

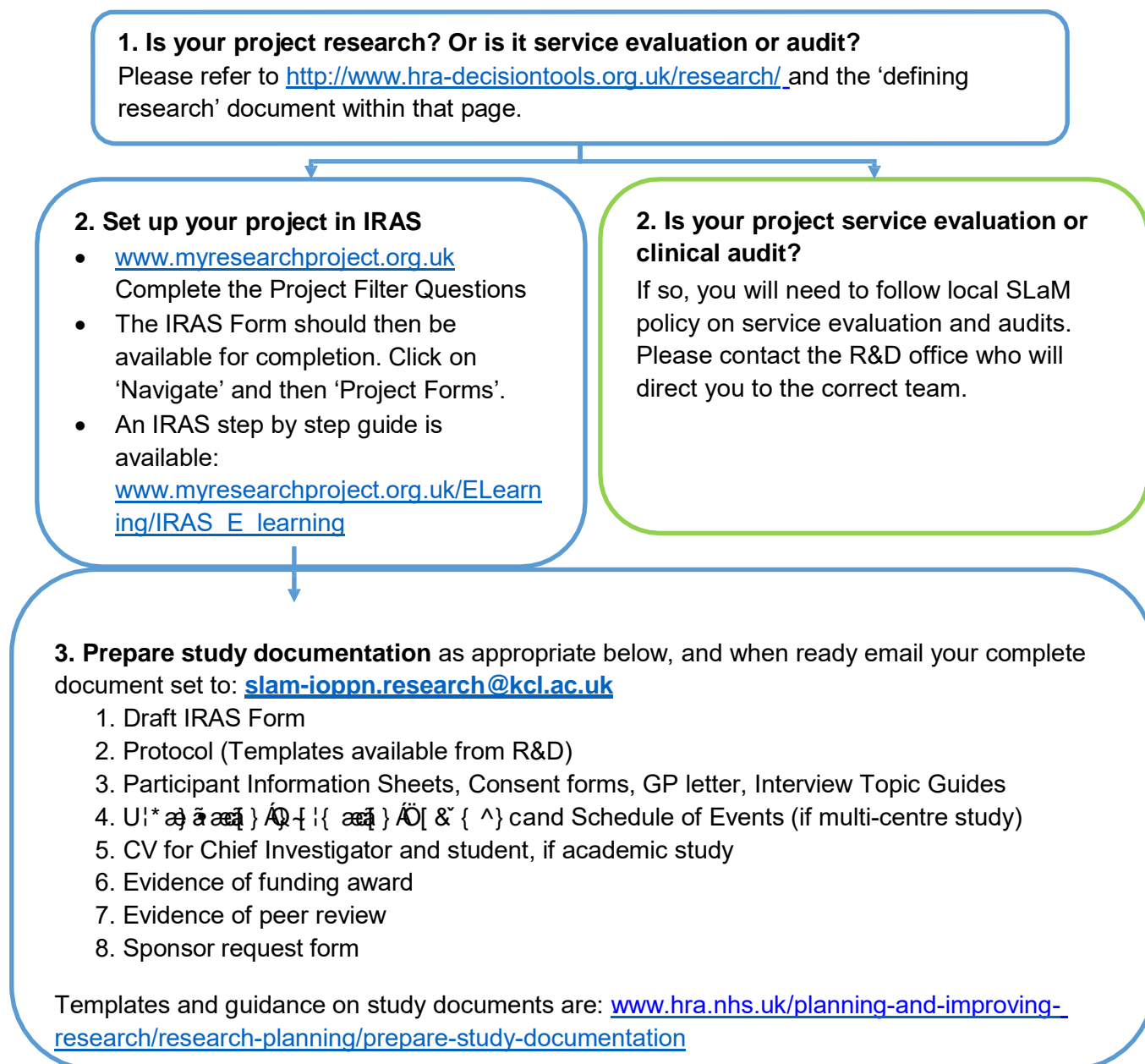
Quick guide: Setting up a clinical research study

If you are leading the research and you are employed by South London and Maudsley NHS FT (SLaM) or Institute of Psychiatry, Psychology & Neuroscience, IoPPN, King's College London:

It is likely that KCL and/or SLaM will be the **Sponsor** for your research. A Sponsor is the institution that takes on responsibility for initiation, management and financing (or arranging the financing) of the research. The Sponsor is usually the employing organisation of the Chief Investigator. **All research in the UK must have a sponsor confirmed prior to assessment by the Health Research Authority (HRA).**

For SLaM and/or KCL to take on the role of Sponsor, you are required to submit your full study documentation for sponsorship review to slam-ioppn.research@kcl.ac.uk **before** you can proceed to electronic HRA submission via IRAS. This is to sign off your application; to ensure that your research is designed and set up in line with all applicable research governance requirements; and to guide you through submission to the relevant regulatory bodies. Please note that confirmation of sponsorship is not approval to start your research, but is the first stage towards obtaining all the approvals you will need.

Please follow the flow chart below.



4. R&D sponsorship review

R&D will conduct an initial review of your documentation and may request further clarification. This is then sent via email to the study CI. Depending on your project, we may need to put some contracts in place. Once any required contracts are in place and clarifications/revisions have been actioned, **sponsorship approval** is issued and we will guide you on how to apply to the Health Research Authority.

5. HRA Submission

Once all authorisations are in place (under IRAS 'authorisation tab') check all your latest documentation is uploaded to the 'IRAS checklist'. Please note that any changes made after authorisations are given will invalidate the application. Proceed to the 'e-submission' tab in IRAS which explains how to complete the submission.

What is HRA Approval?

HRA Approval is the national approvals process for all **project-based research in the NHS led from England**.

HRA Approval brings together the assessment of governance and legal compliance, with the independent REC opinion provided by the UK research ethics service, so you only need to submit one application.

6. Confirmation of Capacity and Capability

Your assigned R&D governance officer will ensure that HRA approval is in place along with all other applicable regulatory approvals. In addition they will also conduct all the appropriate local checks to be able to confirm that SLaM NHS FT has the capacity and capability to host your research.

If your research is led by an external organisation but you would like to run the study at SLaM:

Please send through the document pack from the lead organisation to slam-ioppn.research@kcl.ac.uk. R&D will check that SLaM has capacity and capability to host the study. R&D will issue an e-mail to confirm 'Capacity and Capability' for you to start your research. If your research is led by a commercial company, please e-mail the study documentation to KHPCTO@kcl.ac.uk.