

FHN Study
Manual of Operations Chapter 28. Quality Control

28.1 Introduction to Certification for Quality Control

FHN Personnel must be trained and certified in order to perform the tasks specified in the FHN protocol. The central database will track the certification status of personnel, and no one will be allowed to perform specified study tasks unless they have been appropriately trained and certified. This will help to ensure the quality of the tests and measurements done.

Those trained by a master instructor are considered to be trained as trainers and can train and certify other people. The people the trainers certify will not be considered to be trained as trainers.

Note that although the initial study training session in Cleveland (September 2005) also included training in billing, non-dialytic aspects of treatment, standards of care, and data entry, there are no specific training or certification requirements for these tasks.

28.2 Nocturnal Study Only

Home Blood Pressure Measurements

Home blood pressure training, using the Omron Blood Pressure device, was conducted by master instructor Ruth Bullas, RN, at the September 2005 training session in Cleveland. For details on this procedure, see Manual of Operations Chapter 17.

Those individuals who attended this training session are considered to be fully certified.

Those trained by a master instructor are considered to be trained as trainers and can train and certify other people. The people the trainers certify will not be considered to be trained as trainers.

28.3 Daily Study Only

Holter Monitor Placement

Holter training was conducted by master instructor, Christopher Chan, M.D. at the September 2005 training session in Cleveland. For details on this procedure, see Manual of Operations Chapter 16.

In order to be considered fully certified, personnel must submit test cases to Chris Chan for his approval. This must be done before the first procedure is done on an actual study patient.

Details of holter certification are provided in the Holter chapter of the Manual of Operations Chapter 16.

28.4 Both Daily and Nocturnal Studies

Modified Mini Mental Status Exam (Form 231)

Revision of February 5, 2006

Modified Mini Mental Status Exam training was conducted by master instructor, Manjula Kurella, M.D. at the September 2005 training session in Cleveland. For details on this procedure, see Manual of Operations Chapter 11.

Those who attended this session are considered to be fully certified as 'trainers'.

Those individuals trained by a master instructor are considered to be 'trainers'. These trainers can instruct and certify other study staff members on how to correctly perform a specific test. The additional study staff are not certified to train others.

Physical Function Testing (Form 234)

Physical Function Testing training was conducted by master instructor, Patricia Painter, M.D., at the September 2005 training session in Cleveland. For details on this procedure, see Manual of Operations Chapter 12.

Those who attended this training session are considered to be fully certified as 'trainers'.

Those individuals trained by a master instructor are considered to be 'trainers'. These trainers can instruct and certify other study staff members on how to correctly perform a specific test. The additional study staff are not certified to train others.

Trail Making B (Form 232)

Trail Making B training was conducted by master instructor, Manjula Kurella, M.D., at the September 2005 training session in Cleveland. For details on this procedure, see Manual of Operations Chapter 13.

Those who attended this session are considered to be fully certified as 'trainers'.

Those individuals trained by a master instructor are considered to be 'trainers'. These trainers can instruct and certify other study staff members on how to correctly perform a specific test. The additional study staff are not certified to train others.

Feeling Thermometer (Form 230)

Feeling Thermometer training was conducted by master instructor, Josee Champagne, at the September 2005 training session in Cleveland. For details on this procedure, see Manual of Operations Chapter 14.

Those who attended this session are considered to be fully certified as 'trainers'.

Those individuals trained by a master instructor are considered to be 'trainers'. These trainers can instruct and certify other study staff members on how to correctly perform a specific test. The additional study staff are not certified to train others.

Single Frequency Bio-Electrical Impedance Analysis (Form 242)

Bio-electrical Impedance Analysis training was conducted by master instructor, Glenn Chertow, MD, at the September 2005 training session in Cleveland. For details on this procedure, see Manual of Operations Chapter 15.

Those who attended this session are considered to be fully certified as 'trainers'.

Those individuals trained by a master instructor are considered to be 'trainers'. These trainers can instruct and certify other study staff members on how to correctly perform a specific test. The additional study staff are not certified to train others.

Cardiac MRI

Cardiac MRI training was described by Sanjay Ragajopalan, MD., at the September 2005 training session in Cleveland. MRI technicians were trained on conference calls by Sanjay Ragajopalan, MD, Javier Sanz, MD, and Mbabazi Kariisa, MPH. For details on this procedure, see Manual of Operations Chapter 7.

In order for an MRI lab to be considered fully certified, MRI technicians must submit test cases to Sanjay Rajagopalan for his review and approval. Details of Cardiac MRI certification are provided in the MRI chapter of the Manual of Operations, Chapter 7.

This certification must be done before the first procedure is done on an actual study patient except in highly unusual instances in which test cases cannot be done due to local restrictions. In this case, review Chapter 7 of the MOP for details.

28.5 Data Quality Control

Edit checks are applied upon data entry and discrepant data will not be accepted into the study database. If data already in the study database appear to be discrepant, a data discrepancy inquiry will be sent to the clinical center. The DCC will track when the inquiry was sent, what item was questioned, who responded to the inquiry, what was the response, whether the database was changed, and if so, when.

28.6 Database Back-Ups and Disaster Recovery

Data are backed up nightly, with a full back up done weekly. Data tapes are stored off site monthly.