



# DIAMONDS Training Guideline

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## 1. TRAINING OVERVIEW

Any of the site staff who have previously received and documented training on a study-specific process outlined in section 3 of this document may train another member of staff at the site.

All study specific training must be documented on a Study Training Log and SOP training should be documented on an SOP Training Form.

Throughout the trial send a copy of any updated documentation to [DIAMONDS@nictu.hscni.net](mailto:DIAMONDS@nictu.hscni.net).

## 2. NEW MEMBERS OF STAFF

All members of the site research team must be added to the delegation log, provide a **signed/dated** CV and GCP certificate and complete protocol training as a minimum.

## 3. STUDY-SPECIFIC TRAINING

Depending on each staff member's role and responsibility the following training may be required:

- **Protocol training**

**All members of the research team working on DIAMONDS must complete protocol training.** This consists of reading the current approved protocol and asking any questions to another previously trained member of staff or PI as appropriate.

Depending on each staff member's role and responsibility, the following training may be required:

- **Randomisation training**

Any members of the research team delegated recruitment/registration of patients must complete training on using the randomisation system and have this documented on a study training log.

- **Clinical speciality guidelines**

Any members of the research team delegated to undertake specific clinical assessments or interventions must complete 'Reading and Understanding' training in these processes.

- **CARF Training**

Any members of the research team delegated to upload images of patients selected for submission to CARF must complete 'Reading and Understanding' training in the upload process.

## 4. SOP TRAINING

- **SOP TM02\_Investigator Site File (ISF) and Essential Documents**

Members of the research team delegated responsibility for maintaining the Investigator Site File (ISF) on the delegation log must be trained on SOP TM02, a copy of this SOP is located in the trial manual (section 11). Documentation of this training must be recorded on the appropriate SOP training form.

## 5. GCP TRAINING

All staff on the delegation log must have a current GCP certificate which must be maintained throughout the duration of their participation in the DIAMONDS trial. GCP certificates must be renewed on a **3-yearly** basis.

## 6. AMENDED PROTOCOL

During the trial, if a new version of the protocol is approved, each PI will be asked to sign a new Investigator Protocol Agreement confirming that they have read and understood the amended protocol and will ensure that site staff are trained in the new version of the protocol.

The PI should read the new version of the protocol and direct any questions they may have to ([DIAMONDS@nictu.hscni.net](mailto:DIAMONDS@nictu.hscni.net)). Once the PI has read & understood the new version of the protocol, a new entry in the Study Training Log detailing the protocol version should be created with the PI signing themselves off as trained by stating 'Reading & understanding' in the name/signature of trainer box. The PI may train another site member of staff who can train the remaining members of staff at site which should also be documented on the Study Training Log.

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