Information for REC and R&D applicants

Transfer of Site-Specific Assessment for NHS sites

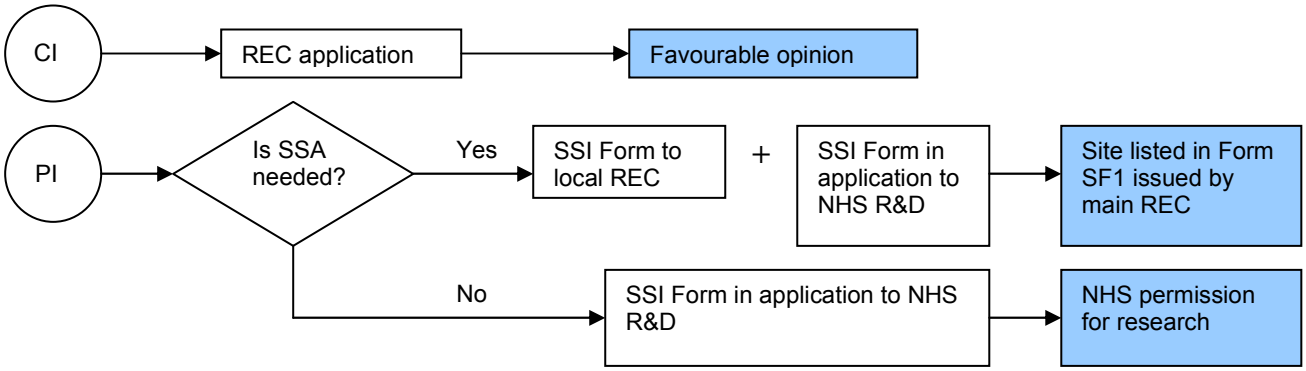
25 March 2009

From 1 April there will be no need to submit SSI Forms to RECs for Site-Specific Assessment (SSA) for NHS sites. As part of the streamlining of unnecessary bureaucracy relating to study approvals, the assessment of site-specific issues will no longer be duplicated by both the REC and the R&D office.

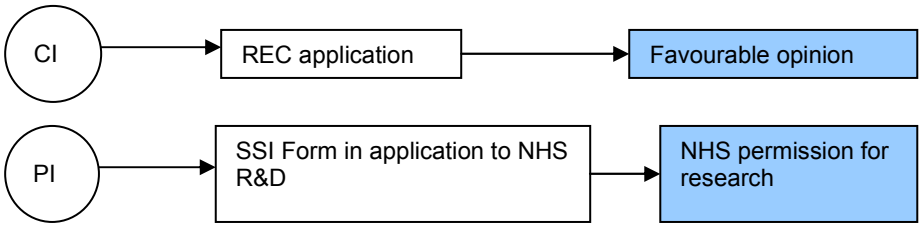
There are no significant changes to the arrangements for SSA for **non-NHS sites**. Where SSAs are required, these will continue to be undertaken by SSA RECs (either a NHS REC or a designated non-NHS REC in the case of a Phase 1 trial site). Approval for sites will be given in a letter from the main REC to the CI copied to the sponsor. Form SF1 will no longer be used to maintain a complete list of approved sites.

The remainder of this bulletin deals with changes to procedures for studies involving **NHS sites**. The arrangements apply to NHS organisations across the UK including HSC services in Northern Ireland.

Before 1 April 2009



After 1 April 2009



There is no change to the process for NHS R&D review as a result of the transfer of SSA. R&D offices already consider the issues relevant to SSA, as appropriate, in the R&D review.

As a result of these changes the NRES form system will be closed to new applications from 1 April.

Users with unlocked forms will be able to complete their forms and submit them up until 1 September 2009. It will also be possible to generate and submit new SSI Forms for ongoing studies until this date.

Access to data held within the NRES on-line form system will continue after 1 September 2009 but it will no longer be possible to make applications. New functionality will be added to IRAS prior to 1 September 2009 to allow users to create a minimal dataset for older studies where the original application was made using

the NRES on-line form and to enable SSI Forms, Notices of Amendment and ARSAC forms to be generated for those studies where necessary.

If you are setting up a new study

Whether or not your study would have previously required SSA, for all NHS sites you will only need to apply for R&D review and you will not need to make separate applications to RECs for SSA.

1. The Chief Investigator (CI) will apply as usual to the main REC using the Integrated Research Application System (IRAS) at www.myresearchproject.org.uk.
2. Each Principal Investigator (PI) will apply as usual for R&D review using the R&D Form and SSI Form. Applications to R&D offices should be made in parallel to review by the main REC.
3. Following satisfactory review, the main REC will issue a letter of favourable opinion. It will state that the favourable opinion is conditional upon obtaining management permission for research (known as R&D approval) from the relevant NHS host organisations prior to the start of the study at each site.
4. Principal Investigators should provide each R&D office with a copy of the REC letter of favourable opinion.
5. Each NHS organisation will issue a letter of permission following the appropriate R&D review
6. When the sponsor is satisfied that a favourable opinion from the main REC and NHS permission from a site have been issued, the study may begin at that site.
7. The sponsor does not need to confirm receipt of the NHS management permission back to the main REC.

If you are adding new sites to an existing study with REC approval

If you created your applications for REC and R&D review in the NRES form system, you will be able to access your application to create new SSI Forms until 1 September 2009. Chief Investigators who prepared applications in IRAS should create SSI Forms by clicking on the “Add SSI” tab visible when either the REC or R&D Form is selected. SSI Forms should then be transferred to Principal Investigators for completion and submission.

Depending on when your study was reviewed, the letter of favourable opinion from the REC may or may not include a statement that the favourable opinion is conditional upon obtaining management permission for research. Whether or not your letter contains this statement, there is no need to apply separately for SSA as the new arrangements apply retrospectively for all studies.

1. Principal Investigators (PI) for new sites will apply as usual for R&D review, following the instructions in either IRAS or the NRES form system, as appropriate. A copy of the REC letter of favourable opinion should be included in the application.
2. Each NHS organisation will issue a letter of permission following the appropriate R&D review.
3. When the sponsor is satisfied that NHS permission from a site has been issued, the study may begin at that site.
4. The sponsor does not need to confirm receipt of the NHS management permission back to the main REC.

For Clinical Trials of Investigational Medicinal Products (CTIMPs) only, if the site or the investigator was not listed in the original REC and MHRA applications, a notice of substantial amendment should be provided to the MHRA and the main REC with the details of the new site and investigator, for information, in order to comply with the Clinical Trials Regulations. The main REC will acknowledge receipt and confirm that the new site has a favourable opinion on condition that NHS management permission is obtained.

For other studies, addition of a new NHS site does not require notification either to the main REC or the local REC.

What about SSA-exempt studies or sites?

There will no longer be a need for researchers or RECs to decide whether a study or a site requires SSA. All studies require applications for R&D review for each NHS research site. Studies that would previously have been regarded as “SSA-exempt” have always required NHS R&D review, and will continue to do so. NHS R&D review already considers the issues that are appropriate to a particular study at that site.

Where can I get more information?

Please contact your REC or R&D office if you need any further clarification on the new arrangements.