

**Hub and Spoke Best Practice Framework**

**This has been adapted with permission, from a checklist developed by**

**NIHR Clinical Research Network: East of England.**

This framework is not finite but will provide a solid base for best practice working for a hub and spoke model of research delivery

1. **Indemnity**

* Hub practice ensures all indemnity arrangements are in place for hub GPs and hub nurses, health care assistants and any other relevant staff, to see patients from spoke practice for research study visits.
* Hub practice receives confirmation from participating Spoke practices that their Defence Organisation has been informed that patients from their practice will be seen by hub practice/staff for research visits, prior to any study specific work being undertaken at spoke practice.

1. **Public liability**

* Hub practice checks public liability insurance cover for Spoke practice patients attending for practice visits (Practice to assure itself as to whether this is covered in its standard public liability insurance or a separate application needs to be made)

1. **Responsibilities**

***Patient care***

* The hub practice clinicians or visiting research nurses or researchers, will carry out all study research visits at the hub practice.
* The patient will be seen at the hub practice for all research activities.
* The hub practice will be responsible for all research related care and follow up. Usual care will continue to be with the spoke GP.
* The hub GP will inform the spoke GP as soon as possible if any other medical condition is picked up during the course of the trial.
* The spoke GP will inform the hub GP of any adverse events related to the research in a timely manner.
* The hub GP will write to the spoke GP at the end of the study advising any ‘sign off’ prescribing / recommendations for individual patients.

***Named contacts***

* The hub practice will identify a named GP lead as Research Lead/Principal Investigator
* The hub practice will identify a named deputy to deal with any urgent problems when the lead is away or a mechanism to ensure prompt communication

* Each spoke practice will identify a named practice lead who will act as the contact for research
* Each spoke practice will identify a named deputy to deal with any urgent problems when the lead is away or a mechanism to ensure prompt communication

***Contractual arrangements***

* The Sponsor will agree contracts or agreements with the hub practice. The Sponsor will not have a contractual arrangement with spoke practices. The hub will manage all contractual arrangements with the spoke practices and ensure that the Sponsor is aware that the hub and spoke model will be used. It is the hub practice’s responsibility to ensure the financial agreements with the Sponsor cover all aspects of the work including spoke practice research activities.
* The hub and spoke practices will agree and document the level of reimbursement to each practice for undertaking the work on a study by study basis. Reimbursements for spoke postage costs for mail-outs will be agreed and documented.
  + It will be agreed whether the spoke practices will invoice the hub practice or the Sponsor for the research costs. Where the spoke practices are invoicing the hub practice, it is important to ensure good administration and prompt payment of spoke invoices for continued support from spoke practices.
  + Where practices can claim service support funding from the NIHR Clinical Research Network, the hub practice will need to ensure the spoke practices have the necessary information to invoice for this funding

***Capacity***

* The hub practice has a nominated Principal Investigator (PI), and lead nurse for each study. Some studies may also require a sub-investigator for holiday or additional cover. The PI must be willing and able to take on all PI responsibilities for the study running at their practice site. Research clinicians will require protected time for conducting the study. Some studies may also provide an opportunity for Healthcare Assistants or other staff to be involved.
* The hub practice must have arrangements in place for patients contacting the practice (by phone or face to face) about research studies they have been invited to take part in or are taking part in.

***Safety***

* The hub practice will need to ensure there is a robust system in place for out of hours if they are hosting a blinded Clinical Trial of an Investigational Medicinal Product (CTIMP).
* The hub practice will need to ensure there is a robust system in place for reporting Serious Adverse Events (SAEs) between the spoke practices, the hub practice and all required agencies.

***Pharmacy***

* The hub practice will need to ensure robust arrangements for storage, monitoring, prescribing and issuing of study drug or intervention are in place.

***Monitoring***

* If requested/appropriate, the hub practice will have a responsibility to allow space and access for Sponsor monitors or local NHS R&D audit teams at the hub site.

1. **Expressions of Interest to participate in research studies**

* Hub practice will receive notifications of new studies from Clinical Research Network. Hub practice will make an initial decision of interest based on criteria e.g. population group being sought, viability for study to run in primary care, equipment, capacity.
* Hub practice will run feasibility at their own practice in 1st instance.
* Hub practice will engage spoke practices regarding feasibility via pre-established spoke contacts. Spoke contacts will respond within a reasonable timeframe to be agreed with the Hub practice.
* If any of the spoke practice contacts are on leave/away, the hub can send in their own and any other spoke practice numbers to express interest in a study.
* Spoke practices can decide on a study by study basis whether it is feasible for the practice to participate although spoke practices are encouraged to take part in all studies offered through the hub and spoke model.
* Hub practice will complete Expression of Interest for study and based on the feasibility obtained from spoke practices by the required deadline.
* Any issues about placement of study in Primary care will be fed back from the hub practice to the NIHR CRN Clinical Studies Development Officer.

1. **Training**

* Hub practices will have a nominated Principal Investigator (PI), and lead nurse for each study. Some studies may also require a sub-investigator for holiday/ additional cover. Some studies may also provide an opportunity for Healthcare Assistants or other staff to be involved.
* The hub practice Lead Research GP and other Hub practice staff involved in research, will have undertaken the National Institute for Health Research (NIHR) Good Clinical Practice (GCP) in research training and update every 2 years as a minimum (this is free to staff engaging on NIHR adopted studies).
* Any additional study training required at the hub practice e.g. paediatric consent, must be reported back to the CRN Clinical Studies Development Officer prior to Expressions of interest being submitted so CRN can identify training needs and source if required/able.
* For most studies, Sponsors are likely to require face-to-face study specific training with all those clinicians and staff at the hub practice, involved in the study. This may include training on particular aspects of the study such as treatments or equipment. Time will have to be allowed at the hub practice for this.

1. **Equipment and storage**

* The hub practice should ensure that records of any practice equipment e.g. blood pressure monitors, weighing scales, that require maintenance and calibration (if appropriate) are maintained at the hub practice. Sponsors may request this information.
* Any specialist equipment specific to the study should be negotiated by the hub practice and Sponsor in the 1st instance e.g. centrifuge, refrigeration.
* The hub practice should make provision for the storage of equipment, any investigational medicinal product, study site files etc at the practice. The hub practice should ensure they are aware of archiving arrangements with the Sponsor.
* Specimen transport arrangements may need to be considered for some studies.

**7 Study specific patient information**

***Pre-approvals stage***

* The hub practice must liaise with the study Sponsor to ensure all participant documentation makes appropriate reference to the Hub & Spoke model for the study: i.e. that patients will be seen at hub practice by GP and nurse for research study visits only and makes clear that the participant will see their own GP for regular care (all non-research study care).
* All contact details on GP invite letters for the study will direct patient enquiries to the nominated contact at the hub practice.

***Patient travel arrangements***

* Patients must be informed about travel arrangements to the hub practice for the study visits. This must be covered in the Patient Invitation Sheet.
* Patients may be able to claim appropriate travel expenses for study visits as agreed by the study Sponsor. The rates should reflect additional distance to Hub practice from the patient’s home. If patient travel is not being reimbursed, patients will need to be made aware of this.
* The hub practice will need a mechanism within the practice for reimbursing patient travel expenses for research visits; this may be per mile by car or for bus fares (agreed with Sponsor). It is recommended a template is developed for patient expenses claims. Records will need to be kept for patient travel expenses for the hub research accounts to ensure sufficient travel funds have been provided by the Sponsor.

1. **Health Research Authority approval**

* The hub practice must ensure that Health Research Authority (HRA) approval is in place before ANY patient is approached at hub or spoke practices, regarding the study. The hub practice must ensure it has all current approved documentation.
* Hub practice must contact spoke practices with all study approved documentation & approval letters as listed
* Health Research Authority approval letter
* GP invitation letter with patient return slip
* Full patient information sheet/consent form
* Short version Patient Information Sheet
* Any additional leaflets/brochures to be included as per Sponsor requirements

**9 Approach to patients**

* Following HRA approval, hub practice will run searches to identify appropriate patients at their own practice for approach
* The hub practice will liaise with spoke practices re timings of mail-outs according to recruitment deadlines and targets, hub practice capacity and numbers expected.
* The hub practice considers the number, type of recruitment and capacity for 1st patient visits for the study with regards to whether all invitation letters (from hub and spoke practices) are sent together or are staggered. Timings of mail outs will be agreed.
* At agreed time points, hub practice will contact spoke practices and ask for searches to be run, sending full approved inclusion/exclusion criteria.
* Hub and spoke practices mail out to the pre-prepared identified patients according to the agreed schedule.
* If a practice list is more than 3 weeks old, a check must be made that there have been no deaths prior to mailing. All patient lists must be checked by appropriate clinician and retained in secure shared drive with reasons for removal if deemed ‘inappropriate’ for mail out.
* Spoke practices feedback the number of patients for approach to the hub practice following clinician list check.
* Hub practice maintains record of mail-out dates and number of patients sent a letter mailed from hub and all spoke practices.
* Patients will be contacted by the hub practice following receipt of patient’s expression of interest / consent to be contacted to arrange an appointment for 1st visit consent and screening at the hub practice.
* Spoke practices will be informed by the hub practice which patients have consented to take part in each study. This should be via a specific nhs.net account

1. **Safety reporting**

* All patients consented and randomised to the study are given the emergency contact number for the hub practice and advised on reporting of the study specific Serious Adverse Events (SAE).This will be as required on a per study basis.
* The spoke GP will inform the hub GP of any adverse events related to the research in a timely manner.
* The spoke practices will have a process in place for informing the hub practice of hospital admissions and deaths of patients who have consented to take part in studies. This should be via a specific nhs.net account or telephone number that is accessed daily by the hub practice research team.
* Any requests for patient identifiable scanned documents from the spoke practice should be carried out via nhs.net account and only with written patient consent.
* The hub practice will report SAEs as per GCP, protocol and local requirements.

**11 Information sharing**

* The hub practice will update the spoke GP by letter of their patients’ progress through the trial. The timing of this will usually depend on the length of the trial.
* Information between practices must take place via nhs.net account or if Systm1 practices via shared access set up, or other communications that comply with other specific information governance requirements (e.g. encryption).
* No patient identifiable data may be transferred between hub and spoke practices without evidence of written patient consent.
* The spoke practice can contact the hub practice at any point if they need information or have concerns re condition of patient. The hub practice will contact the spoke practice if any new medical diagnosis or conditions occur during the course of the study. The patient will be informed that all their normal care i.e. not research related, will always be at their own practice.
* The hub GP will write to the spoke GP at the end of the study advising any ‘sign off’ prescribing/ recommendations for individual patients.

**APPENDIX A**

**SIGNATURE SHEET**

**HUB PRACTICE**

Name of Hub Practice

Name of Lead GP for Research at Hub Practice

Signature of Lead GP at Hub Practice

**FOR EACH SPOKE PRACTICE**

Name of Spoke Practice

Named Practice Lead for Research at Practice

Signature of Practice Lead for Research