved in clinical trials regarding governance and ethical review.
5. Responsibilities to patients, public and staff

The Research Lead is aware of the responsibilities he/she has to his/her patients, the public and staff when they are participating in research studies.

It is very important to have plans in place for succession planning and handover so that there are no gaps in coverage of Research Lead expertise in the pharmacy.

All patients and members of the public must be treated equally, whether they are taking part in projects or not. The ongoing work of the pharmacy must not be compromised by research activity.

For clinical trials, patients may receive trial medication that is helpful to them. From the outset, the pharmacy staff should be aware what might happen at the end of the project – will the patient still have access to the medicine? Managing expectations of study participants – and fully informing them - will be very important.

5.1 Data protection

The pharmacy’s data protection registration includes any research activity in which the pharmacy is involved.

- As a data controller, handling personal information, pharmacies are required to have a Data Protection registration with the Information Commissioner’s Office (ICO). The pharmacy’s Data Protection registration should be up to date, and it should cover collection and storage of research data (and data analysis if this also takes place in the pharmacy).

- The Research Lead should know the name of their Data Controller in their pharmacy company. Data controllers will usually be organisations, but can be individuals. Even if an individual is given responsibility for data protection in an organisation, they will be acting on behalf of the organisation, which will be the data controller. The company can check the provisions of its registration, and add research/analysis if necessary.

- An up to date Data Protection notification form file (including research) should be kept in the study. To add research to your Data Protection registration, contact the Information Commissioner’s Office, quoting the pharmacy’s ICO registration number.

5.2 Consent and patient confidentiality

The pharmacy staff are aware of the guidance relating to the access and use of patient medication records and confidentiality of patient information. The Research Lead will ensure that they are also aware of how this guidance relates to use of information for research.

- The Research Lead must be aware of his/her responsibility to ensure that staff are familiar with the relevant aspects of this guidance and demonstrate that relevant pharmacy staff are aware of appropriate access, use and confidentiality of patient records and patient information e.g. GCP training certificates.

- Many pharmacies have a SOP relating to the access and use of patient information. It may be worth developing such a SOP if you do not already have one, and use it to raise awareness among all staff.
Pharmacists and pharmacy technicians should already be familiar with GPhC guidance on consent and patient confidentiality. Further information on consent for health research can be found on the Health Research Authority website.

5.3 Informed consent

Pharmacy staff who will be involved in recruitment for research studies will be competent in obtaining “informed consent”. Their patients will be fully aware that - should they decline to participate in a study - this will not affect their care or relationship with the pharmacy in any way.

- The Research Lead is responsible for, and can demonstrate, that the pharmacy staff involved in recruitment understand, and are competent in obtaining valid informed consent. If your pharmacy is yet to undertake research, consider how informed consent will be achieved properly. This practice is becoming commonplace in pharmacy with services like MUR and NMS, and it takes time to engage properly with people.

- It is crucial to include a ‘cooling-off period’, for a minimum of 24 hours, during which time a patient can reconsider whether they wish to be involved or not.

- Patients should know about research in the pharmacy and in which they might participate. It must be made clear that if invited, patients can decline or later withdraw without there being any question that this will affect their future care and treatment. It is also useful to explain to patients why research in primary care is important and how studies help improve patient care. It is important to provide patients with feedback on the outcome of studies and ensure they are thanked for their participation.

- It might be useful to have a specific contact person in the pharmacy to deal with patient queries about research; they may or may not be the Research Lead, but act under their guidance.

5.4 Patient and public awareness

Patients and the public will be made aware that the pharmacy is involved in research. This will be adequately publicised, using approved materials for each project (e.g. on pharmacy notice boards, in patient information leaflets and/or on the pharmacy website).

- There are two approaches to raising awareness – generic information about being generally involved in research, and specific information about current studies.
  - Generic information - The Research Lead might demonstrate a general involvement in research by placing an appropriate statement in pharmacy leaflets, documentation, information sheets provided for patients recruited into research, notice boards, electronic display boards, websites.
  - Project-specific information – Materials to promote a specific project to patients have to be approved by an ethics committee, and will therefore be supplied by the investigator. Pharmacies cannot write their own information about the studies they are hosting on their website, but could give a link to a description of the study from another website. A summary of a large NIHR-funded study would usually be listed on the funder’s website.

- It is possible that patients will be surprised on the first occasion that they are approached by pharmacy staff to take part in a research project, especially if they believe that their records have been consulted to determine whether they are eligible to take part. In the future, this is
likely to become much more widespread. The approach must be sensitive, and mindful of the privacy of the patient and their right to refuse. The staff should be ready to explain how this patient came to be approached, and why the pharmacy is taking part in the project.

- All pharmacy staff should be ready to answer questions, or to signpost to those who can, once a specific project is being advertised, as it is likely to generate some interest among patients and the public.

**5.5 Remuneration**

When deciding whether or not the pharmacy should participate in a study, consideration will be given to the remuneration being offered to the pharmacy. The pharmacy understands that this should reflect the time that will be taken and the work to be done in the pharmacy. The pharmacy will 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.

- As you can see from the commitments required in this application, there are many issues that must be costed into a pharmacy’s participation in a study. Time for training, administration of study protocols, writing relevant SOPs, and meeting with study investigators or receiving MHRA monitoring visit teams are all examples of less obvious research costs that must be met by the fee of the investigators.
- NIHR produce a spreadsheet which can be downloaded to record and calculate NHS costs associated with Network-supported (non-commercial) studies in primary care. If you would like advice or help with the template, please contact your local Clinical Research Network.
- It would be unfortunate and detrimental to relationships between patients and pharmacy staff, if patients were to feel that their recruitment to a trial resulted in a large payment to their pharmacy.

**5.6 Indemnity**

The pharmacy understands that all research studies must minimise and carry indemnity for risk to patients.

- The Research Lead will ensure:
  - All pharmacy staff are aware of the difference between negligent harm and non-negligent harm.
  - The Research Lead will discuss the risks to patients from each study, and take steps to minimise them by following the project protocol and associated SOPs.
  - The pharmacy’s Health and Safety policy adequately covers the pharmacy’s research activities.
  - The pharmacy will ensure that, for each project, appropriate indemnity insurance cover is in place.
- The Research Lead must make themselves aware of any risk to patients before the pharmacy participates in a study and ensure that such risks are minimised and adequate indemnity is in place. The possible risks and minimisation strategies should be recorded in the study file.
6 Clinical trials – additional requirements

6.1 Research space and resources

If a pharmacy wants to participate in clinical trials, in addition to health research, it must also address the following points in relation to research space and facilities:

6.1.1 Storage/archive facilities

Storage/archive facilities will be provided to hold records of completed trials.

- Archiving procedures are needed, with the same considerations as for section 2.1. This may include a contract with an external supplier. The costs of storage should be met by the trial investigator. Patient identifiable data related to the study should not leave the pharmacy and archiving details should be kept within the pharmacy. The usual period for keeping trial data records can be 15 years for adults and up to 25 years for children.

- Tags may also have to be applied to patient medical notes where the patient has been on a clinical trial so that the patient medication record is not destroyed within 2 years of death.

- There should be a policy or procedure in place for archiving and destruction of pharmacy data, incorporating the archiving of clinical trial data.

6.1.2 Secure storage for pharmaceuticals

Secure storage will be provided for any pharmaceuticals which may form part of a trial.

This includes separate storage for (a) supplies for dispensing, (b) quarantined medicines, and (c) medicines returned by patients. Prescriptions dispensed for trial patients will be stored away from other dispensed medicines until collected.

- A lockable drug cupboard or separate clinical trials shelf or cupboard in a secure dispensary will be required.

- Room temperature logs may be expected, and a team member should be delegated this task. A thermometer for ambient temperature should be provided by the trial team for this purpose.
The privacy of trial patients should be maintained at all times. For example, it should not be possible for other customers to see that dispensed trial drugs are being kept separately for specific patients in an open plan dispensary. This might openly identify them as trial patients when they come to collect their medicines.

### 6.1.3 Lockable fridge

A lockable fridge (or fridge in a secure dispensary) will be provided by the pharmacy if this is needed for storing pharmaceuticals that form part of a trial.

- This is usually in place in the pharmacy. A separate shelf may need to be provided for the clinical trial product, but often a dedicated plastic container on a shelf will suffice. If a product needs to be kept at a temperature that is not compliant with the usual clinical refrigeration temperature, then a separate fridge may have to be considered. Strict temperature logs will be expected. Pharmacy team members will have to be delegated the checking and recording. A fridge thermometer should be provided by the trial team for this purpose.

### 6.1.4 Desk space and computer access

Desk space and computer access will be provided for visits of external research staff, if this is notified to the pharmacy at the beginning of a trial and advance notice of visits given.

- We recognise that it might be difficult to accommodate extra people at a computer during opening hours. You will need to indicate to the study team whether they can visit the pharmacy when it is open or closed.

- External research staff may need access to a room with computer/internet access to the consented patients’ notes. The pharmacy can use their own confidentiality agreement for this purpose. There may be staffing implications for visits out-of-hours, which should be properly remunerated.

- Where data is collected through web-based systems, remote access by the investigating team may reduce the need for site visits. This should be discussed at the beginning of the project.

### 6.1.5 Meeting room facilities

A suitable room has been identified for meetings between pharmacy staff and external researchers which often occur in clinical trials.

- Access to a room that is of a sufficient size to accommodate a group of people may be required, but is not essential for all study involvement. It is acceptable to identify a meeting room close by the pharmacy, such as one in a practice or community centre. The required presence of the pharmacist in the pharmacy should be considered when arranging such meetings.
6.1.6 Trial equipment

Trial equipment is appropriately maintained and operated by pharmacy staff.

- The pharmacy will ensure that the proper equipment will be available to meet the needs of trials in which it intends to participate and that it will receive regular maintenance and calibration.
- The pharmacy will ensure that all trial staff use a standard operating procedure for the operation of each piece of trial equipment.
- Some trials require the use of particular types of equipment, such as weighing scales.
- Trial equipment is protocol specific. The trial team would be expected to supply such equipment. Training in the use of the equipment should be offered by the study sponsor or delegated other. Requirements for calibration of such equipment should be detailed in the study documentation. Where pharmacy equipment is used, then calibration should follow the study protocol. Further information on standards for registered pharmacy premises can be found on the GPhC website.
- A standard operating procedure should be put in place within the pharmacy for operation and calibration of the equipment in a study. The Research Ready team will encourage investigators to write a central SOP that all pharmacies can follow. It would be helpful to know the equipment supplier's contact details if urgent help is needed.

6.2 Governance and ethical review

If a pharmacy wants to participate in clinical trials, in addition to health research, it must also address the following points in relation to Governance and Ethical Review:

6.2.1 Clinical Trials Regulations

Pharmacies participating in clinical trials will act in accordance with the Clinical Trials Regulations.

The relevant staff members should have been appropriately trained in Clinical Trial regulations (demonstrated through GCP training certificates). The pharmacy must understand the importance of Clinical Trial regulation training for all staff hosting interventional research where participants are seen at the pharmacy.

- Further information on the legislation relating to clinical trials can be found on the Health Research Authority website. The regulations are currently under review and information on relevant consultations is posted on the RPS Research Networks (i.e. Research and Evaluation network, Clinical Trials – NPCTAG network).
- The RPS Research Ready team plan to help pharmacies to know when updates are issued through the RPS Networks.
6.2.2 MHRA inspections

Pharmacies participating in clinical trials will make records and premises available to MHRA teams during inspections.

- For more information on how to prepare for a Good Clinical Practice Inspection by the MHRA see the NHS Research and Development Forum website. This document is aimed primarily at the organisation who designs the trial, but sections 4.3 (p7) and 7.2 (p11) provide detail about the role of investigator sites, which is what the pharmacy is to MHRA.

- In clinical trials, sometimes the pharmaceutical company arrange ‘test visits’ to check that all areas are ready for MHRA inspection. It is worth discussing this aspect of the trial with the company at the start of the project.

6.3 Responsibilities to patients, public and staff

If a pharmacy wants to participate in clinical trials, in addition to health research, it must also address the following points in relation to Responsibilities to Patients, Public and Staff:

6.3.1 Adverse events

An adverse event might occur during the course of a trial. The pharmacy will ensure that it knows how to identify and notify adverse events in accordance with the trial protocol.

- Safety reporting procedures should be set out in the research study protocol and in line with local research governance procedures and local NHS incident reporting procedures.

- Pharmacies may consider applying a “Research Tag” to the PMR of patients on clinical trials. This way the pharmacy team can be alerted if participants attend the pharmacy or hospital services with adverse/ serious adverse events.

- Pharmacies already involved in services like flu vaccination will have experience in dealing with possible adverse events.

- All possible trial-related ADRs and incidents, and action to be taken, should be discussed with the investigator during training for the trial.

6.3.2 Double blind trials

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). It is now common for a central database to have these details so that they can be accessed 24/7 by medical staff.

The pharmacy will ensure that it knows how this will occur, if necessary, for one of their patients taking part in a trial.
• In double blind trials, neither the patient nor the prescriber know which drug is being taken by any individual. In the pharmacy, the drug may only be identified by a code - so the dispensing pharmacist is also unaware of its exact identity. From a safety perspective, we need to ensure that there is a way of identifying what study drug the participant is taking in an emergency. This is important in cases where the participant becomes unwell whilst participating in a trial.

• The procedure for identifying the study drug is set down in the study protocol and must be adhered to.

• In such studies, participants are usually issued with an "emergency card" which is carried at all times. The card usually has the study details and the participants study number.

• Modern code break procedures involve an emergency telephone number being called and an assessment of the patient’s condition prior to code break. In most cases the participant cannot continue on the study once the code has been broken - as a result, caution is exercised.

• For each trial, a system must be in place to ensure that all relevant staff are aware of how to break the code and in what circumstances. This must be covered by the investigator in training for the trial, and the Research Lead must ensure that all staff know what to do if a problem occurs.

• It is highly unlikely that a pharmacist would have to go to the pharmacy 'out-of-hours' to access records. This must be clarified before the project begins, and – if it might be needed – specific procedures must be agreed with the investigator to ensure the safety of the pharmacist who has to go in, and to secure remuneration to do so if this occurs.
Appendix 1: Research Ready assessment summary/checklist

Before logging on to fill in the self-certificate form use the checklist below to check all relevant elements are in place and that you are ready to submit.

Note that, before starting the assessment, it is essential that the Research Lead for the pharmacy has:

1. gained consent from the superintendent/owner of the company for the pharmacy to engage in research activity; and
2. completed the Good Clinical Practice training (as they will be asked to provide the date of their certificate of completion during the Research Ready assessment).

<table>
<thead>
<tr>
<th>Section 1: Research support</th>
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<tbody>
<tr>
<td>The superintendent pharmacist or company owner is supportive of research activity taking place within the pharmacy.</td>
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<table>
<thead>
<tr>
<th>Section 2: Research space and resources</th>
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<tbody>
<tr>
<td>Secure storage for project records and files will be provided.</td>
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<tr>
<td>Pharmacy staff time will be provided to support research activity.</td>
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<tr>
<td>A private consultation space will be provided to support research activity.</td>
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<tr>
<td>The pharmacy staff have access to the Internet.</td>
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<tr>
<th>Section 3: Patient medication record</th>
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<tr>
<td>Basic searches of the patient medication record (PMR) can be carried out.</td>
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<tr>
<td>The pharmacy staff will review the quality (completeness, accuracy) of the information they put into the PMR system, and will regularly discuss how to maintain a high standard of quality.</td>
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<tr>
<td>The pharmacy has identified members of pharmacy staff who know how to use the search facilities to identify groups of patients with specific characteristics.</td>
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<th>Section 4: Governance and ethical review</th>
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<tr>
<td>The Research Lead knows what is required of his/her pharmacy and individual members of staff with reference to research governance.</td>
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</tbody>
</table>
The Research Lead understands that different types of projects need different levels of ethical approval, and will confirm that each project (be it audit, evaluation or research) has achieved the appropriate approvals before agreeing to take part.

The Research Lead is aware that he/she must ascertain who the Sponsor is, and the Sponsor’s role in the project, before the pharmacy agrees to participate in a research study.

Complete records need to be maintained for all research studies in which the pharmacy is involved. The pharmacy has a system to ensure that complete records (protocols, approvals etc.) will be maintained in a project profile.

The pharmacy will have a system to identify the research income and expenditure relating to different studies.

The research lead will have completed GCP training, which will be updated at regular intervals, and other participating staff will receive study-specific training and extracts from GCP training (or consistent with GCP training) applicable to the tasks they undertake (e.g. record keeping).

Date of completion of GCP training - this should be within the last two years.

<table>
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<th>Section 5: Responsibilities to patients, public and staff</th>
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<tr>
<td>The Research Lead is aware of the responsibilities he/she has to his/her patients, the public and staff when they are participating in research studies.</td>
</tr>
<tr>
<td>The pharmacy's data protection registration includes any research activity in which the pharmacy is involved.</td>
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<tr>
<td>The pharmacy staff are aware of the guidance relating to the access and use of patient medication records and confidentiality of patient information. The Research Lead will ensure that they are also aware of how this guidance relates to use of information for research.</td>
</tr>
<tr>
<td>Pharmacy staff who will be involved in recruitment for research studies will be competent in obtaining “informed consent”. Their patients will be fully aware that - should they decline to participate in a study - this will not affect their care or relationship with the pharmacy in any way.</td>
</tr>
<tr>
<td>Patients and the public will be made aware that the pharmacy is involved in research. This will be adequately publicised, using approved materials for each project (e.g. on pharmacy notice boards, in patient information leaflets and/or on the pharmacy website).</td>
</tr>
</tbody>
</table>
When deciding whether or not the pharmacy should participate in a study, consideration will be given to the remuneration being offered to the pharmacy. The pharmacy understands that this should reflect the time that will be taken and the work to be done in the pharmacy. The pharmacy will 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.

The pharmacy understands that all research studies must minimise and carry indemnity for risk to patients:

**Section 6: Clinical trials – additional requirements**

<table>
<thead>
<tr>
<th>1: Research support</th>
<th>Not applicable</th>
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<td>A suitable meeting room has been identified for meetings between pharmacy staff and external researchers which often occur in clinical trials.</td>
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<td>Trial equipment is appropriately maintained and operated by pharmacy staff.</td>
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