



## MEDVANCE FACT SHEET No 3

# SUBMISSION TO RESEARCH ETHICS COMMITTEE SPECIFICALLY FOR MEDICAL DEVICES

### What is a Research Ethics Committee?

A Research Ethics Committee (REC) is an independent body of people whose primary responsibility it is to verify in particular the health, safety and well being of human subjects when voluntarily involved in Clinical Investigations.

### When should a Research Ethics Committee be informed of a Medical Device Clinical Study?

It is paramount that Research Ethics Committee approval is obtained before the commencement of a Clinical Investigation. Within the UK, Research Ethics Committee Approval is required for all Clinical Investigations and for all Post-Marketing Surveillance Studies (PMS) which do not meet the defined criteria as outlined by the UK National Research Ethics Service (NRES).

REC applications are made through the Integrated Research Application System (**IRAS**), a single system for applying for the permissions and approvals for health and social care community care research within the UK. The system enables you to enter all the information about your project once instead of duplicating information in separate application forms and uses filters to ensure that the data collected and collated is appropriate to the type of study, and consequently the permissions and approvals required, this helps you to meet regulatory and governance requirements

**IRAS** captures the information needed for the relevant approvals from the correct review bodies:

### Research Ethics Committee Submission

The **IRAS** application form (including a section combining SSI, R&D and MHRA approval) can be found at [www.iras.gov.sg/](http://www.iras.gov.sg/) using the Integrated Research Application System (**IRAS**). Guidelines on completing the application form; details of specific requirements, documentation required for the application; submission deadlines and timescales for approval can also be found at this website. The following documents are usually required for submission: **IRAS** now also offers the facility for electronic authorisations as an alternative to ink signatures on hard copies

- **Clinical Investigation Plan** including appendices or amendments (6 copies).
- **Clinical Investigator's Brochure**, including any amendments (3 copies).
- **Patient Information Sheet, Informed Consent Form and GP letter.**
- **Product leaflets, questionnaires and diary cards.**
- Details of **compensation** for subjects and any **insurance** or **indemnity** cover provided.
- Details of the **financial arrangements** between the Sponsor and the Clinical Investigator, other hospital departments or the subjects.
- **Curriculum vitae** of the Clinical Investigator.
- Completed **IRAS application form.**

There are currently 13 RECs flagged for medical devices these are;

- Cambridge 1 REC
- Cambridge 2 REC
- Health and Social Care-REC-Northern Ireland

- Leeds West REC
- Lothian 2 REC
- Multi Centre REC for Scotland Committee
- Northern & Yorkshire REC
- Sheffield REC
- North West 6 REC -GM South
- North London REC 2
- South East London REC 3
- South Birmingham REC
- South Manchester REC
- South West 2 REC
- West Midlands REC
- Scotland A REC
- South East Scotland REC

Many REC'S prefer the Investigator/sponsor to attend the REC meeting in person or via telephone.

### Research and Development (R&D) Approval Site Specific Assessment

R&D approval must be obtained for all NHS research sites. Site Specific Information (SSI) should be completed for each participating investigation site to grant investigation site approval (SSI application form found within **IRAS**). The main REC reviews the ethical aspects of the Clinical Investigation and the SSI will be reviewed by each hospitals Research and Development Departments (R&D) who will then address the local issues at that investigation site, and the completion of the Model Clinical Investigator Agreement including financial section (mCIA). The mCIA is designed to simplify and therefore speed up the process for signing off and initiating trials involving NHS patients within NHS hospitals.

The submissions to the main REC and the R&D for the SSI's may take place simultaneously. The main REC usually gives approval but request copies of the R&D approval once it has been received. Once an application is ready to send, the Central Allocation System should be contacted by phone (0845 270 4400) to receive a REC reference number and to confirm the REC of your choice has an available slot to review the Clinical Investigation documentation. The REC reference number must be entered on the application form prior to submission. The REC received and reviewed all submitted documentation, written confirmation will be received confirming that the submission document is a valid application.

### Research Ethics Committee Approval

Research Ethics Committee approval is normally required before Competent Authority approval, but in the UK, both may be submitted in parallel. REC approval will take the form of a letter. However this may stipulate certain conditions to be met or further information to be supplied prior to giving approval. The timescale for a decision may be up to 60 days Post Market Surveillance (PMS) studies of CE marked devices may be classified as service evaluation and may not require ethical review or management, permission from NHS R&D offices. If this option is selected within IRAS, all applications will be disabled.

Medvance are fully skilled in obtaining ethical, MHRA and Site approvals please contact us if you need further help or would like a quote. [enquiries@medvance.co.uk](mailto:enquiries@medvance.co.uk)