Setting up a Clinical Trial

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

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	Date:	30th June 2017

This SOP will normally be reviewed every 3 years unless changes to the legislation require otherwise

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Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Details of significant changes
1.0	31st July 2017	

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1 Introduction, Background and Purpose

All clinical trials where medicines classed as Investigational Medicinal Products (IMPs) are involved must be reviewed, approved and set-up by the Pharmacy Department prior to the study being approved for conduct in the organisation. This is to ensure that pharmacy can support the trial, taking in to account additional costs, workload and other resource implications and practical aspects of the management of IMPs.

In relation to trials sponsored by York Teaching Hospitals NHS Foundation Trust, pharmacy must be involved in discussions with the Chief Investigator and the Research & Development (R&D) Department at an early stage of protocol development and a formal review will be required.

The purpose of the SOP is to ensure that each trial has an appropriate review and is set-up in a timely manner and within the HRA time period.

2 Who Should Use This SOP

This SOP should be followed by all members of the clinical trials team within the Pharmacy Department at Scarborough and York Hospitals, which forms part of York Teaching Hospitals NHS Foundation Trust.

3 When this SOP Should be Used

This SOP should be used as follows:-

- Upon receipt of a clinical trial protocol
- Prior to attending a Site Selection Visit (SSV)
- Setting up a new clinical trial
- To confirm feasibility of a clinical trial
- To review and authorise a clinical trial
- To confirm pharmacy readiness to the R&D Department
- To confirm pharmacy green light

4 Procedure(s)

When setting up a clinical trial the Pharmacy Clinical Trial Set up Guide (in Appendix A) should be used in conjunction with Pharm/F14 Pharmacy Clinical Trial Set Up form.

There are four main stages of Clinical Trial Set-up:

Stage 1 – Feasibility
This is performed when a Principal Investigator (PI) or Research Nurse has expressed an interest in taking part in a clinical trial (often call an Expression of Interest). There is normally a limited amount of information regarding this study available, so Pharmacy are really assessing whether it is feasible for us to set up this clinical trial.

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Stage 2 – Review & Authorisation
This is performed once the site has been selected to open the study. Pharmacy will review the clinical trial protocol and pharmacy manual and confirm that pharmacy are able to proceed with setting up the clinical trial.

Stage 3 – Pharmacy Readiness
Once all of the Pharmacy documents have been created and approved, pharmacy will confirm readiness with the Research Facilitator

Stage 4 – Pharmacy Green Light
Pharmacy Green Light is the confirmation that pharmacy is ready for the first patient to be recruited in to the clinical trial (often call an Expression of Interest). Pharmacy Green Light may be given at the same time as Pharmacy Readiness if we do not get the initial shipment of IMPs until the first patient is in screening otherwise Pharmacy Green Light is not issued until we have received the IMPs and they are fit for use.

4.1 Stage 1 – Feasibility

Pharmacy will be notified of an Expression of Interest by the R&D Department or by the Research Team.

Upon notification of an Expression of Interest the Pharmacy Clinical Trials Manager/Principal Pharmacist will set up an electronic folder and create sub-folders according to Pharm/F52 Pharmacy Clinical Trial File Contents sections for the trial on the x-drive in the Expression of Interest folder and transfer any trial related documents to the relevant sub-folders.

The clinical trial name will then be added to the Expression of Interest board which is located in the Clinical Trials office at York (this will cover both sites).

Print off a Pharmacy Clinical Trial Set Up Form (Pharm/F14) from the R&D Website and complete the trial information on page 1 as far as possible.

Complete Stage 1 – Feasibility on the form. Email the Sponsor to request any missing information you require to complete this section.

- **Date of notification of the study and from whom** – the Research Nurse or the Research Facilitator may have notified pharmacy that there has been interest in the study.
- **Date of Site Selection Visit** – some clinical trials will have a Site Selection Visit where the Sponsor will come to the site and meet with the Research Team, The PI and pharmacy.
- **Drugs involved** – this information can be found in the trial summary and the trial protocol (if provided).
- **Who is supplying the IMP/nIMPs** – pharmacy need to obtain the information about where the drugs are being supplied from and if they are being supplied free of charge. If the drugs are being provided from hospital stock or that there is a charge for the drugs, the cost must be compared to the cost of what the treatment a patient would routinely get if they were not taking part in a study. If there is an excess drug cost this must be recorded in this section.

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- **Temperature requirements for the storage of IMPs** – What is the storage temperature for the IMP? Do pharmacy have adequate space and are we able to offer storage at the required temperature range?
- **Aseptic involvement** – do any of the drugs need to be prepared by aseptics, if so inform aseptics of a possible trial that may be opening.
- **Satellite involvement** – Does the clinical trial involve chemotherapy and will the prescription be validated by the satellite unit and will there be any dispensing that they will undertake?
- **Number of dispensing episodes per patient** – number of items per visit and the total number of visits. Some trials will have a set number of dispensing visits for other trials this may be unknown as the patient may continue treatment until disease progression.
- **Frequency of dispensing** – How often will pharmacy be expected to dispense medication for a patient.
- **Number of patients expected** – how many patients are the Research Nurses planning to recruit into the study?

Do not invest too much time in the study at this point, as it is not guaranteed that we will be selected to open as a site. We are only really checking that it is feasible for pharmacy at this stage.

Any printed documents for this study should be placed in a folder clearly named for that study along with the Pharmacy Clinical Trial Set Up Form (Pharm/F14) in the Pending studies section in the clinical trials dispensary at York or in the filing cabinet marked for Pending Studies in the clinical trials room at Scarborough.

The Clinical Trials Manager/ Principal Pharmacist will assess whether it is feasible to undertake the clinical trial and sign the bottom of the Stage 1 form and inform the Research Facilitator of the Pharmacy Feasibility using email template Pharm/T25 (do not mail the cover pages to the template) and attach a copy of the completed stage 1 Feasibility.

Pharmacy will be notified of the date of the Site Selection Visit (if applicable) and should ensure that a member of the pharmacy clinical trials team can attend (ideally this should be the person who is involved in setting up the clinical trial), so that any questions or queries can be addressed before we are selected as a site. Some Sponsors may wish to visit pharmacy during this visit.

Amend the Expression of Interest board to indicate that stage 1 has been completed.

4.2 Stage 2 – Review & Authorisation

Stage 2 will commence once the site has been selected by the Sponsor and pharmacy have been notified by the R&D Facilitator. The Research Facilitator will send a confirmation email to confirm that pharmacy are to progress with stage 2. The Pharmacy Clinical Trials Manager/ Principal Pharmacist will nominate a member of staff to complete stage 2. The trial details should be removed from the Expression of Interest board and added to the Pending Trials board.

Move the electronic trial folder that is currently in the Expression of Interest folder to the current trial section of the x-drive. As electronic documents are received they will need to be saved in the electronic trial folder and then printed and filed

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in the file marked for that study which should be stored in the Pending Trials section in the clinical trial dispensary.

Complete Stage 2 of the Pharmacy Clinical Trial Set Up form (Pharm/F14).

- **Date of when site was selected** – this can be found on correspondence confirming that the site has been selected.
- **Any additional drug cost** – if pharmacy are having to procure any drugs that are not standard of care that the sponsor is not reimbursing.
- **Any additional cost to pharmacy** – e.g are we having to provide taxis to transport the drug?
- **Additional equipment required** – fridges, denward loggers, cool bags etc.
- **Commercial costing template reviewed and approved** – only applicable to commercial studies, check that dispensing fees, set up fees are correct, this will then need to be approved by the Pharmacy Clinical Trials Manager/Principal Pharmacist (this can be done at the same time that the Pharmacy Clinical Trials Manager/Principal Pharmacist signs off stage 2)
- **Open label/single blind/double blind** – if blinded how will drugs be allocated at each dispensing, will it involve an IXRS system or a randomisation list held within pharmacy
- **Is pharmacy involved with unblinding** – will pharmacy have to unblind, if so how is this done?
- **Drug supply after completion** – who will fund the study drug after completion of the trial, this may not be applicable to all trials.
- **IXRS/IWRS/other web based program to be used by pharmacy, if yes what for?** – will pharmacy acknowledge receipt or dispensing
- **Is manual ordering involved** – will pharmacy have to complete order forms for initial and further supplies of medication.
- **Additional sponsor training required** – Are pharmacy staff expected to perform on-line training for study specific training, and the estimated time for each staff to complete the training. Are there any additional funds available for training if the training will take longer than one hour per staff member.
- **Estimated date of opening** – confirm with the Research Team and the Research Facilitator the date planned for opening, considering HRA time limits and the date of the Site Initiation Visit (SIV).
- **Aseptic approval** – Send a copy of the protocol and pharmacy manual to Aseptics, once approved by Aseptics the form must be signed by a senior member of Aseptics. Aseptics/Clinical Trials Pharmacist will also have to create a chemocare prescription.
- **Trial Monitoring Company** – if different from Sponsor.
- **Details of Trial CRA or Monitor** – Name, email and telephone of CRA or Monitor
- **IMP dispensing requirements** – any tear-off labels to be applied to the accountability logs, controlled drug etc.
- **Stability/storage requirements of reconstituted IMP** – after aseptic preparation, or a liquid that has been reconstituted with water the expiry date and storage will differ from the original. Consider if any additional paperwork will be required to maintain the coldchain. For Scarborough trials consider the transportation between sites if Aseptics are involved.

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Create a plan for setting up the pharmacy site file, review what documents will need to be created, for example:-

- Dispensing Instructions
- Drug Maintenance
- Trial Summary/Unblinding
- Accuracy/ Clinical Checking Checklist
- Labels
- Accountability Logs
- Prescriptions

Once Stage 2 of the Pharmacy Clinical Trial Set Up form has been completed the Pharmacy Clinical Trials Manager/Principal Pharmacist will sign, print and date and attach a copy to the Pharmacy Review/Authorisation email (Pharm/T30) and send to the Research Facilitator.

Amend the Pending Trials board to indicate that Stage 2 has been completed.

4.3 Stage 3 – Pharmacy Readiness

The Research Facilitator will send a confirmation email to confirm that pharmacy are to progress with stage 3. The Pharmacy Clinical Trials Manager/ Principal Pharmacist will nominate a member of staff to complete stage 3.
Complete Stage 3 of the Pharmacy Clinical Trial Set Up form with the following:-

Date Pharmacy Site File was requested – contact the trial CRA/Monitor and request the Pharmacy Site File, if the file is not available as yet as for all the relevant documents to be sent to pharmacy.
Date Pharmacy Site File was received – in the event that the Sponsor will not be providing a Pharmacy Site File, ensure that all of the trial related documents have been sent to pharmacy.
Date of Site Initiation Visit (SIV) – This is the date by which we should have everything written and approved by, so that Pharmacy readiness could be issued.
Are the accountability logs supplied by the sponsor, if not, date they were created – this will include drug inventory and patient specific drug accountability logs, if logs are created ensure there is version controlled on each one.
Date IB received – if applicable record the date the Investigator Brochure was received.
Date labels were created – create labels using SOP Pharm/S105.
How will QP/Batch/C of As releases/certificates be sent to site - confirm with the Sponsor the process for receiving QP/Batch releases or any Certificates of Analysis that are required for the IMPs.
Date Trial Summary & Unblinding instructions were completed – the date which they were written.
Date Trial Dispensing instructions were completed – the date which they were written.
Date Trial Drug Management instructions were completed – the date which they were written.
Is a prescription supplied, if not date completed (for Chemocare prescriptions include date requested) – if a prescription is supplied, is it suitable for use (NHS Number, allergy status etc). If we have to get the prescription amended, ask the Sponsor if they can do it as they will then be responsible for version control. If we have to amend this prescription we will have to remove the Sponsor's version control and add our own.

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Has the Pharmacy Site File been set up according to Pharm/F52 – The file should be indexed according to Pharm/F52 and the Sponsor's original index should be filed in the superceded section of the file so that we can archive it in its original order if we are asked to.
Have Pharmacy staff signed the main site delegation log – all pharmacy clinical trials staff should sign the site delegation log (unless specified not to).
Have pharmacy received a copy of the completed site delegation log – The completed delegation log should have all staff signed off by the PI.
Procedure for initial supply of IMPs/nIMPs – pharmacy need to confirm whether IMP will be sent before the greenlight has been given or if the initial supply will be released once the first patient is being screened.
Has the codebreak/unblinding procedure been tested – For blinded studies where pharmacy are expected to unblind, the unblinding process has to be tested and this is recorded on form Pharm/F53 "Code Break Test Form".
Date documents have been reviewed and approved – when the documents have been reviewed by a second person (Pharmacy Clinical Trials Manager or a delegate) and approved by a third person (Principal Pharmacist Clinical Research/Clinical Trials Pharmacist)
Batch(es) of labels printed and approved for use – Once the Master label has been approved batches of labels should be printed and approved then placed in the Pharmacy File.

Once Stage 3 of the Pharmacy Clinical Trial Set Up form has been completed the Pharmacy Clinical Trials Manager/Principal Pharmacist will sign, print and date and attach a copy to the Pharmacy Readiness email (Pharm/T49) and send to the Research Facilitator.

4.4 Pharmacy Green Light

Once the IMPs have been delivered to site and are suitable for use (i.e no temperature excursions occurred during shipping) and all Pharmacy staff training has been done complete stage 4 of the Pharmacy Clinical Trial Set Up form.

Once stage 4 of the Pharmacy Clinical Trial Set Up form has been completed the Pharmacy Clinical Trials Manager/Senior Pharmacy Technician will sign, print and date and attach a copy to the Pharmacy Green Light email (Pharm/T50) and send to the Research Facilitator.

The Research Facilitator will then send an email confirming that recruiting can now start into the trial.

5 Related SOPs and Documents

Appendix A - Pharmacy Clinical Trial Set-Up Guide

Pharm/F14 - Pharmacy Clinical Trial Set Up Form

Pharm/F38 – Clinical Trial Patient Log

Pharm/F39 – Pharmacy Personnel Log

Pharm/T25 – Letter Template Study Set-Up Feasibility

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Pharm/T30 - Letter Template Study Set-Up Review/Authorisation

Pharm/T49 - Letter Template Pharmacy Readiness

Pharm/T50 - Letter Template Pharmacy Green Light

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6 Appendix A

Pharmacy Clinical Trial Set-Up Guide

This set up guide should be used in conjunction with the Setting up a Clinical Trial SOP (Pharm/S45) and the Pharmacy Study Set Up Form (Pharm/F14). This document has been designed to assist members of the Pharmacy Clinical Trials Team when setting up a new clinical trial within Pharmacy.

These are the stages involved when setting up a clinical trial:

- Stage 1 – Feasibility
- Stage 2 – Review and Authorisation
- Stage 3 – Pharmacy Readiness
- Stage 4 – Pharmacy Green Light

Stage 1 – Feasibility

This is often performed when there is an interest in a particular study (often called Expression of Interest) by a Clinician or a Research Nurse. There is normally a limited amount of information regarding the study available, so Pharmacy are assessing whether it is feasible for us to set up this study.

Clinical Trials Manager/Principal Pharmacist Responsibility

1. Upon notification of an expression of interest the Pharmacy Clinical Trials Manager/Principal Pharmacist will set up an electronic folder and transfer any trial documents to this folder.
2. The study will then be added to the Expression of Interest whiteboard which is located in the Clinical Trials office at York and this will be for both sites.
3. The Clinical Trials Manager/Principal Pharmacist will print off the Clinical Trial Set Up Form (Pharm/F14) from the York R&D Website www.northyorksresearch.nhs.uk and complete the trial information on page 1. A member of the Pharmacy Clinical Trials Team will be allocated the responsibility of completing Stage 1 by the Clinical Trials Manager.

Staff Member Allocated Responsibility for Completing Stage 1

1. Complete Stage 1 – Feasibility of the Clinical Trial Set Up Form.
   - **Date of notification of the study and from whom** – the Research Nurse or the Research Facilitator may have notified pharmacy that there has been interest in the study.
   - **Date of Site Selection Visit** – some studies will have a Site Selection Visit (SSV) where the Sponsor will come to site and meet with the Research Team, the PI and Pharmacy. Pharmacy will normally be notified of when this will take place.

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- **Drugs Involved** – this information can be found in the trial summary and the trial protocol (if provided).
- **Who is supplying the IMP/nIMPs** – pharmacy need to obtain the information about where the drugs are being supplied from and if there are any additional costs to factor in.
- **Temperature requirements for the storage of IMPs** – can pharmacy offer storage at the required temperature range and will there be adequate space. Confirmation of the IMP packaging size and the quantities that will be dispatched to site may need to be obtained from the Sponsor.
- **Aseptic involvement** – do any of the drugs need to prepared by the aseptic unit, if so inform them of a possible trial that may be opening.
- **Satellite involvement –** will the prescription be validated by the satellite unit and will there be any dispensing that they will undertake.
- **Number of dispensing episodes per patient –** number of items per visit and the total number of visits. Some trials will have a set number of dispensing visits for other trials this may be unknown as the patient may continue treatment until disease progression.
- **Frequency of dispensing –** how often will pharmacy be expected to dispense medication for a patient.
- **Number of patients expected –** how many patients are the Research Team planning to recruiting into the study.

The above information may not be readily available with the limited documents that have been provided, if this is the case email the Sponsors/Research Team to obtain the information.

Do not invest too much time in the study at this point, as it is not guaranteed that we will be selected to open as a site at this stage.

2. Any printed documents for this study should be placed in a folder (clearly marked with the study title) along with the Pharmacy Clinical Trial Set Up Form (Pharm/F14) in the Pending Studies section in the Clinical Trials Dispensary at York or in the drawer of the filing cabinet marked Pending Studies in the Clinical Trials Room at Scarborough.

3. Once this stage has been completed the form should left in the tray on the Clinical Trials Manager desk marked Study Set Up Forms (for Scarborough studies email a copy of the form).

Clinical Trials Manager/Principal Pharmacist Responsibility

1. The Clinical Trials Manager will sign the bottom of the Stage 1 – Feasibility form and inform the Research Facilitator of the pharmacy feasibility outcome using email template Pharm/T25 attaching a copy of the completed Stage 1 – Feasibility.
2. The Clinical Trials Manager will be notified of the date of the Site Selection Visit (if applicable) and will nominate a member of the Pharmacy Clinical Trials Team to attend (this should be the person who has the responsibility of setting up the study if possible), so that any

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questions or queries can be addressed before we are selected as a site. Some Sponsors may wish to visit Pharmacy during this visit.
3. Amend the Expression of Interest board to indicate that Stage 1 has been completed.

Stage 2 – Review & Authorisation

Stage 2 will commence once the site has been selected by the Sponsor and Pharmacy have been notified by the R&D Facilitator. The R&D Facilitator will send a confirmation email to confirm that pharmacy are to progress with Stage 2.

Clinical Trials Manager Responsibility

1. Once the confirmation has been received to begin Stage 2, allocate a member of the Clinical Trials Team to complete Stage 2 (this should be the same person who completed Stage 1, if possible).
2. The Trial details will be removed from the Expression of Interest whiteboard and added to the pending studies board.

Staff Member Allocated Responsibility for Completing Stage 2

1. Move the study file that is on the x-drive in the Expression of Interest section to the current trial section. As electronic documents are received they will need to be saved in the electronic folder and printed off. The printed documents will be placed in the file and stored in the Pending Trials section in the Clinical Trials dispensary.
2. Complete stage 2 of the Pharmacy Clinical Trial Set Up Form (Pharm/F14).
   - **Date of when site was selected** – this can be found on correspondence confirming that the site has been selected
   - **Any additional drug cost** – if the pharmacy are having to procure any drugs that are not standard of care that the Sponsor is not reimbursing.
   - **Any additional cost to pharmacy** – e.g are we having to provide taxis to transport the drug?
   - **Additional equipment required** – e.g fridges, denward loggers, cool bags
   - **Commercial costing template reviewed and approved** – only applicable to commercial studies, check that dispensing fees, set up fees and maintenance fees and any prescription charges are correct, this will then need to be approved by the Pharmacy Clinical Trials Manager (depending upon the urgency the approval can be done when stage 2 is signed off)
   - **Open-label/single blind/Double-blind** – do Pharmacy have to blind the treatment?
   - **Drug supply after trial completion** - who will fund the study drug after completion of the trial, this may not be applicable to all studies (this can be found in the protocol)

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- **IXRS/IWRS/other web based program to be used by pharmacy, if yes what for?** – will pharmacy acknowledge receipt and/or dispensing via this program
- **Is manual ordering involved –** will pharmacy have to complete order forms and fax/email for initial and further supplies of medication
- **Is pharmacy involved with unblinding –** will pharmacy have to unblind, if so how is it done?
- **Additional Sponsor training required –** are all pharmacy staff expected to complete specific Sponsor training (this could be online training)
- **Estimated date of opening –** confirm with the Research Team and the Research Facilitator the date planned for opening, considering HRA time limits and the date of the Site Initiation Visit (SIV)
- **Aseptic approval –** send a copy of the protocol and pharmacy manual to Aseptics, once approved by Aseptics the form must be signed by a senior member of Aseptics. Aseptics/Satellite will also have to create a Chemocare prescription for any cancer treatment.
- **Trial Monitoring Company –** if different to the Sponsor
- **Details of Trial Monitor or CRA –** name, email and telephone number
- **IMP dispensing requirements –** will pharmacy receive a copy of the randomisation, will pharmacy have to remove tear-off labels at the time of dispensing, what accountability records will need to kept
- **Stability/storage requirements of reconstituted IMP –** after aseptic preparation, or a product that has been reconstituted with water the expiry and storage may differ from the original. Consider if any additional paperwork will be required to maintain the cold chain. For Scarborough trials consider the transportation between sites if the aseptic unit is involved.

3. Once stage 2 Pharmacy Review/Authorisation has been completed place the form in the study set up forms tray on the Pharmacy Clinical Trial Manager's desk (for Scarborough studies email a copy of the form).

Clinical Trials Manager Responsibility

1. The Clinical Trials Manager will sign the bottom of the Stage 2 – Review/Authorisation form and inform the Research Facilitator of the pharmacy Review/Authorisation using email template Pharm/T30 attaching a copy of the completed Stage 2 – Review/Authorisation.
2. Review the Commercial Costing Template, if applicable.
3. Amend the Pending Studies board to indicate that Stage 2 has been completed.

Stage 3 – Pharmacy Readiness

Stage 3 will ensure that all documents that pharmacy require have been received/created and approved, this will need to be done in a timely fashion and any delays will need to be communicated to the Research Facilitator and the Research Team.

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Clinical Trials Manager Responsibility

1. Upon receipt of the Research Facilitators email to commence stage 3 of the Pharmacy Clinical Trial Set Up form, allocate a member of the Clinical Trials Team to complete Stage 3 (this should be the same person who completed Stage 2, if possible).

Staff Member Allocated Responsibility for Completing Stage 3

2. Complete stage 3 of the Pharmacy Clinical Trial Set Up form (Pharm/F14)
   - **Date Pharmacy Site File was requested –** contact the Trial CRA/Monitor and request the Pharmacy Site File, if the file is not available (or not being supplied) ask for all the relevant documents to be sent to pharmacy.
   - **Date Pharmacy Site File was received –** in the event that the Sponsor will not be providing a Pharmacy Site File, ensure that all of the trial related documents have been sent to pharmacy – this will include Pharmacy Manual, IXRS Manual, Investigator Brochure(s).
   - **Date of Site Initiation Visit (SIV) –** this is the date that we should have everything written and approved by, so that Pharmacy readiness could be issued.
   - **Are the accountability logs supplied by the Sponsor, if not,date they were created –** this will include drug inventory and patient specific drug accountability logs, if logs are created ensure there is version control on each log.
   - **Date IB received –** if applicable record the date the Investigator Brochure was received.
   - **Date labels were created –** create labels using SOP Pharm/S105.
   - **How will QP/Batch/C of As releases/certificates be sent to site –** confirm with the Sponsor the process for receiving QP/Batch releases or any Certificates of Analysis that are required for the IMPs. In some circumstances these may be held by the Sponsor and will require a File Note in the Pharmacy Site File.
   - **Date Trial Summary & Unblinding Instructions were completed –** the date which they were written.
   - **Date Trial Dispensing Instructions were completed –** the date which they were written
   - **Date Drug Management Instructions were completed –** the date which they were written
   - **Is a prescription supplied, if not, the date completed (for Chemocare prescriptions include the date requested) –** if a prescription is supplied, is it suitable for use (NHS Number, Allergy Status etc). if the prescription needs to be amended, ask the Sponsor if they can do it as they will then be responsible for version control. If we have to amend the prescription we will have to remove the Sponsor's version control and add our own (to include the author, approver, date and version), under no circumstances do documents have 2 version control.
   - **Has the Pharmacy Site File been set up according to Pharm/F52 –** the file should be indexed according to Pharm/F52 and the Sponsor's original index should be filed in the superceded

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section of the file so that we can archive it in its original index if we are asked to.

- **Have Pharmacy staff signed the main site delegation log –** all pharmacy clinical trials staff should sign the site delegation (unless specified not to)
- **Have Pharmacy received a copy of the completed site delegation log –** the completed delegation log should have all staff signed off by the PI.
- **Procedure for initial supply of IMPs/nIMPs –** pharmacy need to confirm whether IMP will be released to site before greenlight has been given or if the initial supply will be released once the first patient is being screened.
- **Has the codebreak/unblinding procedure been tested –** for blinded studies where pharmacy are expected to unblind, the unblinding process has to be tested and this is recorded on form Pharm/F53 "Code Break Test Form"
- **Date documents have been reviewed and approved –** when the documents have been reviewed by a second person (Senior Pharmacy Technician/Pharmacy Clinical Trials Manager) and approved by a third person (Principal Pharmacist Clinical Research)
- **Batch(es) of labels printed and approved for use –** once the Master label has been approved, batches of labels should be printed and approved then placed in Pharmacy Site File.

3. Complete any file notes for the Pharmacy Site File (such as location of temperature graphs, staff CVs and GCP etc)
4. Once Stage 3 of the Pharmacy Clinical Trial Set Up form has been completed place the form in the study set up forms tray on the Pharmacy Clinical Trial Manager's desk (for Scarborough studies email a copy of the form).

Clinical Trials Manager Responsibility

1. The Clinical Trials Manager will sign the bottom of the Stage 3 – Pharmacy Readiness form and inform the Research Facilitator of the Pharmacy Readiness using email template Pharm/T49 attaching a copy of the completed Stage 3 – Pharmacy Readiness.
2. Amend the Pending Studies board to indicate that Stage 3 has been completed.

Stage 4 – Pharmacy Green Light

Stage 4 is to confirm that everything is in place for the clinical trial to start recruiting.

Clinical Trials Manager Responsibility

1. Upon receipt of the Research Facilitators email to commence stage 4 of the Pharmacy Clinical Trial Set Up form, allocate a member of the Clinical Trials Team to complete Stage 4 (this should be the same person who completed Stage 3, if possible).

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Staff Member Allocated Responsibility of Completing Stage 4

1. Complete stage 4 of the Pharmacy Clinical Trial Set Up form (Pharm/F14)
    - **Initial supply of IMPs/nIMPs received –** this only applicable if shipment of drugs is due prior to opening.
    - **Date initial supply received –** record the date the drugs were received or removed from quarantine (some IMPs need to be put in to quarantine until the Sponsor can review the temperature during transit).
    - **Date pharmacy training completed –** all members of the pharmacy clinical trials team will need to have read the trial instructions and sign the training log.
2. Once stage 4 of the Pharmacy Clinical Trial Set Up form has been completed place the form in the study set up forms tray on the Pharmacy Clinical Trial Manager's desk (for Scarborough studies email a copy of the form).

Clinical Trials Manager Responsibility

1. The Clinical Trials Manager will sign the bottom of the Stage 4 – Pharmacy Green Light form and inform the Research Facilitator of the Pharmacy Green Light using email template Pharm/T50 attaching a copy of the completed Stage 4 – Pharmacy Green Light.
2. Amend the Pending Studies board to indicate that Stage 4 has been completed.
3. Once confirmation that recruitment can start from the Research Facilitator has been received, delete the trial details from the pending study board.

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