CHAPTER 16 ULTRASOUND CORE PROCEDURES

16.1 What the Core Does

The responsibilities of the HFM Study Ultrasound Core are to train and certify HFM Study sonographers in the HFM Study preoperative and postoperative ultrasound imaging protocols, and to read the ultrasound examinations obtained. Quality control of the data obtained will be crucial to ensure protocol adherence and uniform image procedures and accurate, reproducible ultrasound data. After the ultrasound has been performed, a worksheet will be filled out by the study sonographer for each ultrasound. Each ultrasound with its accompanying worksheet needs to be transmitted to the US Core in a timely fashion for quality control and interpretation. It is crucial that the ultrasounds be transmitted on the same day that they are performed. There is a very tight time window in which missing ultrasound images or improperly performed measurements could be repeated by bringing the patient back for additional ultrasound images. Additionally, protocol drift can easily occur if the ultrasounds are not read roughly contemporaneously with the performance of the study. Unexpected findings will be reported through the DCC. If adherence to study protocol is incomplete or the study is not evaluable, the DCC will be contacted to transmit this information to the respective site in a timely fashion so that additional images may be obtained and quality control implemented.

16.2 Data Transfer to DCC

Once the Ultrasound Core has performed quality control on the images, they will be read by the US Core physicians and the data from the ultrasound electronically entered into the DCC database.

16.3 Feedback from DCC to Clinical Centers

The clinical centers will be notified if the ultrasound examination is not evaluable, or images and/or data is missing. This missing images or data will be judged as requiring the patient to come back for additional images (if possible), or not requiring the patient to come back. Ultrasound examination Protocol violations will be communicated from the DCC to the individual centers.