



## **TARDIS - Working Practice Document No: 011**

### **Start-up of UK site**

#### **A. Action taken by TARDIS office**

1. TARDIS investigator or member of team contacts potential site.
2. Investigator sends email outlining TARDIS and directs them to the TARDIS website ([www.tardistrial.org](http://www.tardistrial.org)) where they can find the following:
  - Full protocol
  - Expression of Interest Form
3. TARDIS office receives completed expression of interest form by post or fax.
4. TARDIS team discusses with Chief Investigator whether to include site.
5. TARDIS team member notifies collaborator to register with NRES (IRAS) and forwards the SSI form via the NRES website for completion.
6. TARDIS team member advises potential site that the following documents can be obtained from the website:
  - Consent forms
  - Consent for patients with previous relative consent form
  - Consent for DNA sample
  - Independent Physician Consent
  - Patient information sheet
  - Patient information sheet for patients with previous relative consent
  - Relative information sheet
  - Independent Physician Information Sheet
  - GP letter
  - MHRA approval email/letter
  - MREC approval letter
  - Sponsor letter
  - BHF award confirmation
7. TARDIS Co-ordinator forwards a copy of Contract between site and Sponsor, to potential site for completion and signing of two copies by R&D Office.

#### **B. Action taken by potential site**

1. Lead investigator or nominated person completes Section C of SSI form and submits the application local R&D approval only (as from 1/4/09)
2. Lead investigators respond to any clarifications requested by R&D.
3. Lead Investigator/R&D staff completes the designated signature log, obtains original, signed and dated CVs of all staff on the log, and faxes these to the Co-ordinating Centre(CC).

4. Once written confirmation of R&D approval is received, Lead Investigator to fax a copy to the CC.
5. Once two signed original copies of the contract signed by R&D, site to return both of these to CC.

### **C. Action taken by TARDIS office**

1. TARDIS office requests documents outlined in the start-up checklist; to include R&D approval letter, signature log, signed and dated CVs.
2. TARDIS office sets up access to website and generates passwords for each investigator listed on site delegation/signature log (to take at Initiation Visit).
3. TARDIS UK Centre Coordinator produces an Investigator Site File with essential documents.
4. TARDIS UK Centre Coordinator arranges date for Site Initiation Visit.

### **D. Site Initiation Visit**

During the Site Initiation Visit, the TARDIS UK Centre Coordinator will:

1. Carry out a powerpoint presentation, providing an overview and current status of the trial, and answer any questions that are generated.
2. Go through the ISF contents, including the Protocol, Working Practice Documents and other forms.
3. Discuss the process of consent and local policy at their site.
4. Discuss the flow chart for entering patients into TARDIS and the documents that require faxing to the CC.
5. Provide the investigators with their TARDIS passwords and check that they are functioning.
6. Go through the website and demonstrate how to add data onto the live TARDIS website using the demo website.
7. Go through the Working Practice Documents on both sub-studies (TCD and P-Selectin)
8. Check that the centre has the contact details for the CC – give laminated copy. (A copy can be found in the Investigator Site File)
9. Discuss/demonstrate the CT scan upload facility.
11. Discuss/demonstrate the TCD upload facility (if site taking part in this sub-study).
12. Discuss whether the site will be participating in blood collection, and if so go through the blood sample freezer log form. Also the P-selectin sub-study requirements. Leave a supply of blood packs with pre-paid Royal Mail boxes for Site to send samples direct to Queen's Medical Centre.
13. Discuss Follow-Up procedures.

14. Inform the site about monitoring visits eg: requirements, frequency etc.
15. Obtain pharmacy details and check the system they are using (i.e. medication labelling, drug dispensing records).
16. Ensure that the site is now ready to recruit patients into TARDIS.