

Checklist for Research in Primary Care

Name of study:

Name of Chief Investigator:

Who is responsible for the study conduct overall?

Name of Principal Investigator:

Who is responsible for the study conduct at your site?

Name(s) of staff at practice involved in the study:

Practice staff who will be involved need to have research CVs stored in the study site file

Start Date:

End Date:

Please tick when seen and authorised:

HRA Approval Letter

Ensure this is the approval letter, rather than the initial assessment letter

REC Favourable Opinion Letter (if required)

This is required for any studies involving patients

R&D email advisory on Capability and Capacity

This indicates that the R&D team have had sight of the local documents

Letter(s) of Access

There should be one letter of access for each individual who is accessing your site to undertake research activity

Local information pack, containing:

NB this replaces the Statement of Activities from 5th June 2019

- Covering email
- Organisation information document
- Schedule of Events or Schedule of Events Cost Attribution Template
- Delegation log (may be finalised at the site initiation visit)
- Supporting documents to be used in the study

Sites will each need to negotiate and finalise/localise the organisation information document in discussion with the Sponsor.

Site agreement

This should be either the local information pack or a model agreement

Where there has been a change/update to the study:

- HRA Amendment Approval Letter/Acknowledgement

All amendments should be notified to sites during the study