



# MR Imaging Site Operations Guide

for

***[Name of MRI Imaging Site]***

Sponsor: **Anika Therapeutics Inc.**

Protocol Name: **FastTRACK** (Hyalo**FAST** Trial for Repair of Articular Cartilage in the Knee)

**Protocol Number: Hyalofast 15-01**

Qmetrics Internal ID: **040-0003**

Guide Version: **2.0**

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## **About Us**

Qmetrics Technologies is an imaging core lab dedicated to providing the highest quality image analysis services, expert consulting for trial set-up and implementation, and scientific and medical expertise, allowing our clients to more cost-effectively determine therapeutic efficacy with precise, reliable and measurable results.

Visit our website for more details:  
[www.qmetricstech.com](http://www.qmetricstech.com)



1250 Pittsford-Victor Rd ~ Building 200, Suite 110 ~ Pittsford, NY 14534  
Phone: 585.301.4300 ~ Fax: 585.270.4686  
[www.qmetricstech.com](http://www.qmetricstech.com)

## Qmetrics Contact Information

### Main Study Contact:

Name: Amber Carr  
Title: Project Manager  
E-Mail: amber.carr@qmetricstech.com  
Phone: +1.585.301.4300 Ext. 143

### Back-up Contacts:

Name: Patricia Gonzalez  
Title: Chief Operating Officer  
E-Mail: patricia.gonzalez@qmetricstech.com  
Phone: +1.585.301.4300 Ext. 145

Name: Edward Schreyer  
Title: Chief Executive Officer  
E-Mail: Edward.schreyer@qmetricstech.com  
Phone: +1.585.301.4300 Ext. 141

## Study Overview

Anika Therapeutics is conducting a prospective, randomized, active treatment-controlled, evaluator-blinded (radiologist reviewer and physician evaluator) multicenter study intended to establish superiority of Hyalofast® scaffold with bone marrow aspirate concentrate (BMAC) in the treatment of symptomatic cartilage defects of the medial or lateral femoral condyle or femoral trochlea as compared to microfracture treatment, using the Knee Injury and Osteoarthritis Outcome Score (KOOS) Pain and International Knee Documentation Committee (IKDC) Subjective Knee Evaluation Score as the co-primary endpoints.

The study will be conducted both in Europe and in the US.

The study is composed of two arms:

Group A: Hyalofast® with BMAC treatment

Group B: Microfracture treatment

Both study arms will include first line treatment of subjects with one femoral condyle or femoral trochlea defect with a size of 1-6 cm<sup>2</sup> that is classified as an ICRS grade III or IV defect. All subjects who meet pre-operative screening eligibility criteria will be randomized to treatment with Hyalofast® with BMAC or Microfracture. Treatment will be completed during the Index Arthroscopy.

All subjects will be assessed at intervals post-procedure (1 month, 3 months, 6 months, 12 months, 24 months, and 36 months). Measures to assess effectiveness will be conducted at follow-ups, with the primary effectiveness endpoint assessment done at the 24 month timepoint.

Magnetic Resonance Imaging (MRI) will be conducted at Screening, 1 month, 12 months, 24 months, and 36 months. Evaluation of the MRIs, including MOCART scoring, will be done by blinded radiologist reviewers. The one month MRI will be used as the baseline MRI for evaluation of treatment effectiveness.

Qmetrics Technologies is supporting Anika Therapeutics with the imaging aspects of this study, including:

- Imaging protocol and procedure design and continual monitoring
- Imaging protocol and procedure training for imaging site personnel
- Image analysis for study imaging data

All study related image data will be transferred to Qmetrics Technologies for quality evaluation, imaging protocol compliance, and analysis.

The image analysis for this study involves highly precise, computer-assisted processes, which depend on the image data conforming exactly to the specified protocol. Therefore, it is crucial that the imaging protocols and procedures specified in the guide are followed, precisely, for every subjects' imaging data acquisition. The study specific imaging protocols must be applied to every study-related imaging exam. Further **it is crucial that the MR scanner used to acquire the images along with the imaging protocol stay consistent with all**

**timepoints related to that subject.** This Site Operations Guide has been prepared to help sites comply with study and imaging requirements.

## Study Imaging Time Points

Subjects enrolled in this study will have imaging exams at the following timepoints:

- Screening
- 1 month post-op
- 12 months post-op
- 24 months post-op
- 36 months post-op

### Screening Time Point

Each subject will have both a Screening MRI and Screening plain radiograph as part of the inclusion/exclusion criteria assessment for this study.

### Post-Operative Time Points

After each enrolled subject has undergone his or her surgical treatment, MRIs will be performed at 1, 12, 24 and 36 months from the date of the study treatment. Plain radiographs are required at screening only and not for those post-operative time points.

## Supplies to be Provided to Site from Qmetrics

Qmetrics will provide the following items to the imaging site:

- T2 Phantom belt: This small belt contains five T2 signal phantoms. T2 phantoms are provided for inclusion with every subject's imaging exam. They provide calibrated signal values enabling the standardization of image data across sites and timepoints. Instructions for positioning the T2 phantoms on the study subjects prior to each of the imaging exams are provided in this guide.
- Foot Rest: this positioning device helps ensure the knee is positioned consistently across scans and improves patient comfort.
- Imaging Site Operations Guide(s): this will be a site-specific document which will be sent to each site before Imaging Training.
- Uniformity and Linearity (UAL) Phantom (European sites or sites without ACR accreditation only): this will be provided by your CRA before site training and then shipped periodically as necessary. The UAL phantom is required to be scanned during site qualification process as well as periodically during the course of the study. The phantom scans demonstrate the geometric linearity of the MRI B0 field and ensure that significant geometric distortions are not present in the acquired image data. Instructions for scanning the UAL phantom are provided in this guide.
- Water Bottle (European sites or sites without ACR accreditation only): a water bottle will be provided for filling the phantoms with distilled water.

For sites without ACR accreditation or those in Europe, the imaging supplies (T2 Phantom Belt, Footrest, UAL Phantom, Water Bottle) will be sent to your CRA for distribution to your site. For sites in the US, the imaging supplies (T2 Phantom Belt and Footrest only) will be provided directly to your imaging center.

The site is expected to keep the provided supplies in a secure area during the study to ensure that they are available as needed. If any of them became damaged or lost, please contact Qmetrics Field Operations Manager immediately to determine steps for replacement.

## Supplies the Site Must Provide (not ACR-accredited)

Sites without ACR accreditation or European sites will need to provide the following items:

- Distilled water: The phantom will need to be filled with approximately 12 liters of distilled water. It is important that tap water is not used as the mineral content may cause signal problems.

## Required System Access at Site

In addition to the supplies routinely used to conduct imaging studies, the following equipment is necessary for this study:

- Internet-enabled computer system for upload of data. The data upload process is supported via a secure web portal, which allows sites to browse the site's system and select a file or folder for upload. Sites will need to be able to access study imaging data via this computer system in order to upload it to the Qmetrics Core Lab, either directly, by USB, or by CD/DVD.

## Study Subject Naming Convention

Every study subject will be assigned a unique identification number in place of their name which must be used throughout the study.

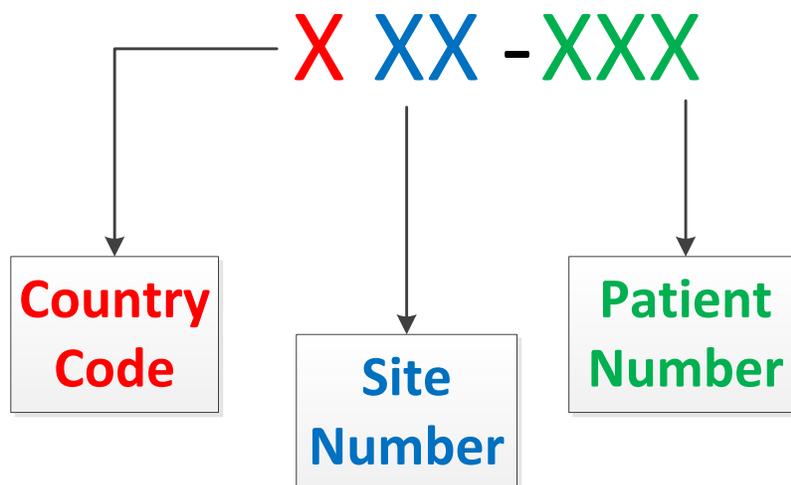


Figure 1 Naming Convention

The first digit of the Patient ID is the country code, with the following 2 digits representing the site number within that country. Next there is a dash (-) and the last three numbers are the patient number. The correct Subject ID must match the ID that is entered into Axiom's Fusion.

This naming convention will remain the same regardless of whether there are multiple rescans. For instance, if a subject's MRI scan is rescanned multiple times, the Subject ID for each one will be the 3-digit country and site number, a dash, and the three digit subject number.

Similarly, UAL Phantom scans will have a naming convention of the site number, a dash, and then "UAL" so that the complete Subject ID is 101-UAL. Volunteer scans will be indicated as Subject ID 101-Vol.

## Image Quality and Imaging Protocol Adherence

Adherence to the study specific imaging protocol is critical for this study. Also, good image quality is essential for study success. Due to these strict criteria, all image data that is transferred to Qmetrics for this study will be reviewed for imaging protocol adherence and image quality, and any non-conformances or quality issues will be communicated to the imaging site and require re-scans. Repeated deviations from imaging protocol as well as image quality issues are grounds for withdrawal of qualification status for an imaging site. See "Site Re-Qualification" for specifics about this process.

### ***Important Things to Remember:***

- **Always use the same scanner to image the study subjects. Should your site have multiple scanners that are approved for use in the study, each subject should be imaged on the same scanner for consistency. If a subject is scanned on an incorrect scanner, they must be re-scanned on the correct scanner.**
- **Scanner software and hardware upgrades shall be communicated to Qmetrics prior to scanning more patients and will require a UAL phantom scan to requalify the scanner.**
- **If any scanner maintenance (re-shimming, upgrades, etc.) is performed, the UAL phantom shall be re-scanned to verify geometric linearity prior to scanning additional study subjects.**
- **Inform Qmetrics in advance about every planned scanner upgrade.**
- **The site lead tech will be trained to perform study subject imaging. Qmetrics will provide a record of the training. If other techs will be acquiring study-related image data, the lead tech is responsible for training other techs and monitoring their compliance. Training of techs by the lead tech must be documented. Training records will be filed on site with study documents and a copy collected for the Sponsor's records.**
- **Only trained techs can perform imaging for this study.**

- **The trained lead tech is responsible for the quality of all images acquired during the trial.**
- **Study subject comfort is crucial for successful imaging. Excessive motion artifact may cause a recall/rescan.**

## Site Qualification and Training Process Overview

### Pre-Qualification

All imaging sites will first be pre-qualified by completing a technical questionnaire. After Qmetrics staff has reviewed the information submitted via the questionnaire and confirmed that the site meets technical and personnel requirements for the study, Qmetrics will then communicate to Anika that the site meets the imaging pre-qualification requirements. Anika will assess all pre-qualification information and identify sites that are eligible for a Site Qualification Visit. Based on information collected during the Site Qualification Visit, Anika will select sites for participation in the FastTRACK trial. Sites selected for participation will go through an activation process during which Qmetrics will conduct a training event (or visit, if applicable) for the site. In preparation for the training, Qmetrics will provide the site-specific electronic Imaging Site Operations Guide to the site and the other study materials (T2 phantom belt, footrest, and a UAL phantom and water bottle for sites without ACR accreditation or European sites only) will be distributed to the imaging site.

### Training and Qualification

During the site training, the Qmetrics trainer will instruct the site's lead tech on:

- How to input the imaging protocol into the scanner
- All procedures for imaging study subjects
- How to image the UAL phantom (for European sites or sites without ACR accreditation) or submit an ACR scan (for US sites that participate in the ACR program)
- How to complete all the required documentation
- How to transfer the image data to Qmetrics
- Any additional details in the Site Operations Guide

### For European Sites or Those Without ACR Accreditation

Following the training, the UAL phantom will be scanned by the site lead tech, followed by the scanning of a volunteer. These images will then be transferred to Qmetrics per study procedures. These scans are done to demonstrate understanding and compliance with required study protocol and procedures, as well as to provide image data enabling Qmetrics to assess image quality suitable for study requirements.

The UAL and volunteer scans are then reviewed by Qmetrics

- If the UAL phantom scan is found to be unacceptable, the site will be asked to contact the field engineer for calibration. The site cannot participate in the study as long as the scanner is not calibrated.
- If any of the scans are not compliant with the associated imaging protocol, then the site will be asked to repeat the scan and transfer the image data to Qmetrics for review. The

site cannot participate in the study as long as they are not able to acquire subject data that is compliant with the study protocol and procedures.

After the UAL and volunteer scans have been approved by Qmetrics and determined to meet all requirements, the site will be then informed that they can scan the first study subject. After the first study subject scan has been transferred to and approved by Qmetrics, then the imaging site will be qualified. This will be communicated to the site by the Qmetrics staff.

### **For US Sites that Participate in the ACR Program**

Following the training, the US sites that participate in the American College of Radiology (ACR) program will send their qualifying scan to Qmetrics for review. Sites will also submit a volunteer scan which is done to demonstrate understanding and compliance with required study protocol and procedures, as well as to provide image data enabling Qmetrics to assess image quality suitable for study requirements.

The ACR and volunteer scans are then reviewed by Qmetrics

- If the ACR scan is found to be unacceptable, the site cannot participate in the study as long as the scanner is not calibrated.
- If the volunteer scan is not compliant with the associated imaging protocol, then the site will be asked to repeat the scan and transfer the image data to Qmetrics for review. The site cannot participate in the study as long as they are not able to acquire subject data that is compliant with the study protocol and procedures.

After the volunteer scan and ACR scans have been approved by Qmetrics and determined to meet all requirements, the site will be then informed that they can scan the first study subject. After the first study subject scan has been transferred to and approved by Qmetrics, then the imaging site will be qualified. This will be communicated to the site by the Qmetrics staff.

### **Maintaining Qualification**

This section applies to all image data acquired by the study site for this study.

#### **Site Study Activity**

In order to maintain qualification for study imaging, sites will have to meet the following requirements:

- Successful study subject image acquisition and transfer within the past 6 months,
- OR;
- Successful acquisition and transfer of UAL phantom or ACR data within past 6 months prior to acquiring new study subject images.

#### **Ongoing Site Quality Monitoring**

Qmetrics will continually monitor the performance of each site in terms of imaging protocol adherence and image acquisition quality. All issues and deviations from protocol or quality are

communicated back to the site by Qmetrics. Information about the issues will be provided, and the site will be instructed on how to correct the specific issue/deviation.

In the event that two consecutive scans are received by Qmetrics from the site which are not acceptable due to image quality or imaging protocol issues, Qmetrics will communicate to the site that the site is no longer qualified, and that no further study subject scans may be performed at the site. At this point Qmetrics will consult with the Sponsor on further steps, and possible re-qualification.

## **Site Re-Qualification**

### **Site re-qualification due to inactivity**

If it has been longer than 6 months since a study subject, UAL or ACR phantom was scanned or submitted, the site will need to scan a volunteer and submit the image data to Qmetrics. Upon successful evaluation of the volunteer scan at Qmetrics, the site will be re-qualified to resume scanning study subjects.

### **Site re-qualification due to protocol non-compliance**

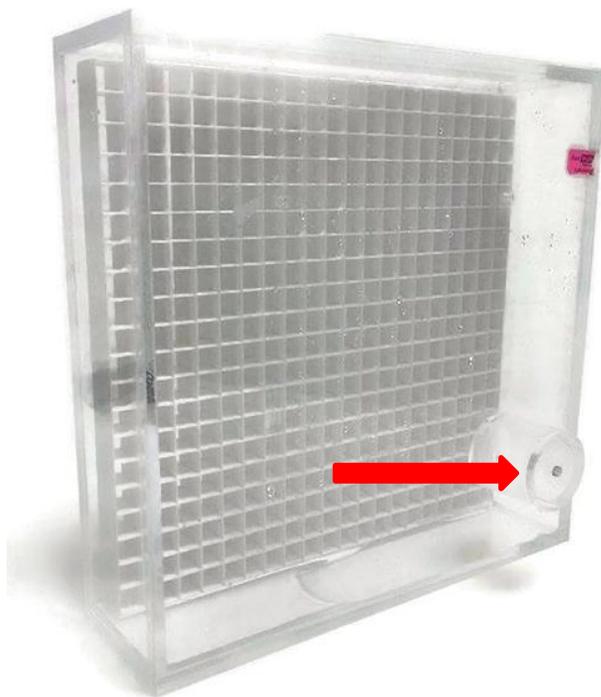
In the event a decision is made to re-qualify the site after two consecutive non-conforming scans, Qmetrics will schedule a retraining session with the site lead tech on the details in the Site Operations Guide and imaging protocols. After the retraining, the site will be instructed to scan a volunteer according to study procedures. If the volunteer scan is found to be acceptable by Qmetrics, then Qmetrics will communicate to the site that their qualification status has been reinstated and that they may resume scanning study subjects.

## UAL Phantom Procedures (Sites without ACR Accreditation)

The image quality of the study scans will affect the quality of the image analysis results and scoring results. The imaging procedures depend on the quality of the acquired images. This quality depends on the quality of the scanner and the imaging equipment, adherence to the specified imaging protocol, and the performance of the technologist. The quality of the scanner is first checked and then subsequently monitored by imaging the Uniformity and Linearity (UAL) phantom with the MRI scanner used for this study.

### Filling the Phantom with Distilled Water

Before imaging, unscrew the three openings so that air can escape through the opposite hole. Fill the UAL phantom slowly with approximately 12 liters of **distilled water** using the water bottle that was provided. Air bubbles should not be present. After the main section of the phantom has been filled, fill the raised reservoir as indicated below with the red arrow.



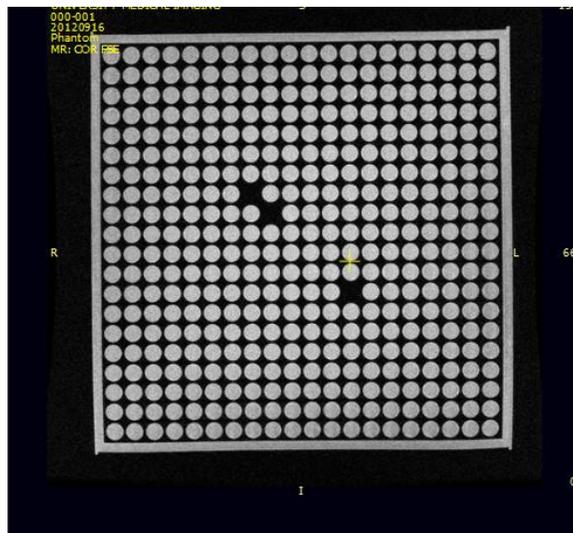
*Figure 2 UAL Phantom*

### UAL Phantom & Scan Entry

At the scanner, both the Patient ID and Patient Name should be the site number with a dash and then "UAL" (example: 101-UAL). In addition, the Study Description would be the site number and the Date of Birth would be the current year.

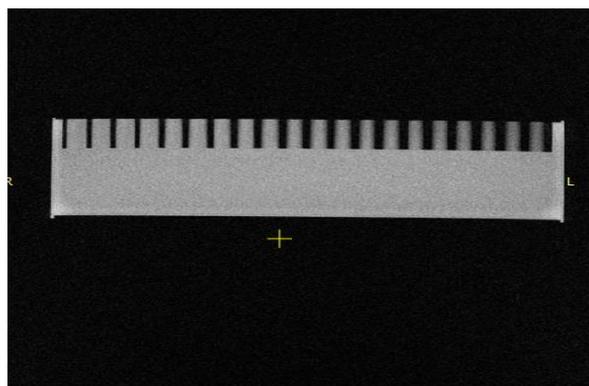
## MR Imaging the UAL Phantom

The phantom is imaged in both the coronal plane and in the axial plane. For coronal images, position the phantom flat on the MRI table; please do not remove the table pad. Below, the coronal view of the UAL Phantom is pictured.



*Figure 3 Coronal View*

For axial imaging, position the phantom on the table so that it stands on its side across the width of the table. Secure it using Velcro straps. Below is an image of what the axial view of the UAL Phantom would look like:



*Figure 4 Axial View*

## UAL Phantom Imaging Protocol

Sequence	2D Fast Spin echo
Repetition Time (TR)	4000
Echo Time (TE)	60
Echo Train Length (ETL)	8

Slice thickness	3 mm
Space between slices:	3 mm
Matrix	512 x 384
Field of View (FOV)	36 cm

## UAL Phantom Quality Check

In order to ensure a high quality UAL Phantom scan, check that the following things have taken place:

- The landmark is at the center of the UAL Phantom
- The scan covers the entire UAL Phantom so that the first and last images do not have any part of the phantom in them
- The whole phantom needs to be in the image field without any corners being cut
- Make sure that the naming convention for this scan has a 3-digit site number, a dash, and then "UAL" (example: 101-UAL)

## Saving and Transferring Phantom Images

Save the image series into the site's data archival system as you would any routine clinical study using the naming convention described above. Then transfer the image data to Qmetrics as described in the section named "Image Data Transfer to Qmetrics."

## ACR Procedures (for ACR accredited/US Sites)

Many US sites participate in the American College of Radiology program<sup>1</sup> which includes a component that evaluates image quality standards for MRI. In order to maintain membership within this program, sites must submit a qualification scan of an ACR phantom every 6 months which is then evaluated by the American College of Radiology Association for compliance. In addition to sending the qualification scan to the ACR, the site would also send this scan to Qmetrics. It is recommended that the site send their qualifying ACR scan to Qmetrics at the same time that they send the scan to the ACRA.

Any US sites that do not participate in the ACR program should refer to the section "For European Sites or Those Without ACR Accreditation" on page 9 above.

## ACR Naming Convention

The naming convention for this particular scan should include the 3-digit site number, a dash, and then "ACR." This will help Qmetrics distinguish the type of image data that is received.

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<sup>1</sup> American College of Radiology and American College of Radiology Association, <http://www.acraccreditation.org/Modalities/MRI>

## **Saving and Transferring Phantom Images**

Save the image series into the site's data archival system as you would any routine clinical study using the naming convention described above. Then transfer the image data to Qmetrics as described in the section named "Image Data Transfer to Qmetrics."

## **Volunteer Scans**

The volunteer scan helps Qmetrics ensure that the site understands and is able to implement the protocol successfully, and also allows an opportunity to improve that protocol, if needed.

After the UAL Phantom scan has been submitted and approved, the site will scan a volunteer using the site-specific protocol that has been established by Qmetrics. The volunteer can be anyone, including a staff member. Once approved by Qmetrics, the site is ready to scan the first patient.

## **Study MRI Scans**

### **Scheduling Study Subjects for Imaging**

Your Investigator's Study Coordinator will schedule study subjects for imaging using your routine patient scheduling procedure. The study subject must be pre-screened for imaging contra-indications according to your sites pre-screening guidelines.

During the scheduling the study coordinator will identify:

- Study name
- Subject's study ID number
- Index knee (the knee to be imaged)
- Visit (Screening, 1 mo, 12mo , 24mo, or 36mo)

The Subject's ID number will be a 3-digit number, a dash, and another 3-digit number. The first three digits will correspond to the investigator's country and site number while the last three digits correspond to the subject number (Example: 101-001). The sponsor will be made aware of any deviation from the protocol and this will result in a Memo to File.

When scanning a volunteer, the naming convention would be the 3-digit site number, a dash, and then "Vol" so that it is easily discernable within the data upload portal (Example: 101-Vol). The naming convention doesn't change, despite the time point and the number of rescans.

### **Prescreening the Study Subject for MRI**

All study subjects must be pre-screened for MR imaging contra-indications according to the site-specific clinical screening procedure. All subjects with contra-indications for MR imaging will be excluded from the study.

ALL acquired STUDY MRIs must use the same imaging protocol and T2 phantom belt.

## Subject Preparation Before Imaging

This study does not require specific preparation. Follow your imaging center's guidelines regarding subject's clothing, time of arrival, etc.

## Subject Imaging Procedures

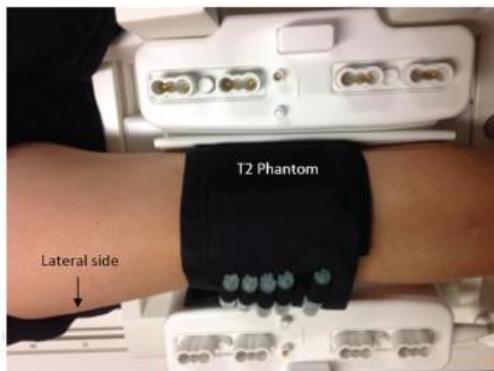
### 1. Subject Preparation

- Identify the subject; check wrist name tag and other identifiers used by your imaging center, then verify which knee is the index knee.
- Screen for MR imaging contra-indications according to your site's guidelines and screening forms.

If there are no contra-indications, continue to the next step.

### 2. Subject Positioning

Position the knee coil on the gantry to accommodate feet-first position of the subject and the side of the index knee. Strap the T2 phantom belt around the knee so that the T2 phantoms are laterally just distal to the patella. Secure the strap using the Velcro.



*Figure 5 T2 Phantom belt placement*

Use a knee bag or folded towel under the knee for subject comfort. Position the footrest at the end of the table and strap the subject's foot to it for stability. Make sure the Subject's knee is at the center mark of the coil at the caudal end of the patella.



*Figure 6 Foot rest placement*

### **3. Landmark**

Should be in the center of the coil.

### **4. Subject Identification**

Enter subject's study ID into the Patient ID and Patient Name fields, the index knee in the Study Description field, and enter a date of 1/1/2016 into the Date of Birth field. Do not fill in subject's height, weight, address or any other personal health information corresponding to the subject.

***\*Note: any time that the Subject's study ID isn't correctly assigned to image data will result in a protocol deviation and a Memo to File.***

### **5. MR scanning**

Select the Anika imaging protocol from your scanner's imaging protocol library. Scan the subjects according to this MR imaging protocol. Please follow the order of imaging sequences as indicated in the protocol; this protocol is also in Appendix A.

### **6. Documentation**

All image series acquired during this session need to be recorded in your patient log book.

### **7. Image Quality Check**

Check the quality of acquired images according the following guidelines. Please do not let the subject off the table before verifying good image quality.

- The FOV of all images must cover the *bony components* of the knee
- No wrap in the area of imaged bones or ligaments
- T2 phantoms must be visible
- No motion artifact
- Homogenous fat suppression
- No zipping or overlapping slices
- See Figure 7 for acceptable images versus unacceptable images in Figures 8 & 9

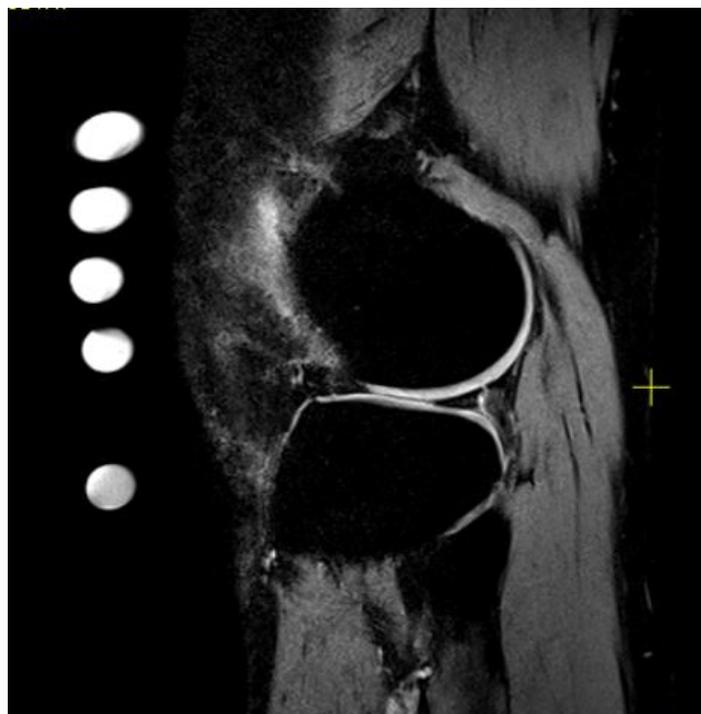


Figure 7 Acceptable: high quality 3D sequence showing good fat suppression, no patient motion, and all T2 phantoms in the phantom belt



Figure 8 Unacceptable: first echo of dual echo series shows considerable subject motion

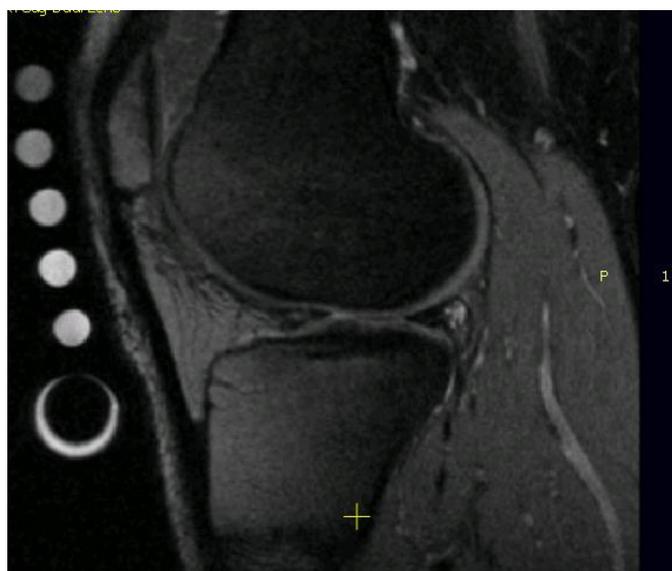


Figure 9 Unacceptable: shows no fat suppression, leading to water suppression in the anterior knee

## 8. Rescanning

If you find image quality of one of the image series unacceptable, rescan that series.

**9. Saving image data**

Save the image data on your site's image archival system as you routinely do.

**10. Create copy of image data on CD**

Save all image series onto the CD (the imaging series only). Please do not add any viewer or compress the files.

## Image Data Transfer to Qmetrics

### Preparing Image Data for Transfer

To securely transfer the screening image data, you must be able to access the image data from the system logged into the Qmetrics data transfer page. Typically, the study is burned to a CD and the CD is loaded into the system that will be used to perform the image data upload via the Web. The CD will be stored with the subject's study records.

### Access to the Qmetrics Technologies Data Transfer page

Qmetrics will provide you with login credentials to the data transfer page, using a Web browser. Your site may have several individuals authorized to access the transfer website and enter or upload image data. Please do not share login information with anyone. If you have additional people who need to access the site, please contact Qmetrics for additional login credentials.

The web form enables you to easily provide the required information about study subjects and their imaging study, and also see information about the status of transfers for all subjects enrolled at your site.

### Logging into the Secure Qmetrics Technologies' site

Please direct your web browser to the Qmetrics image data transfer page:

**<https://web.qmetricstech.com/040-0003/>**

You will be prompted to enter your username and password, which will be provided to you by Qmetrics. If you do not have a username and password, contact Qmetrics ([datamanager@qmetricstech.com](mailto:datamanager@qmetricstech.com)) and they will provide it to you.



Language: English

**Osmosis Login Form**

User Name:

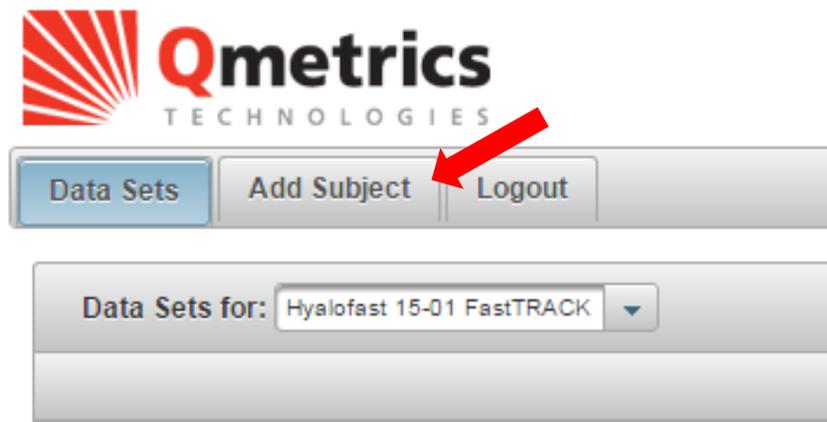
Password:

©2012 Qmetrics Technologies

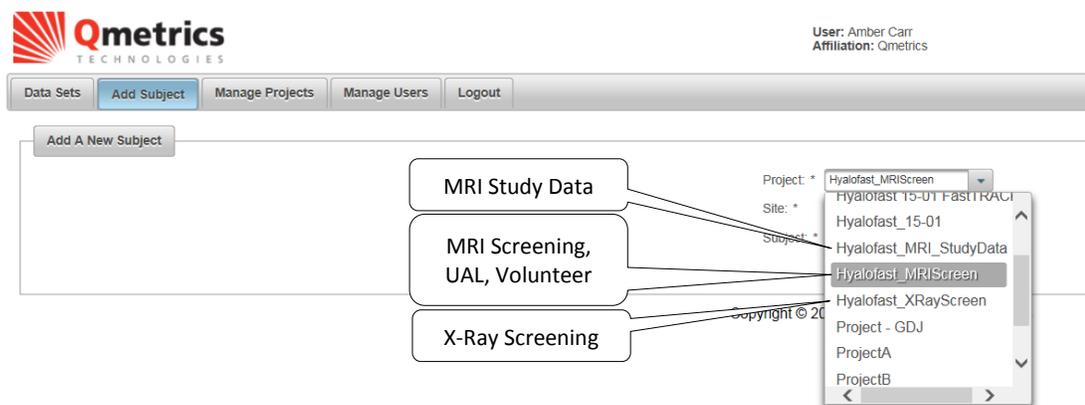
If you have forgotten your password, please click the "reset password" link and follow the instructions for resetting your password.

## Adding a New Subject

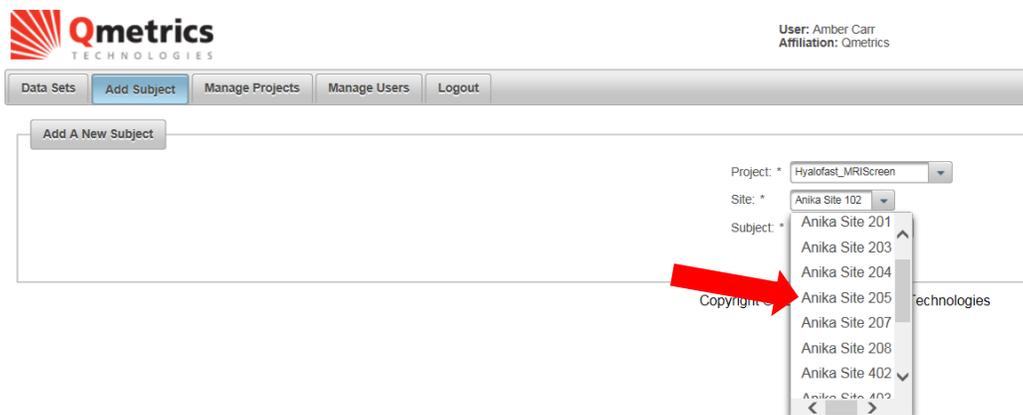
1. On the menu bar, click on the Add Subject tab.



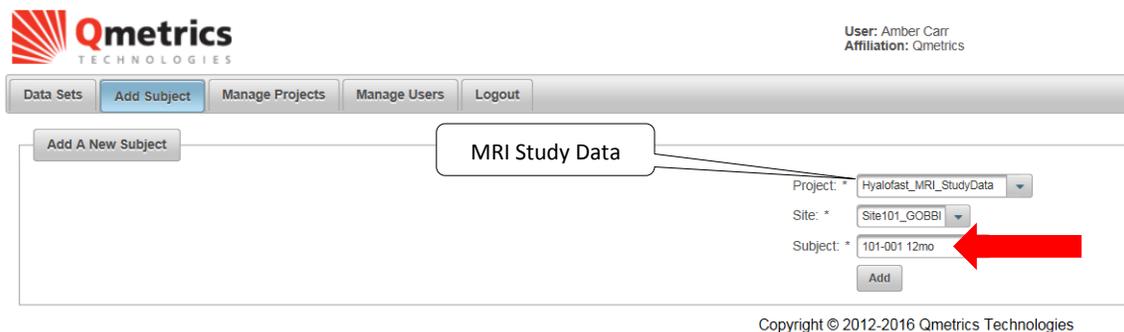
2. Ensure that the correct Project is selected by clicking on the arrow for the drop-down menu. You will be able to choose between three different projects:
  - For MRI Screening data (including UAL, ACR, or volunteer scans), select "Hyalofast\_MRIScreen"
  - For X-ray Screening data, select "Hyalofast\_XRayScreen"
  - For ALL MRI Study data, select "Hyalofast\_MRI\_StudyData"



3. Next, select your site number from the drop-down list. (Note: Unless you are supporting multiple sites, you will only have one menu choice with your site number).



4. Enter the subject ID in the subject field. In addition, if you are uploading Study Data, add a brief description indicating the time point that was uploaded. (**Example: 101-001 24mo**)



5. Click the **Add** button.



## Locating New Subject

- On the menu bar, click on the **Data Sets** tab. You should now see the subject you just added in the list of subjects. (Hint: you may need to go to the last page of the list.)

Subject ID: \*   
 Description: \*   
 Estimated Date: \*

Data Sets for: Hyalofast\_MRI\_StudyData Search all fields:

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Action	Site Visible	Site	Subject ID	Status	Description	Reason	Estimated Date	Uploaded Date	Details
	<input checked="" type="checkbox"/>	Anika Site 201	201-001-MRI Screening	Accepted	Image Set			Feb 12, 2016	
	<input checked="" type="checkbox"/>	Site 202_Szody	202001	Rejected	Image Set	Images did not pass because of motion - Rescan needed		May 22, 2016	
	<input checked="" type="checkbox"/>	Site 202_Szody	202-001	Accepted	Image Set			Jun 2, 2016	
	<input checked="" type="checkbox"/>	Anika Site 203	203-001	Not Received	Image Set				
	<input checked="" type="checkbox"/>	Anika Site 204	204-002 1mo MRI	Rejected	Image Set	Motion on both SAG 3D and 2D, rescan needed		Aug 2, 2016	
	<input checked="" type="checkbox"/>	Anika Site 204	204-002 1mo MRI	Accepted	Image Set-Rescan		Aug 5, 2016	Sep 6, 2016	
	<input checked="" type="checkbox"/>	Site 202_Szody	202-003	Accepted	Image Set			Aug 15, 2016	
	<input checked="" type="checkbox"/>	Anika Site 207	207-VOL_2	Rejected	Image Set	Site needs training first		Sep 28, 2016	
	<input checked="" type="checkbox"/>	Anika Site 207	207_VOL2_1	Rejected	Image Set	Site needs training first		Sep 28, 2016	
	<input checked="" type="checkbox"/>	Anika Site 207	207_VOL2_3	Rejected	Image Set	Site needs training first		Sep 28, 2016	
	<input checked="" type="checkbox"/>	Anika Site 207	207_UAL_1	Rejected	Image Set	Site needs training first		Sep 28, 2016	
	<input checked="" type="checkbox"/>	Anika Site 207	207-UAL_2	Rejected	Image Set	Site needs training first		Sep 28, 2016	
	<input checked="" type="checkbox"/>	Anika Site 207	207-UAL-VOL	Not Received	Image Set				
	<input checked="" type="checkbox"/>	Anika Site 207	UAL-VOL	Not Received	Image Set				
	<input checked="" type="checkbox"/>	Anika Site 102	Volunteer scan	Not Received	Image Set				
	<input checked="" type="checkbox"/>	Anika Site 102	volunteerMRIsCan	Received	Image Set			Sep 30, 2016	
	<input checked="" type="checkbox"/>	Site101_GOBBI	101-001 12mo	Not Received	Image Set				

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## Uploading the Image Data

- On the web form, you should see the subject's study ID in the Subject ID column. Click on the "Upload" link at the far left to begin the process of uploading the image data for the subject. Be sure to select the correct row corresponding to the subject you are uploading image data for.

	<input checked="" type="checkbox"/>	Anika Site 207	207-UAL-VOL	Not Received	Image Set
	<input checked="" type="checkbox"/>	Anika Site 207	UAL-VOL	Not Received	Image Set
	<input checked="" type="checkbox"/>	Anika Site 102	Volunteer scan	Not Received	Image Set
	<input checked="" type="checkbox"/>	Anika Site 102	volunteerMRIsCan	Received	Image Set
	<input checked="" type="checkbox"/>	Site101_GOBBI	101-001 12mo	Not Received	Image Set

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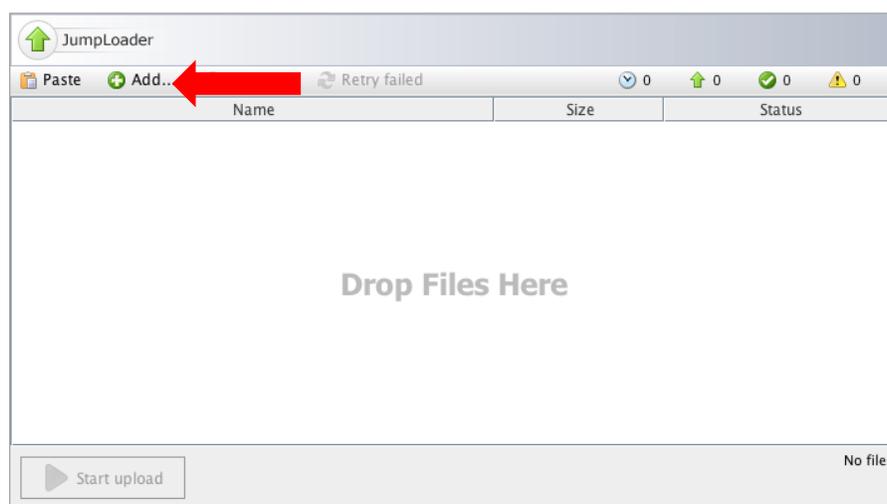
Copyright © 2012.

**NOTE: This dialog requires Java and Javascript to run. Depending on your browser and system configuration, you may see warnings or prompts to confirm your intent to run Java. Please respond to the prompts to enable the dialog to run.**

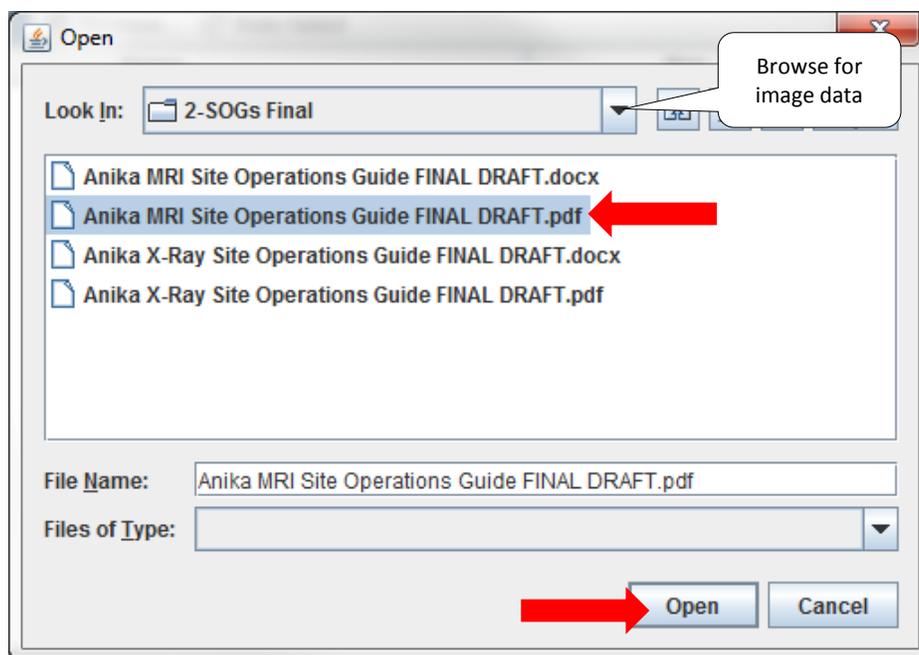
- If Java has been properly enabled, you may see this symbol on your screen as it initiates.



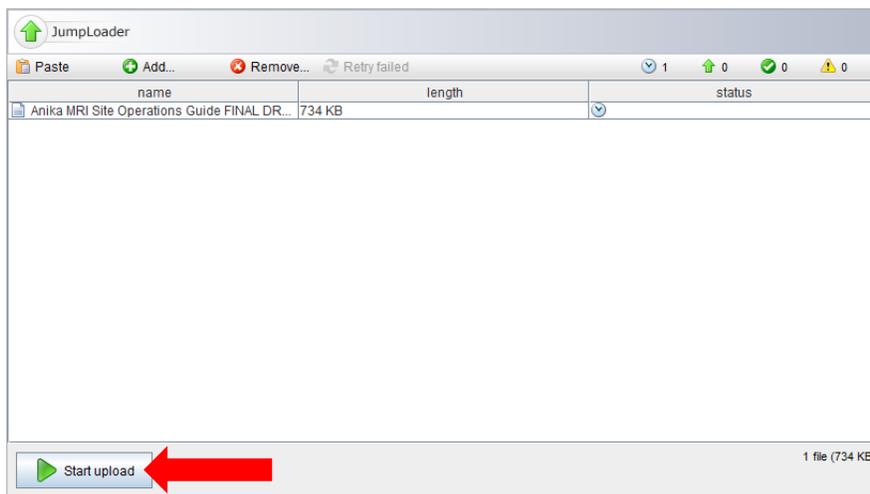
9. You should see the dialog below. Click the **Add** button.



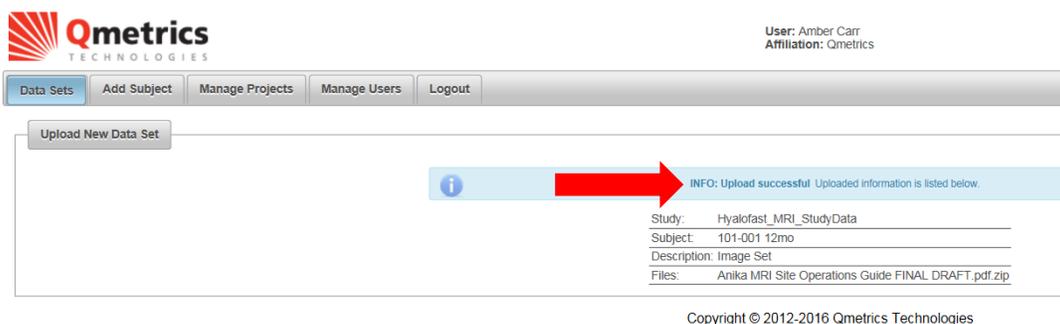
10. Now you will be able to browse your system to search for the image data for the study. Once it has been located and selected, click **Open**.



- The data that you chose will show up in the JumpLoader dialog box. This is where you can upload multiple files if needed. Once all the data has been put into this dialog box, click **Start Upload**.



- As the data is being transferred, the dialog will indicate the progress of the transfer. After the transfer is complete, you should see confirmation that the upload was successful:



- When you return to the **Data Sets** view, the subject information should be updated to reflect the receipt of the image data. Notice that the Status is now "Received."

Upload					
	<input checked="" type="checkbox"/>	Anika Site 207	UAL-VOL	Not Received	Image Set
	<input checked="" type="checkbox"/>	Anika Site 102	Volunteer scan	Not Received	Image Set
	<input checked="" type="checkbox"/>	Anika Site 102	volunteerMRIscan	Received	Image Set
	<input checked="" type="checkbox"/>	Site101_GOBBI	101-001 12mo	Received	Set

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## Communications

### Status of Data Transfer to Qmetrics

After you have uploaded the image data, the status of the image transfer will be available in the Data Sets view. After the image data has been successfully transferred to the Qmetrics Core Lab, the Status field will show Received, to indicate receipt of data. As the data is processed by Qmetrics, the status will update to reflect progress. The possible status indicators are:

- NOT RECEIVED
- RECEIVED
- ACCEPTED
- REJECTED
- CANCELLED

#### **Not Received**

This indicates that the image line item has been created but the image itself has not been uploaded into the web portal yet.

#### **Received**

This indicates that Qmetrics has received the uploaded data. It does not indicate that the data is suitable for conducting the enrollment screening analysis.

#### **Accepted**

This indicates that Qmetrics has reviewed the uploaded data and found it to be acceptable for conducting the enrollment screening analysis. No further action is required.

#### **Rejected**

In the event that the data is unacceptable for conducting the enrollment screening analysis, the status will be updated to Rejected, with corresponding information in the Reason field. You must schedule the subject to re-acquire the screening image data. You will be contacted by Qmetrics to discuss the issues with the image data and ensure that the re-scan will address the issues.

#### **Cancelled**

In the event that a subject is removed from the study prior to acquisition of image data, the Status may indicate Cancelled. No further action is required.

## **Questions and Issues**

If you have questions or issues related to the activities and tasks described in this Site Operations Guide, please contact your Site Coordinator, or Qmetrics using the contact information listed in the front of this guide.

## **APPENDIX A – Site Specific Imaging Protocol**

### **Subject MR imaging protocol**

- GE imaging protocol
- Siemens protocol
- Philips protocol