

New Arrangements for Site-Specific Assessment of Research Projects from 1st April 2009

From 1 April 2009, Site Specific Assessment (SSA) for research involving NHS sites, has transferred from being an Research Ethics Committee (REC) responsibility to a R&D office responsibility.

1. What does this mean?

1. You no longer have to submit the Site-Specific Information (SSI) form to South Manchester REC.
2. Whereas previously a Principal Investigator (PI) would have to submit a SSI form to the REC (via the R&D Directorate), SSA is now integrated into the research governance review process. The favourable opinion from the main REC is given on condition that permission to conduct the research is granted by the R&D office. Neither the main REC, nor the local REC, will review site-specific issues.
3. There is no requirement for the outcome of the SSA or the final decision on R&D approval to be notified to the main REC by the R&D office, or for the main REC to confirm ethical approval for each site.

2. What do I need to submit to a REC?

- If you are the Chief Investigator (CI) then you will need to submit the NHS REC form from IRAS (parts A & B of NRES form) to the main REC, together with accompanying documentation, as previously.
- If you are a local PI (e.g. a recruitment site for a multi-centre study) then you do not need to submit any documentation to South Manchester REC.

3. What will I need to submit to the R&D office?

- You should continue to submit all the documentation required for research governance approval. This should include a copy of the main REC application and the SSI Form.

4. When can I start my research project?

- If you are the CI, then you need to obtain NHS REC approval and research governance approval.
- If you are a local PI, then you only need to obtain research governance approval, provided a main REC has approved the project (this will be arranged by the CI site).

5. What do I do if I want to add a new site to a study already approved?

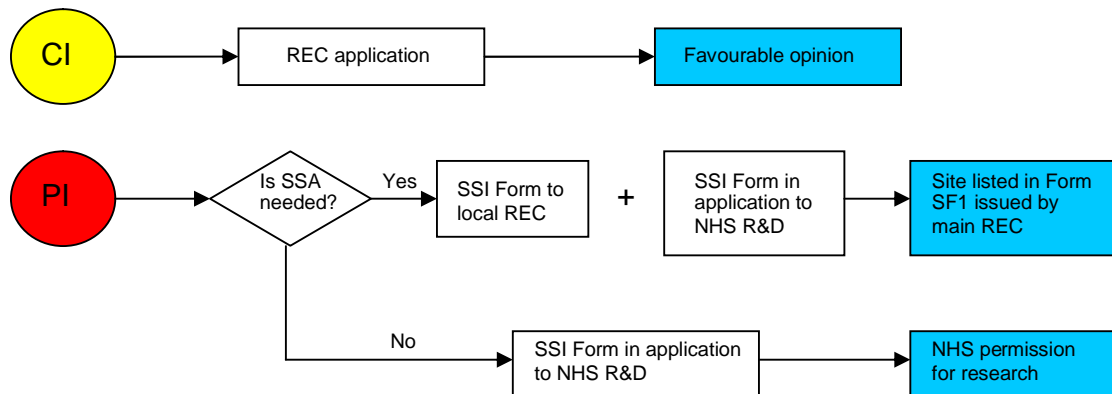
- For Clinical Trials of Investigational Medicinal Products (CTIMPs), the addition of a new site not listed in the original application is a substantial amendment which requires the submission of a Notice of Substantial Amendment to the main REC and the MHRA, in addition to the submission to the R&D office described in point 3 above.
- For other studies, regardless of whether or not it would previously have required SSA, there is no requirement to notify the main REC of the new site. The study may be extended to additional NHS sites, subject to obtaining permission from the R&D office prior to starting

the research at the site. Site-specific assessment is undertaken by the R&D office as part of the research governance review. Once you have obtained research governance approval from an R&D office, the site is deemed to be approved within the terms of the favourable opinion for the study from the main REC.

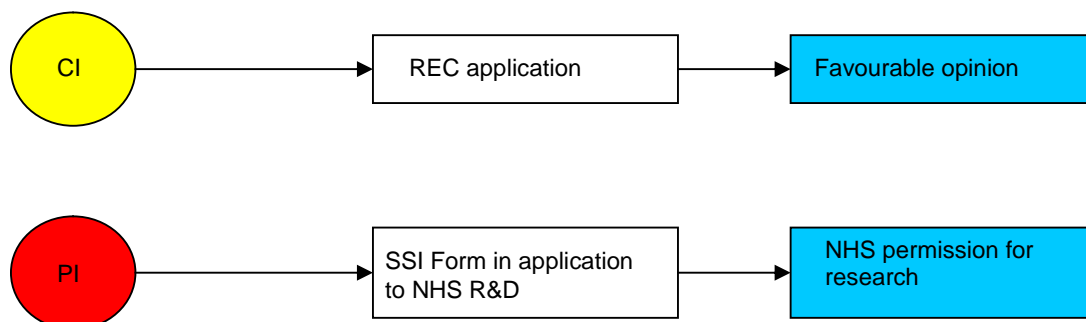
6. What if I need to appoint a new Principal Investigator at a site?

- For CTIMPs, the appointment of a new PI at a site is a substantial amendment, which requires the submission of a Notice of Substantial Amendment to the main REC, the MHRA, and the R&D office. The REC will confirm a favourable opinion on condition that permission is continued by the R&D office for the NHS organisation involved. The trial should normally continue at the site but, if no PI is in place, no new participants should be recruited until a favourable opinion has been given and confirmation of continued management permission has been given by the R&D office.
- For other studies, whether or not it would previously have required SSA, there is no requirement to notify the main REC of a new PI or Local Collaborator at a site. The study should normally continue at the site but, if no new PI is in place, no new participants should be recruited until confirmation of continued management permission has been given by the R&D office.

Before 1 April 2009



After 1 April 2009



As a result of these changes the NRES form system will be closed to new applications from 1 April 2009. All new applications will have to be made through the IRAS system www.myresearchproject.org.uk

- 7. But I have already started my application in NRES**
 - Users with unlocked forms will be able to complete them and submit them through NRES until 1 September 2009.
- 8. I need to create SSI forms for new sites to an ongoing study**
 - You will still be able to generate new SSI forms for ongoing studies until 1 September 2009.
- 9. What will happen to my projects in the NRES system after 1 September 2009?**
 - You will still have access to data within the NRES on-line form system after this date but it will no longer be possible to make applications.
 - New functionality will be added to IRAS prior to this date to allow you to create a minimum dataset for older studies where the original application was made using the NRES on-line form system and to enable SSI forms, Notices of Amendment and ARSAC forms to be generated where necessary.
- 10. I want to set up a new study, so what do I need to do?**
 - 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 or research governance 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.
- 11. I want to add new sites to an existing study with REC approval, so what do I need to do?**
 - 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.

- 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 applies to the research sites on the attached form, and, further, that the favourable opinion is conditional upon obtaining management permission for the research. Whether or not your letter contains these statements, there is no need to apply separately for SSA as the new arrangements apply retrospectively for all studies.
1. Principal Investigators (PIs) 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 Trial 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.

12. 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 approval for each NHS research site. Studies that would previously have been regarded as “SSA-exempt” have always required NHS R&D approval, and will continue to do so.

13. Where can I get more information?

Visit the R&D Directorate website at <http://www.researchdirectoraterg.org.uk> or contact UHSM R&D:

Andrew Maines	Head of R&D	0161 291 5775
Louise Fletcher	R&D Manager	0161 291 5777
Deepti Sebastian	Research Governance Manager	0161 291 5773
Anne-Marie Taylor	Information Officer	0161 291 5770

Visit the NRES website www.nres.npsa.nhs.uk