

Alfred Radiology and Nuclear Medicine Services for Clinical Trials Guideline

The Radiology and Nuclear Medicine Departments provide imaging and procedure services for research to Alfred Health, the Alfred Research Alliance community and external research institutions. Services include:

Radiology - General x-ray, Computed Tomography (CT), Magnetic Resonance Imaging (MRI), Spec MRI (SMR), Fluoroscopy, Ultrasound, Bone Densitometry (DEXA), Mammography, Angiography, Biopsy, Interventional Radiology procedures, Image guided injections.

Nuclear Medicine - Positron Emission Tomography (PET), Gated Cardiac Blood Pool, Bone, Lung (V/Q), and Myocardial Perfusion Scans

Site Capability Survey Questionnaires

For commercial studies, Sponsors require Site Capability Survey Questionnaires to be completed. Alfred Radiology and Nuclear Medicine has a comprehensive <u>Site Capability and Equipment Document</u> that can be provided to Sponsors in place of the Questionnaires. (*Click to download*)

Please complete the Radiology and Nuclear Medicine Service Online Resource Form

The link for the online form is http://j.mp/3bLlgCF

The link can also be found on the Alfred Ethics Committee Website under Use of Hospital Resources

USER GUIDE AVAILABLE ON PAGE 4

Before you begin you will need the following essential items:

- Alfred HREC number (Call the Alfred HREC to assign a HREC number to your study x 63619)
- PI e-signature,
- Study protocol,
- Imaging protocol.

A copy of your imaging protocol is essential.

For commercially sponsored trials the imaging protocol is a separate document to the study protocol. In the document the Sponsor specifies how they want the imaging to be done across all sites participating in the study to ensure uniformity of the imaging data across all sites. If your imaging protocol is different to The Alfred standard imaging protocol it will be incorporated into the suite of protocols programmed into the appropriate imaging scanner.

The Radiology and Nuclear Medicine Department will determine if your imaging requirements are standard or above/different to standard of care based on the imaging protocol.

The information required includes the imaging modality (eg CT or MRI), how many subjects are expected, the frequency of visits, duration of the study and any other study specific requirements.

After you 'submit' the online form, you can download it and send it to the Alfred HREC with your study registration files.

The completed form with the costings and service manager signature will be sent to you via email for submission to the Ethics Committee.

Prior to the commencement of your study

You will receive a customized e-order **Request Form Template** (eRFT) for your study.

It is <u>essential</u> to use the eRFT for every trial imaging request as it will contain the technical, patient study ID, additional services and billing information for your trial.

If it is not used, your patient will be scanned incorrectly or not be scanned.

All requests must be ordered on CERNER. Instructions will be provided with your eRFT.

If you are ordering from outside The Alfred, you will be provided with a **Request Form Template** that you can email or fax to our Bookings Office.

Arrange a meeting to discuss your imaging protocol, scheduling requirements and QA/phantom scans with:

Radiology: The supervising radiographer for the modality required (see your eRFT)

Nuclear Medicine: Dr Martin Cherk / Mian Ti

Scheduling Scans

Every effort will be made to provide you with reliable scheduling (within follow-up windows) for research imaging and procedures. Designated days are set aside for research appointments. You can discuss streamlining your scheduling requirements during your meeting. You will be contacted if any changes to your scheduling need to be made.

Copies of Anonymised Images and Reports

Imaging at The Alfred is digital. Copies of anonymised images can be obtained from our digital platform, XNAT. You will be provided with a login to XNAT and your trial images can be downloaded from XNAT on to your own computer.

USER GUIDE AVAILABLE ON PAGE 13

Standard of Care Scans

Scans that are not additional to standard of care can be bulk billed. Any extra requirements (see Fee Schedule below) will be billed to the requesting department.

Above Standard of Care

All scans that are above standard of care will be billed to the requesting department. The imaging fees will be based on the Medicare Benefits schedule and fees will apply for extra requirements (see Fee Schedule below)

MRI scans

Please note that the government sets strict limits on the frequency and the type and of MRI scans that can be performed. There is also a limit on the number of licensed scanners (Medicare Scanners) for each hospital.

Standard of care MRI scans can only be performed on the licensed outpatient scanner, which has a **3-month waiting list**. The Radiology Department will aim to prioritise trial scans, however adherence to trial-specific timeframes cannot be guaranteed.

The ED scanner has a much shorter waiting list. However, the ED scanner is not licensed, therefore all scans performed on the ED scanner cannot be bulk billed and will be billed to the requesting department.

If **urgent MRI scans** are required, such as for baseline/screening, the participant can be booked on the ED scanner to avoid impacting recruitment.

Fee Schedule

Trial set-up and administration fees

Radiology: \$200 for internal & funding agencies \$450 for commercially sponsored trials **Nuclear Medicine:** \$200 for internal & funding agencies \$450 for commercially sponsored trials

XNAT (XSYNC) image transfer set up fee: \$400

Service	Fee	
Training of technical staff for commercial trials	\$70 per hour	
Anonymised images	\$25 per scan	
Image transfer to Sponsor by radiology staff	\$60 per scan	
XNAT image transfer fee	\$60 per scan	
XNAT image Storage > 3 months	\$5:00 per scan per year	
Q/A phantom scans	Equivalent to cost of the trial imaging scan	
Specialised reporting (eg RECIST, RANO)	\$150 per scan	
3D image reconstruction	\$60 per hour	
Advanced image analysis	\$60 per hour	
Development of an imaging protocol	\$500	

Imaging Fees:

The imaging fee is based on the Medicare Benefit Schedule, any additions to the standard imaging protocol plus a 35% on cost. External study accounts incur a 10% GST charge.

Alfred Health trial set up and imaging fees will only be charged to an Alfred Health Cost Centre. Invoices will not be sent directly to study sponsors.

For Alfred trials, your Alfred Health Cost Centre number is required. The ICAN (Internal Charge Advice Note) is incorporated into the sign-off of the online Radiology and Nuclear Medicine Services Form.

For external institutions you will have completed an ECAN (External Charge Advice Note) and invoice/s will be forwarded to you.

Procedure Costs

To assist with preparing a study budget, the table below contains the cost for commonly requested procedures. Complete costings for trials will be given in the Resource Form (see Quick Reference Guide, pg. 6).

PROCEDURE	COST (AUD)
СТ	
Brain - contrast Brain + contrast	263.32 337.50
Neck	310.50
Brain-Neck	573.82
Chest	357.75
Hi-Res Chest - contrast Hi-Res Chest + contrast	368.25 540.00

Abdo - contrast Abdo + contrast	337.50 486.50
Chest/Abdo/Pelvis (cap) - contrast Chest/Abdo/Pelvis (cap) + contrast	629.84 756.00
CAP Quad Phase Liver	756.00
MRI	
Contrast	60.48
Hepatobiliary-specific contrast	337.50
Brain Tumour Stroke Inflammation Epilepsy	544.32
Head trauma	544.32
Demyelinating disease	
CNS	494.15
Brain	544.32
Neck	514.08
Chest	604.80
Abdo	
Colorectal or liver Biliary or pancreatic	742.50 544.32
Chest, Abdo, Neck (Extra)	607.50 ea. 742.50 ea.
ULTRASOUND	
Abdo	150.26
Renal biopsy	259.81
Liver biopsy	158.29
PET/CT	
Extramedullary disease assessment	1200.00
XRAY	
Chest	63.65
DEXA	
Bone densitometry	140.47
MAMMO	
Single / Bilateral	72.86 / 120.82

Radiology & Nuclear Medicine Services

Online Request Form



USER GUIDE

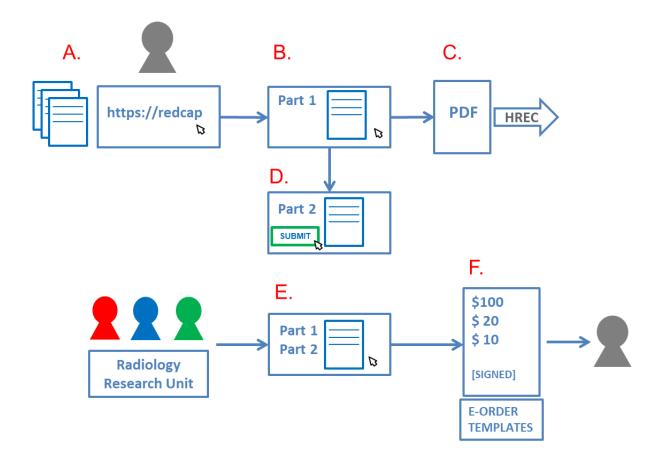
Technical Support:

Adil Zia

x62126

a.zia@alfred.org.au

QUICK REFERENCE GUIDE



- A. Trial Coordinator collects documents (Study Protocol, Imaging Guidelines, Procedure Manual, Medical Physicist Report)
- B. Trial Coordinator completes **Part 1** of the Online Resource Form.
- C. Follow prompts to download PDF version of **Part 1**. This document can be used for Alfred HREC Registration.
- D. Complete **Part 2** of the Online Resource Form. This is where you enter the imaging requirements and schedule for the trial. Submit **Part 1** and **Part 2**.
- E. The Radiology Research Unit, Modality Supervisors and Radiologists will access **Part 1**, **Part 2** and the uploaded documents and provide costing information.
- F. A Monash Partners PDF will be generated, which contains all trial information uploaded by the Trial Coordinator and costing information provided by the Radiology Department. The PDF will be emailed to the Trial Coordinator

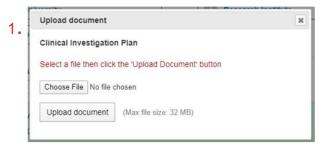
FULL GUIDE

PLEASE OBTAIN ALL STUDY- OR SPONSOR-SPECIFIC IMAGING OR PROCEDURAL GUIDELINES PRIOR TO COMPLETING THE FORM. IF THESE DOCUMENTS ARE NOT UPLOADED THEN STANDARD ALFRED PROTOCOLS WILL BE USED.

Radiology Service Request Form (Part 1)

Part 1 of the Online Resource form captures trial details, study staff contact details, invoicing information, and service requirements. See **GLOSSARY** for more information on each of the fields in Part 1.

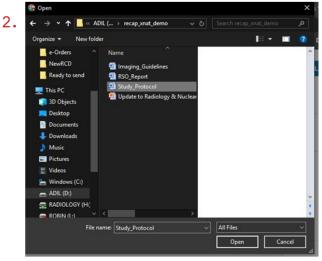
Uploading Documents

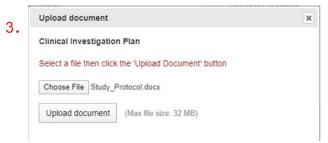


To upload documents:

Click on the Upload document link

Select Choose File (1) and locate the file on your computer (2). Then click Document Upload (3).



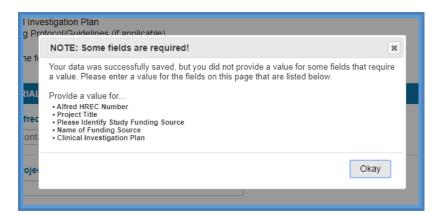


Submitting Part 1

The following fields are required:

- Alfred HREC Number
- Project Title
- Funding Source/Name
- Clinical Investigation Plan
- PI Signature

If any of these fields are empty, an error message listing the missing fields will appear when trying to submit. See **Save & Return Later** for instructions on how to save and come back to the form.



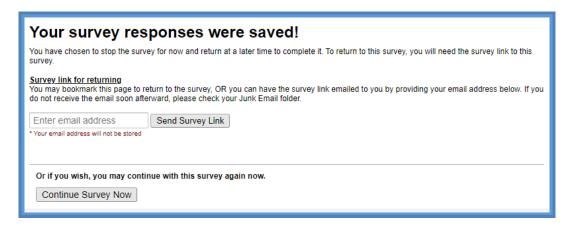
Once completed and all required fields have been filled, click **Submit** at the end of the webpage.

ONCE THE FORM HAS BEEN SUBMITTED YOU CANNOT RETURN TO THE FORM.

CONTACT RADIOLOGY RESEARCH UNIT FOR ASSISTANCE.

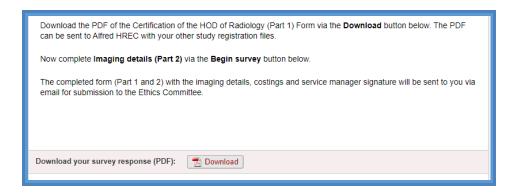
Save & Return Later

To save the form and return later, click **Save & Return Later** at the bottom of the webpage. Follow the directions and enter your email address to receive a link that will direct you back to the form. This link will be usable until you **Submit** the form.



Download Part 1 PDF

Once Part 1 has been submitted, you will be directed to download a PDF copy.



The PDF of Part 1 can be used for Alfred HREC Registration.

Imaging Details (Part 2)

Part 2 of the Online Resource form captures imaging schedule, number of patients and standard of care status. See **GLOSSARY** for more information on each of the fields in Part 2.

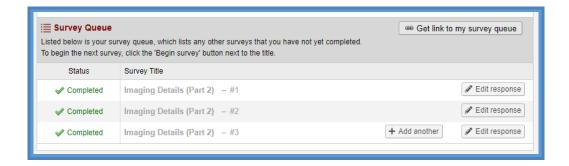
Example:

Modality	X-ray	MR	СТ
Body Region	Chest	Brain c-	CAP c -/+
Number of Patients	10	10	10
Imaging Sched./Freq.	Screening	Week 4, 16	8 weekly for 1 year
Standard Clinical Time points	1	Week 16	All

Click **Add another** to generate another set of fields. Each time **Add another** is clicked, the previous scan details will be saved.

For scans that are "CT (or MRI if contraindicated)", enter as two separate scans.

Click **Submit** once all scans have been entered. All scan entries will be listed as Imaging Details (Part 2) #1, #2, #3 etc.



Click on **Edit response** to edit any of the scans, or **Add another** to continue adding scans.

Click Close Survey when all scans have been added.

Completed Resource Form

The Radiology Department will review the submitted form (Part 1 and 2) and documents, and provide costings for each scan. A completed and signed Resource Form will be emailed to the Trial Coordinator along with e-ordering templates and instructions.

Amendments

Submit any amendments via email to the Radiology Research Unit, who will update and re-issue any documents that need revising. All documents will be emailed to the Trial Coordinator.

GLOSSARY

REQUEST FORM (PART 1)

CLIMI	CAL	TDIAL	DETA	11 6
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Alfred HREC Number Format: XXX/XX (Example: 001/20). Contact Alfred HREC

Office to be assigned an HREC Number

Project Title Full or short project title. No character/word limit

Funding Source Select all that apply

Name of Funding Source No character/word limit

Protocol Number No character/word limit

Expected Start Date Format: D-M-Y. If Day not specified, select 01-M-Y

Expected Completion Date Format: D-M-Y. If Day not specified, select 01-M-Y

TRIAL COORDINATOR & PRINICPAL INVESTIGATOR

Name Full names of Coordinator/PI

Email addresses for Coordinator/PI

Telephone Alfred extension (Format: x62126)

CONTACT FOR INVOICES

Name Full name of contact for invoices

Email E-mail address for invoices to be sent

Alfred Cost Centre? Will invoices be charged to an Alfred Cost Centre

Yes Enter Alfred Cost Centre (Format: A1234)

No Enter Company/Institution name

Address Enter Alfred department or Company/Institution address

Name of Campus involved in the

project

Example: The Alfred, Caulfield Hospital, Sandringham

Hospital.

SERVICE REQUIREMENTS	
Clinical Indication/Pathology	Brief description on the clinical indication/pathology of the trial cohort.
	Example: Stroke, Melanoma, HCC, Multiple Myeloma
Service Requirements	Radiology: X-ray, CT, DEXA, MRI, US
	Nuclear Medicine: PET, PET/CT, Bone scans, Blood pool
	Select all that apply
Do you have a study specific imaging protocol	If the trial has specific imaging requirements, please select Yes and <u>Upload Document</u> . The Modality Supervisors will determine if the requirements are standard or non-standard.
	By selecting No, standard Alfred imaging protocols
Study specific procedural protocol	If the trial requires any procedures (e.g. imaging guided biopsy), please <u>Upload Document</u> .
Will you require anonymized image download?	See XNAT User Guide and XNAT Fee Structure for information on creating an XNAT account, requesting and downloading images.
Do you require more than a standard patient report	Additional reporting includes RECIST, RANO, Lugano, Spleen volume. Please provide the name of the report and which images/time points require the additional reporting.
Do you require reporting by a specific consultant?	
Yes	Please provide the name of consultant.
Do you have any time critical	E.g. Baseline images for recruitment.
images that need to be to the sponsor?	The Trial Coordinator has to take responsibility for sending time critical scans to the sponsor.
	Radiology may provide assistance. Please see the <i>Fee Schedule</i> in the guideline.

Do any study specific forms need to be completed by Radiology/Nuclear Medicine?

Please Upload any documents or forms that need to be completed by Radiology staff.

Or email documents to a.zia@alfred.org.au

Does the sponsor require training

of Radiology technical staff?

Please see Fee Schedule for radiographer time required.

Will you require any other

measurements?

Yes/No

Will you require QC imaging data to

be sent to the sponsor?

Yes/No

Will you require an Accreditation

Certificate?

Yes Please download "NATA DIAS Cert- ALF Rad-NucMed

2018.pdf"

Will you require a signed copy of the Head of Department CV

Yes Please download "CV LAW 2018 signedDated.pdf"

IMAGING DETAILS (PART 2)

Modality Select only one

Body Region Area of body that requires scanning.

Example: CAP, Chest-Abdo-Pel, Brain, Brain-Neck

Include if contrast is needed

Example: CAP +/- contrast

Number of patients Expected number of patients

Imaging Schedule/Frequency Imaging schedule for scans Use either time point (e.g.

Baseline, Week 4, Week 8) or frequency (e.g. 4 weekly, 6

weekly)

Standard Clinical Time points Enter how many/which scans are standard of care for this

indication and patient group

Additional Notes Include any additional notes you deem relevant for this

scan.

Radiology & Nuclear Medicine Services

Anonymised Image Download



USER GUIDE

Technical Support:

Robin Lee 63606

ro.lee@alfred.org.au

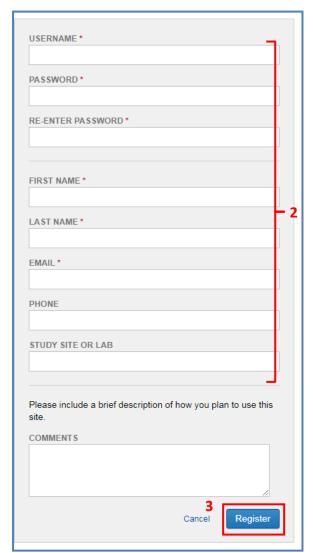
The primary function of XNAT is to de-identify DICOM files (Digital Imaging and Communication in Medicine) such as Computed Tomography and Magnetic Resonance images, from the Alfred Hospital Radiology PACS system or directly from the medical imaging system. XNAT operates within the Alfred Health network and firewall.

NEW USER REGISTRATION

Account Registration Link:

http://ahmldicom01.baysidehealth.intra/app/template/Login.vm





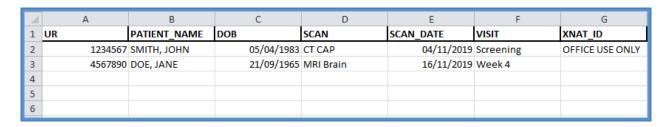
- 1. Click Register.
- Complete personal details. Use Alfred username (John Smith: smithj) and email (j.smith@alfred.org.au).
 "Study Site or Lab" = Department
- 3. Click Register.

Once the user has been authorised, a confirmation email will be sent to the email address provided.

Trials will be linked to the user upon request.

REQUESTING IMAGES

Use the XNAT Order Template to request images. The file can be found on <u>The Alfred Ethics & Governance Website</u>.



Email the table to Robin Lee (ro.lee@alfred.org.au)

Subject: <HREC No> Image Request

XNAT's anonymization function removes all patient identifiers and assigns an **XNAT ID**. The XNAT ID is a string of random characters unique to that patient. Due to the robustness of the anonymization algorithm, the XNAT ID <u>cannot</u> be edited – for example, to match the Study ID.

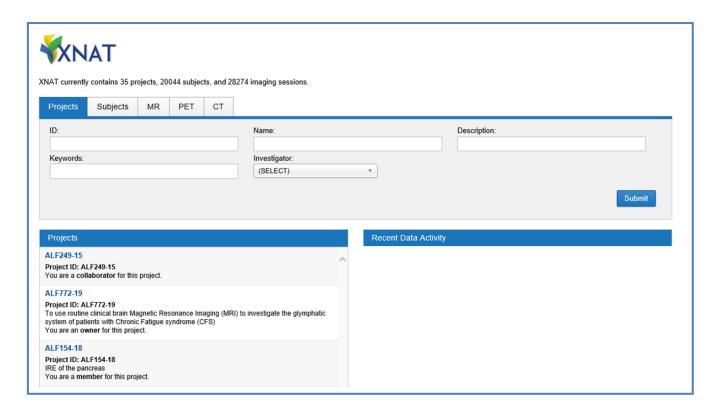
When requesting images using the XNAT Order Template, the Radiology Research Unit will enter the XNAT ID for each patient on the same spreadsheet and return it to the Trial Coordinator. This also notifies the Trial Coordinator that the requested images are ready for download.

	D	Е	F	G
	SCAN	SCAN_DATE	VISIT	XNAT_ID
983	CT CAP	04/11/2019	Screening	719ca134c55398c5d5cc32e3e51ace19e48e2528
965	MRI Brain	16/11/2019	Week 4	7393fc7371529984bd6bf623ad0df98b02cf9d0b

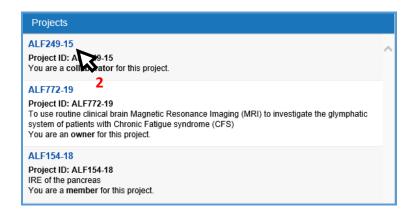
DOWNLOADING IMAGES

1. Logon to XNAT

Trials are listed in the **Projects** tab. Trials are titled **ALF<HREC No>** e.g. Trial 001/20 = ALF001-20.

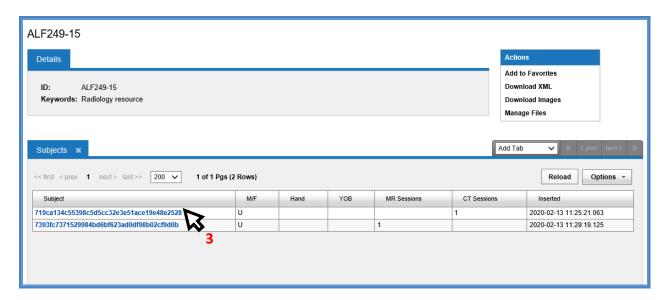


2. Select the Trial you require images from by clicking the Project.



All patients in the trial will be listed under the **Subjects** tab by their **XNAT ID** (e.g. 719ca1...) Refer to the XNAT Order Template to link the XNAT ID with the patient details.

3. Select the patient you require images from by clicking their XNAT ID.

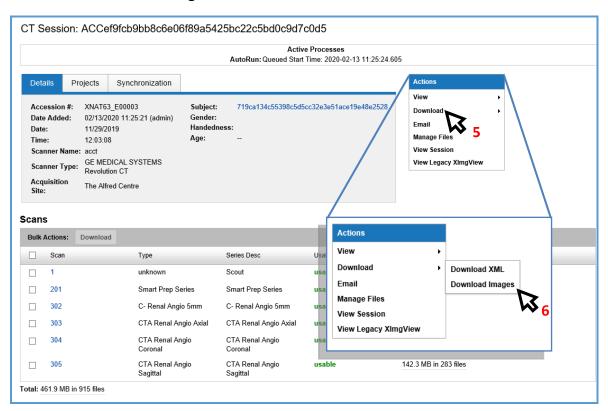


All scans that have been uploaded for this patient will be listed under **Experiements in <Project>**. The **Date** listed referes to the Scan Date (YYYY-MM-DD).

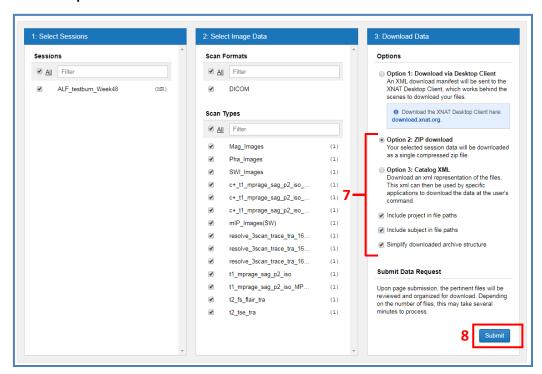


Select the scan you require:
 CT scans will be displayed as <u>CT Session</u>;
 MRI scans will be displayed as <u>MR Session</u>.

- 5. Under the Actions tab, click Download.
- 6. Click Download Images



7. Select Option 2 and all THREE CHECKBOXES



- 8. Click **Submit** and **Download ZIP**. In the ZIP folder, the file path is *Trial > Subject > Scan > Scan Series*.
- 9. Repeat Steps 3 8 for all scans required.