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# **Bulletin**

**January 2009**

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

"*Building on improvement: Implementing the recommendations of the Report of the Ad Hoc Advisory Group on the Operation of NHS Research Ethics Committees*" recommended that responsibility for Site-Specific Assessment (SSA) should be transferred to NHS hosts for NHS sites and the four UK Health Departments have agreed that this should be implemented from April 2009.

### **Background**

To support the transfer of SSA to R&D offices, the NHS R&D Forum issued a UK-wide Standard Operating Procedure (SOP) for SSA by local assessors in R&D offices in May 2007. Since then, a number of Research Ethics Committees (RECs) have transferred the role of provision of advice on the SSA to local R&D offices via a formal agreement using these SOPs. Plans to complete this transfer have been delayed by a range of factors affecting both the research ethics service and R&D offices.

### **New arrangements from 1 April 2009**

Arrangements are being put into place to support the complete transfer of SSA for NHS sites to R&D offices from 1 April 2009. The principles of the arrangements are that:

- RECs will rely on the checks undertaken by R&D offices.
- The favourable opinion of the REC for a site will be conditional upon the permission of the relevant NHS organisation.
- The checks that form the SSA are already part of standard R&D review.
- The Health Departments will formally confirm that these checks are included in the procedures for R&D review.

This approach is different to that taken so far by R&D offices that have been undertaking SSA. Previously the system has relied on direct provision of advice from the R&D office to the REC about SSA. This new system ensures that the favourable ethical opinion relies on the appropriate review of local issues, without requiring complex administrative arrangements between RECs and R&D offices.

### **Principles for SSA by R&D offices**

The Medicines for Human Use (Clinical Trials) and Blood Safety and Quality (Amendment) Regulations 2008 (S.I. 2008/941) came into force on 1 May 2008. The Regulations made provision for 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. These approval conditions are actions the sponsor must take prior to the start of the trial or initiation at a particular site.

National Research Ethics Service (NRES) SOPs set out detailed guidance on the use of conditions by RECs. These SOPs apply to all research reviewed by RECs, not only to Clinical Trials of Investigation Medicinal Products (CTIMPs).

One of the standard conditions for all studies is that the sponsor must obtain management permission or approval from the relevant host organisations prior to the start of the study at each site (SOP 3.19B). The new arrangements announced in this bulletin make clear that, for NHS sites, this requirement will include SSA as an integral part of the R&D review.

### ***Current arrangements***

Current NRES SOPs require that the chief investigator or sponsor should notify the main REC, for information, once the conditions have been met and provide copies of final documentation for reference purposes where appropriate. The co-ordinator should acknowledge receipt. Neither the REC nor the co-ordinator is required to undertake any further review of the actions taken, or to confirm approval of final versions of amended documentation.

It should be noted that RECs can currently issue guidance to sponsors and investigators on their responsibilities following review. This guidance is distinct from the conditions described above. The REC can also give advice or make suggestions that are not binding on the applicant. Such non-binding advice should be clearly distinguished from conditions. If an applicant opts not to implement any non-binding advice, this does not affect the REC's favourable opinion of the research.

### ***Key changes***

Under the new arrangements, the requirement described above to notify the main REC that a condition of favourable opinion has been met will not apply to the condition relating to R&D review at NHS sites. Therefore the study can start at a NHS site as soon as any other conditions have been met and the main REC notified, and local permission has been obtained. The chief investigator or sponsor will not need to notify the main REC that NHS permission has been obtained. Amendments will be made to the NRES SOPs to clarify this process.

Further details will be issued in another joint bulletin.

### **Benefits of the new arrangements**

The new system aims to achieve the requirements of legislation and policy whilst creating minimal administrative burden for reviewers and simplifying procedures for applicants. It will:

- Avoid the need for additional paperwork or information systems and complex communication routes between RECs and R&D offices to advise the REC about the outcome of SSA.
- Minimise the confusion to researchers resulting from the use of categories of studies or sites requiring or exempt from SSA.
- Help to reinforce the requirement for NHS/ HSC permission for research.
- Not require changes to R&D review. The current appropriate and proportionate review, using information provided in the standard R&D application, will continue to inform the provision of NHS permission for research.

### **Actions required for 1 April 2009**

#### ***Applicants***

From 1 April 2009, researchers will no longer need to send Site Specific Information (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. This will require changes to the existing online application systems.

**IMPORTANT:** The NRES online form system will not be updated to implement this change as it would constitute an inappropriate use of resources. **The NRES online form system will therefore no longer be available for new applications from the end of March 2009.** Applicants will need

to use the Integrated Research Application System (IRAS), which is available at [www.myresearchproject.org.uk](http://www.myresearchproject.org.uk)

IRAS will provide guidance to applicants on the new arrangements. From 1 April 2009 IRAS will include the facility to enter brief details about existing studies with applications previously completed in the NRES online system (or earlier paper systems). This will allow applicants to set up new sites and submit amendments for existing studies using IRAS.

To avoid unnecessary work in future for amendments or new sites, **applicants are recommended to use IRAS now for all new applications for REC or R&D review.**

#### ***NHS R&D staff***

From 1 April 2009, R&D offices that have been undertaking SSA through formal agreement with a REC will receive SSI Forms directly from applicants and will no longer need to communicate the outcome of the SSA to the REC system.

All R&D offices should continue to conduct appropriate and proportionate R&D review in accordance with relevant national or local procedures.

#### ***Research ethics committees***

##### *For NHS Sites:*

From 1 April 2009, no further SSAs will be undertaken by RECs for NHS sites, whether alongside the main ethical review or separately by a SSA REC. Further guidance will be issued about transitional arrangements for applications in process.

Main RECs will no longer receive notifications of SSAs for NHS sites. Form SF1 will no longer be used to maintain a complete listing of approved sites.

The principles for addition of new NHS sites during the study will be similar. The conditions of the ethical opinion will include the addition of new sites, subject to obtaining management permission or approval from each host organisation. For CTIMPs only, 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.

##### *For non-NHS Sites:*

For non-NHS sites, SSAs will continue to be reviewed by SSA RECs (either a NHS REC or a designated non-NHS REC in the case of a Phase 1 trial site). A filter on the SSI Form in IRAS provides appropriate questions for non-NHS sites. A standard letter will be used by the main REC instead of form SF1 to confirm approval of non-NHS sites as part of the favourable opinion.

*Signed by*



**Dr Janet Wisely, Director,  
NRES**



**Dr Janet Messer, Deputy Director,  
NHS R&D Forum**