

Student Research Supplement v2 September 2015

This supplement must be read in conjunction with the document, "A Guide for Researchers"

This supplement is for SGUL students as well as those students from the Faculty of Health, Social Care and Education (FHSCE)

This supplement covers three key areas; Sponsorship, Ethics and Trust Approval. **You should read the entire document and understand what is required of you before you begin.** If in doubt, please contact the JREO.

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****For a full list of acronyms and explanations please see pages 5 – 8 of the main Handbook****

Sponsorship

Documents

The JREO needs all the documents that you plan to submit to NRES ethics. You should use the protocol templates available on the JREO website.

<https://portal.sgul.ac.uk/research/research-office/research-office-home> (Governance Template documents and logs zip file)

This link also has the JREO's standard operating procedures. (See page 24 of A Guide for Researchers).

This zip file also contains template information sheets, consent forms etc. so it is recommended you use them as they are structured to what ethics committees expect to see.

The document set needed depends on what type of study you are planning to conduct. If using IRAS, there is a checklist which will give you an idea of what is needed. While this guide cannot give every possible document set, as a general rule, the minimum we would expect to see:

- Protocol
- IRAS form
- Participant/patient information sheet
- Consent form

All documents submitted must have a version and date. You must submit each form and supporting document as separate files so that they can be assessed and edited individually.

NOTE: IF YOU ARE ONLY CONDUCTING RESEARCH ON NHS STAFF, you will still need to complete the IRAS form to obtain SGUL sponsorship but it will be a shortened version as you do not need to tick the box for NHS ethics. Only tick the R&D approval box in this instance.

Applications to the Faculty of Health, Social Care & Education Research Ethics Committee (FREC)

We do not need to see your FREC application form if you are part of the FHSCE. Please note that you will need to use one of our suggested templates for use as a protocol for an NHS REC committee or an NHS R&D office.

Insurance Statement

Where the protocol and template documents such as the participant information sheet asks you to remove either references to St George's, University of London or St George's Healthcare NHS Trust, you should always remove the reference to the Trust as it is the University that will Sponsor and insure your study.

How do I use IRAS?

We recommend you do the online training before attempting the IRAS form.

http://myresearchproject.org.uk/ELearning/IRAS_E_learning.htm

Timelines

We aim to complete the initial review within 5 working days upon receipt of all of the documents. How long it then takes to be allowed to submit to ethics or R&D depends on how quickly you respond to the requested changes.



What is the difference between the Chief Investigator and Principal Investigator?

The Chief Investigator is responsible for the overall study. There will then be a principal investigator at each site participating in the study. If the study is a single site, the Chief Investigator will also be the principal investigator.

Am I allowed to be the Chief Investigator?

St George's policy is that no student is allowed to be the Chief Investigator of a Clinical Trial of an Investigational Medicinal Product (CTIMP).

Otherwise PhD students are expected to act as Chief Investigators (unless a CTIMP)

Below a PhD level, students are allowed to act as Chief Investigator depending on their level of experience and qualifications if the study is Sponsored by St George's. This may differ from Trust to Trust so you should ensure that you check with the R&D department of the Trust that you intend to conduct the research at.

Who Do I Need to Send my Application to?

Joint Faculty students should send their application to Research Governance Officer 1 (see contacts insert).

For pure SGUL degrees, the student should send their application to the Research Governance Officer assigned to the Chief Investigator's division (see contacts insert)

How do I submit my application to the JREO?

All the documents should be sent as attachments via email to your Research Governance Officer. We do not need you to give us hard copies. We do not need to see your FREC application.

Ethics

National Research Ethics Service (NRES)

You **will** need to get approval from NRES if you are involving NHS patients.

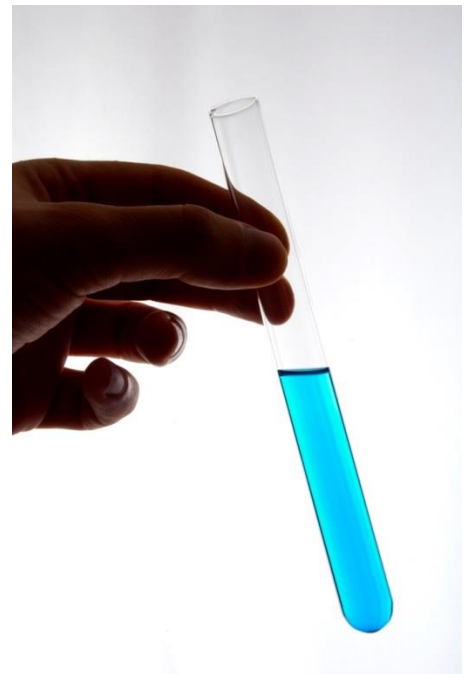
Research involving patient records only, is a slightly grey area and whether you need to obtain ethical approval depends on, amongst other things whether you are part of the normal care team, what the data is and whether you are doing a retrospective or a prospective study. For these types of studies, we recommend you to contact the Clinical Research Governance Manager (see contacts insert) **before** you start your paperwork.

If you are a FHSCE student, you **will** need to notify the Faculty Research Ethics Committee (FREC) once you have received NRES approval (please see page 5 for further information).

If your study involves NHS staff only, you **do not** need to obtain ethical approval from NRES, but you will need to obtain R&D approval. If you are a FHSCE student, then you **will** also need to obtain FREC approval.

If your project involves online surveys or questionnaires, please contact the Clinical Research Governance Manager (see contacts insert) **before** you start your paperwork.

If you are unsure as to whether your study requires NHS ethical approval, visit <http://hra-decisiontools.org.uk/ethics/>



Faculty of Health, Social Care and Education Research Ethics Committee (FREC)

The Faculty Research Ethics Committee (FREC) receives proposals from Faculty staff and students (including those on KU and SGUL courses) concerning research involving human subjects, this includes proposals that have received ethical approval elsewhere from a known source of competence (e.g. National Research Ethics Service [NRES]).

If a Faculty staff member or post-graduate student has received ethical approval elsewhere from a known source of competence (e.g. NRES) the FREC will not provide secondary scrutiny of the proposal. However the committee **will** need to see the following: all documentation submitted to the approving body, a formal approval letter and RE4 application form with the relevant sections completed. The approval will then be noted at the next available committee meeting.

When proposals are not receiving scrutiny from another source of known competence (e.g. National Research Ethics Service [NRES]), the FREC's function is to scrutinise these proposals to ensure they reach current ethical standards.

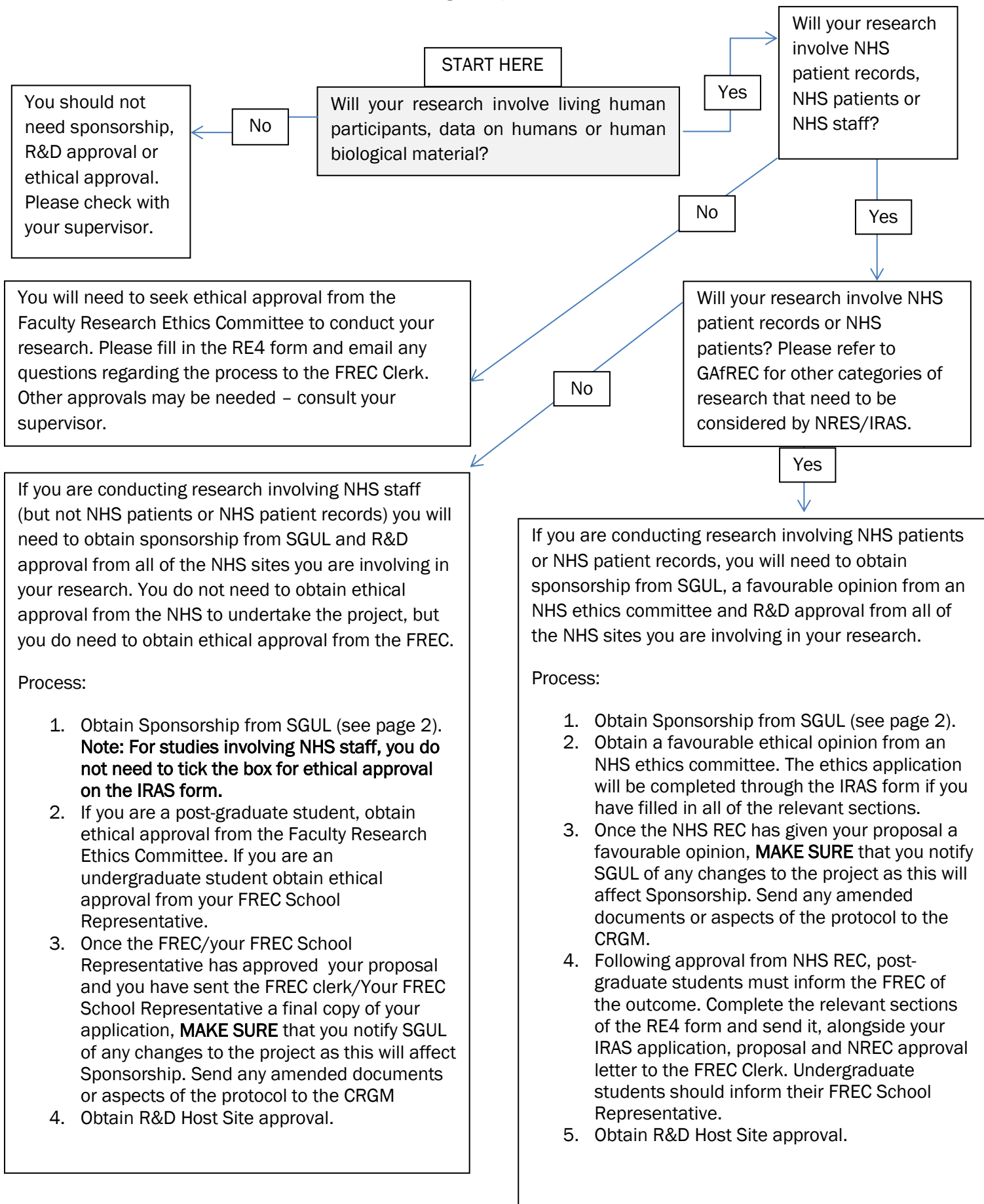
Faculty undergraduate students should submit their research proposals to their Research Supervisor in the first instance and then to the FREC School/Centre Representative for ethical approval. The FREC School/Centre Representative should refer the application onto FREC if s/he has any concern about ethical aspects of the research. Supervisors will provide advice to students regarding the process for ethical approval of undergraduate proposals.

If you are unsure of whether your application should be submitted to the FREC please discuss this with your Supervisor in the first instance. They may refer your application onto the FREC School Representative. If after doing so you require further clarification, please contact the FREC clerk for assistance (see contacts insert). Please see the flowchart on the next page for the process of applying.

Faculty of Health Social Care and Education Students - Research Governance

Application Process

There are a number of governance approvals that are required before conducting any type of research. The process may change depending of the content of a research project but this chart should help to guide you through the process.



FREC Applications

You need to submit your application to FREC before the deadline, which is approximately two weeks before the monthly meeting at 9am (this date changes monthly).

Your proposal and all the relevant supporting documents should be submitted to the FREC clerk in one MS Word (or pdf) document. Along with the electronic version you must also submit a paper version that has been hand-signed and dated by the applicant, any co-applicants and your Supervisor (see contacts insert for address and contact details of the FREC clerk).

Ensure that the pages of your application are numbered consistently throughout.

Email or telephone the Clerk with any queries regarding FREC applications (see contacts insert)

Timelines

NHS REC – Depends on the date the applicant is given for ethical review. Allow 2-3 months for this.

FREC – There is one scheduled meeting per month (except in August) and the deadline is approximately 2 weeks prior to the meeting date. Please ask your Supervisor for the FREC submission/ meeting dates. Comments and ethical opinions are usually relayed to the student within 2 weeks of the meeting date. If the application only needs minor changes, your application will be dealt with via email with the Chair. Please note that most applications require some form of amendment before approval can be granted. .

Documents Submission

IRAS – you submit your supporting documents on IRAS.

FREC - email the electronic version of application to the FREC Clerk and submit a paper version that has been hand-signed and dated by the applicant, any co-applicants and your Supervisor(s) (see contacts insert for address and contact details of the FREC clerk).

Trust Approval

If the study is happening at St Georges Healthcare NHS Trust (SGHT)

See Section Three of “A Guide for Researchers” (Starts on page 29).

If the study is happening at another Trust.

You should contact that Trust’s R&D office as soon as possible to discuss your study and to find out what is needed. As a general rule, it is all documents that are or will be approved by ethics and then a Site Specific Information (SSI) form.

It is important to contact them as soon as possible as they may have additional processes or paperwork or committees etc. that you will need to complete before they will accept your study.

If you are conducting the study at another site and it is R&D approval only that is needed – you should contact that Trust R & D department as soon as possible to find out what their requirements are in terms of paperwork.

Timelines

For studies seeking approval to open at SGHT, we aim to approve the study in 15 days from receipt of all of the documents.

Documents

The documents needed for Trust approval are all those documents approved by NRES if the study went to ethics. In addition, a Site Specific Information (SSI) form needs to be generated for each NHS organisation that you intend to run the study at.

If the study needs R&D approval only, not ethics – you will need to submit all the documents approved by the JREO.

If the study is Sponsored by St Georges University of London and is happening at the SGHT – then Sponsorship and Host site approval is normally granted at the same time.



What is the difference between an NHS SSI form and a non NHS SSI form?

An NHS SSI form needs to be completed for each NHS organisation involved in the study. It is submitted to that Trust's R&D office.

A non NHS SSI form needs to be completed when the study has a site outside the NHS e.g. a private hospital, University or a nursing home. This form needs to be submitted **with** your ethics application to an NHS REC.