

The Independent Scientific & Advisory Committee (ISAC)

03 March 2008

Following a recent review of the standard operating procedures of the Independent Scientific and Advisory Committee (ISAC), the ISAC has adopted a number of changes to align its function with current UK requirements. This is in relation to the UK National Health Service (NHS) governance framework for undertaking research and the Multiple Research Ethics Committee (MREC) approval that underpins the operations of the GPRD.

These changes are outlined below and will take place with *immediate effect*. Please note that all changes are applicable to both current GPRD and its historical extract, EPIC.

1. All study approval previously granted by the ISAC and its predecessor Committee, the Scientific and Ethical Advisory Group (SEAG), to undertake multiple research studies on the basis of a single approval ('blanket' approval) is hereby withdrawn.

Researchers who currently hold such approvals and who wish to undertake future research using the GPRD or its historical extract, will now be required to submit a new and separate application for each study for consideration by the ISAC.

2. All requests for amendments to protocols approved *prior to* 20 March 2006 should now be submitted as a new application for evaluation under the ISAC. This will be subject to full review by the ISAC.
3. All *new* requests to undertake validation work (requiring GP input and/or free-text searches) as an extension of a previous or ongoing study which was approved *prior to* 20 March 2006, should now submit a new application for evaluation under the ISAC. This will be subject to full review by the ISAC.

Exceptions to this requirement include:

- a. Study approval granted prior to 20 March 2006 which included a validation component which was assessed at the time of protocol review.
4. All requests for amendments to protocol, for studies initially approved on or after 20 March 2006 and within 2 years of initial approval, will constitute an amended protocol and reviewed by the Chair of the ISAC only.
 5. All requests for amendments to protocol, for studies initially approved on or after 20 March 2006 and outside 2 years of initial approval, will be treated as a new submission and subject to full review by the ISAC.
 6. Where a protocol has been found to be unsatisfactory upon initial review and assigned the outcome of 'reject', applicants should not respond to reviewer's comments (except in the case of an appeal) and/or submit an amended protocol. Applicants can however, on the basis of the comments provided by the Committee, submit a new application for scientific evaluation. This will be subject to full review by the ISAC.

ISAC Secretariat