

# **Bulletin**

**March 2009**

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## **Information for NHS/ HSC R&D Offices and RECs on Site-Specific Assessment for NHS/ HSC sites**

This bulletin provides further information to RECs and R&D Offices about the transfer of Site-Specific Assessment (SSA) for NHS sites. The first bulletin, which was issued in January 2009, provided introductory information which you are strongly advised to read. The first bulletin is available on the [NRES website](#) and [NHS R&D Forum website](#).

New arrangements are being put in place to allow responsibility for Site-Specific Assessment (SSA) to be transferred to NHS hosts for NHS sites from April 2009. The arrangements in this bulletin apply to NHS organisations across the UK including HSC services in Northern Ireland.

### **What are the principles behind the new arrangements?**

Under the new arrangements, a standard condition of all REC approvals involving NHS sites will be that the sponsor must obtain 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. R&D review will include the issues previously reviewed separately by RECs for SSA. Therefore, once management permission has been issued by an NHS organisation, the main REC can be assured that the site-specific issues that relate to its ethical opinion have been considered.

This new arrangement will not require any paperwork, emails or forms to be passed between R&D offices and their local REC.

### **What are “conditions of approval”?**

A REC may issue a favourable opinion for a particular project subject to specific conditions being met. These approval conditions are actions the sponsor must take prior to the start of the study or, for site-specific conditions, before opening the study at a particular site.

It is already a standard condition for all studies that the sponsor must obtain management permission from the relevant host organisations prior to the start of the study at each site (NRES SOP 3.19B). Under the new arrangements for SSA, this standard condition will also include SSA as an integral part of the R&D review that leads to NHS management permission.

### **How will this work in practice?**

1. The Chief Investigator (CI) will apply as usual to the main REC using IRAS
2. Each Principal Investigator (PI) will apply as usual for R&D review using the R&D Form and SSI Form
3. The main REC will issue a letter of favourable opinion subject to the condition that management permission from each host NHS organisation is obtained prior to the start of the study at that site
4. Each NHS organisation will issue a letter of permission following the appropriate R&D review
5. 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
6. The sponsor does not need to confirm receipt of the NHS management permission back to the main REC

### **How does this differ from other conditions of approval?**

For other conditions of the favourable opinion (e.g. final amendments to participant information sheets) additional processes apply once the condition has been met.

1. The CI or Sponsor should notify the main REC, for information, once the conditions have been met and provide copies of final documentation (with revised version numbers) for reference purposes where appropriate
2. Neither the REC nor the co-ordinator is required to undertake any further review of the actions taken. The REC coordinator will acknowledge receipt of the documents.
3. Copies of the final documentation (with revised version numbers) should be sent, with the REC letter of favourable opinion, for R&D review (the original application for R&D review should be made in parallel to REC review)
4. Each NHS organisation will issue a letter of permission following the appropriate R&D review

### **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 is exempt from SSA. NHS R&D review already considers the issues that are appropriate to a particular study at that site. Incorporating SSA into R&D review will simply mean that there will no longer be a duplication of review of the same issues by the NHS R&D office and the local REC.

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.

### **Does this mean that the SSI Form is no longer required?**

No. The Site Specific Information (SSI) Form is currently a form used for both SSA and as part of the R&D application. Under the new arrangements there will be no need to send SSI Forms to RECs for any NHS site for any type of study.

SSI Forms for NHS sites will be used solely for applications for NHS management permission. SSI Forms should be submitted as part of the R&D application for all research sites and all types of study. These new arrangements avoid confusion for researchers about when SSI Forms are and are not required.

### **Do these arrangements comply with the Clinical Trials Regulations?**

Yes. The regulations specify the matters that a REC should consider in giving its opinion. Some of these matters relate to the specific sites where the research will be conducted. The following issues are relevant site-specific issues that should be considered in giving a favourable opinion, as described in the current NRES Standard Operating Procedures:

- a) The suitability of the PI, taking into account his/her professional qualifications, knowledge of the research field, expertise in the procedures involved, previous research experience, training in research methods (including informed consent), training in Good Clinical Practice (if applicable), and ability to take clinical responsibility for the local research team.
- b) The adequacy of the local facilities available for the research.
- c) The arrangements for notifying other local health care staff who may have an interest in the care of the participants, about the research.
- d) The availability of any extra support that might be required by research participants as a result of their participation.
- e) The local arrangements for making legal representatives available to give informed consent on behalf of minors or adults unable to consent for themselves, where this is a legal requirement for the research. This includes consideration of the appointment and training of legal representatives.
- f) The practical arrangements to be made at the site for providing information to potential participants who might not adequately understand verbal explanations or written information given in English, where it is planned to include such groups in the study as a whole.

- g) Specific assurances may be sought that the following site-specific information will be included in the local version of the information sheet for the study or provided as additional standard information for local research participants:
- The address and telephone number of the site (normally to be included on the headed paper to be used locally)
  - Contact details for the local investigator(s) and, if applicable, other staff such as research nurses
  - Emergency contacts if appropriate
  - Contact information for complaints and, where appropriate, independent advisers.

All the above are issues that already form part of the wider NHS R&D review and are included in the standard R&D application in IRAS. R&D offices do **not** need to establish committees or groups to review these issues from April 2009. Existing R&D review procedures should already consider these matters and this will provide adequate assurance to the main REC about the site-specific issues of any study.

The Medicines for Human Use (Clinical Trials) and Blood Safety and Quality (Amendment) Regulations 2008 (S.I. 2008/941) allow an ethics committee to give a favourable opinion "subject to conditions specified in writing". A trial is only considered to have a favourable opinion if the specified conditions are satisfied.

#### **What about adding new sites to existing studies?**

The principles for addition of new NHS sites during the study will be similar to those described above and will apply to all studies. The conditions of the ethical opinion will include the addition of new sites, subject to obtaining management permission from each host organisation.

For studies approved since 1 May 2008, the requirement to obtain NHS permission has already been a standard condition. The new arrangements will also apply retrospectively to all studies approved before that date. **There will be no need to apply for separate SSA for any NHS sites for either existing or future studies.**

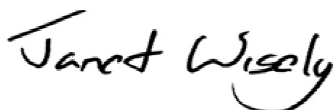
For CTIMPs only, if the site or the investigator was not listed in the original REC and MHRA applications, a notice of substantial amendment should be provided to the MHRA and the main REC with the details of the new site and investigator, for information, in order to comply with the Clinical Trials Regulations. Once the EudraCT form is included in IRAS (March 2009) it will be possible to prepare substantial amendments in IRAS.

In all cases, new sites will require NHS permission.

#### **Where can I get more information?**

Detailed information about changes to standard letters and SOPs will be communicated to REC staff and members shortly. Any relevant information about the detailed arrangements for supporting transfer of SSA as part of NIHR Coordinated System for gaining NHS Permissions (NIHR CSP) in England, NHS Research Scotland in Scotland and the Central Primary Care RMG Office in Wales will, if necessary, be provided to R&D staff by the respective coordinating centres.

*Signed by*



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