Royal Papworth Hospital
NHS Foundation Trust

GD010

Clinical Data Management User Training

1. Training – Part 2 (8) of Schedule 1 to SI 2004/1031 requires that '*Each individual involved in conducting a trial shall be qualified by education, training, and experience to perform his or her respective task(s).*' And the GCP guide includes '*role-specific training relevant to the post holder's duties and clinical trial role(s) and responsibility*' as one of the training requirements.

   This Guidance document cover the training required within Clinical Data management, for both users and data managers. The documentation from the training would be recorded as per R&D SOP002 Training Records for Research Active Staff.

2. Users
   a. Papworth Staff
      i. All Papworth staff that will have access to the data repositories should have training by a member of the data team, or the study coordinator. These training sessions should be in small groups, 5 or less ideally. The training should cover all the tasks the users are expected to do, and then the users should have access to a training or test environment to actually use the system for themselves, before moving on to the production site. The training record (FRM056) should be completed for each individual. This can be updated if their role changes and new tasks are added.
   b. External Site Staff
      i. Staff at sites, are usually trained at site initiation visits (SIV) by the study team. This again should cover all the tasks they will expect to complete. This can be documents of the training record form (FRM052) or in a study specific form. The site staff should then use the training/test site to familiarise themselves with the study. A study can choose if the will to set a training test for sites, this should be documented in the Data Management Plan (DMP, SOP078).