DOD ADNI
PET Technical Procedures Manual
Florbetapir F 18

V1.0
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General Information

Evidence suggests that both traumatic brain injury (TBI) and posttraumatic stress disorder (PTSD) increase risk for cognitive decline, AD, and dementia. TBI and PTSD are common problems resulting from military service. Thus far, there have been no prospective studies using imaging and biomarkers, which directly measure changes in the brain and AD pathology to study the effects of TBI and PTSD. The DOD ADNI study will provide novel data to test these hypotheses. The results will have major implications for identifying, subjects at increased risk for AD, a possible need for early detection of AD in military Veterans with histories of TBI and PTSD, and a possible need to employ prevention and treatment measures to avoid accelerated development of AD in US military Veterans. This study is a first step toward a larger, more comprehensive study of dementia risk factors in Veterans. The results will lead to a design and statistical powering of a prevention trial. Therefore, this project could be the first step toward the prevention of AD in Veterans, and in the general population.

Using the ADNI infrastructure, this project will use many of the ADNI sites, ADNI methods, and the ADNI data collection and analysis model.

The purpose of this manual is to further explain the PET imaging component of the DOD ADNI protocol. Standard procedures are needed to ensure consistency of data collection in the pilot study, and additional longitudinal follow-up visits, as we anticipate additional funds may be available to extend the study.

This manual contains information for study-site clinical staff involved with the care of study participants during the imaging procedure and those involved with the processing and transfer of PET imaging data.

Florbetapir F 18 PET imaging will be performed on all study participants during the baseline DOD ADNI clinic visit. Follow-up visits that may include Florbetapir F 18 PET imaging may be added, as funding permits.

Contact Information

If you have any questions or concerns regarding PET imaging please contact

adnipet@ucsd.edu

If you have any specific questions regarding Florbetapir F 18 ordering please contact:
Jennifer Payne

payne@avidrp.com

If you have question regarding the scan uploading to the LONI website please contact

adni@loni.ucla.edu

If you have any questions or concerns regarding individual participants please contact the study coordinator at your referral site.

Site Qualification

PET Scanners

It is preferable for sites to use existing qualified ADNI scanners for DOD ADNI. If a new scanner or hardware or software upgrades of the PET imaging system has occurred, the scanner will need to be qualified using standard ADNI scanner qualification before imaging can be performed.

Ideally, no hardware or software upgrades of the PET imaging system should occur during the duration of the study. In the event an upgrade occurs during the course of the study, we ask that you inform the PET core ***prior*** to the anticipated upgrade. Depending on the nature of the upgrade the site may be asked to repeat the phantom scans prior to scanning any additional subjects.

Contact adnipet@ucsd.edu prior to imaging if a new scanner will be used for DOD ADNI or if hardware / software upgrades have occurred.

Regulatory

Sites must be appropriately licensed through appropriate state or federal agencies to receive and use Florbetapir F18 prior to imaging.

Sites must also receive **IRB** approval, **DOD** approval and **radiation safety committee (RSC) or the equivalent** approval, before scanning any subjects.

Continued Quality Monitoring During Execution Phase

To ensure scanner/ancillary equipment stability and quality throughout the project, each site is required to perform ongoing quality control procedures.

Dedicated PET Scanner:

- PET scanner should have an up to date calibration and normalization on the date of each imaging session.

- A daily QC/blank scan (empty port transmission) scan should be done at the beginning of the day the scanning is to be completed. This scan should be visually inspected for abnormalities. If there is a possibility that the abnormality could impact the quality of the PET scan the study should be reschedule.

PET/CT Scanner:

- PET scanner should have an up to date calibration and normalization on the date of the imaging session.

- A daily QC check should be done at the beginning of the day the scanning is to be completed. This scan should be visually inspected for abnormalities. If there is a possibility that the abnormality could impact the quality of the PET scan the study should be rescheduled.

- Daily CT should be performed as recommended by the specific vendor, but typically should include a "checkup/calibration" procedure and a water phantom scan. The checkup/calibration procedure guarantees optimum image quality by warming up the x-ray tube and should be performed at startup and within 1 hour prior to any scan. The water phantom provides quality measurements of 3 parameters. The parameters are the CRT value of water calculated in Hounsfield units (HU), the pixel noise of images calculated as a standard deviation, and the tube voltages measured directly on the x-ray tubes. These three measurements should be determined for all available kVp values.

Ancillary Equipment:

- Quality control of dose calibrator should be performed throughout the course of the study. This typically will include daily constancy, quarterly linearity and annual accuracy.

PET Pre-Scan Procedures / General Information

Participants Pre-screening

All participants should have been screened by the study coordinator for the following contraindications

- Inability to cooperate/claustrophobia (sedation is not offered for this protocol)
- Inability to lie on the scanner bed for **30** minutes
- Total radiation dose exposure to the subject in any given year exceed the limits of annual and total dose commitment set forth in the US Code of Federal Regulations (CFR) Title 21 Section 361.1.

Florbetapir F 18 Ordering

Study coordinators and PET technologists will need to reference the Avid Radiopharmaceuticals, Inc. **Clinical Supplies Guidance Document (CSGD)** for all relevant documents regarding ordering, shipping and receiving Florbetapir F 18 for injection. Study coordinators will coordinate Florbetapir F 18 ordering with the PET imaging facility using the Florbetapir F 18 drug request form (DRF). AVID typically require a 5 day notification ***prior*** to the desired day of imaging to coordinate production and delivery.

Subject Preparation

Florbetapir F 18 Scans:

There are no specific dietary restrictions for the Florbetapir F 18 PET scans.

Participant Positioning

Proper patient positioning is a key aspect of the successful completion of the PET exam. It is important to take the time necessary to ensure not only that the patient is properly positioned but can comfortably maintain that position throughout the duration of the scanning session. **Excessive motion and in particular a difference in the subjects' position between the emission scan and the transmission (or CT) scan used for attenuation correction is the single most common cause of failed studies.**

- Have the patient remove any bulky items from their pockets such as billfolds, keys, etc. In addition, they should remove eyeglasses, earrings, and hair clips/combs if present. If possible they should try and remove hearing aids also.

- Position the patient so that their head/neck are relaxed. It may be necessary to add additional pads beneath the neck to provide sufficient support. Use the lasers to ensure there is little or no rotation in either plane. The head should be approximately positioned parallel to the imaginary line between the external canthus of the eye and the external auditory meatus.

- Use support devices under the back and/or legs to help decrease the strain on these regions. This also will assist in the stabilization of motion in the lower body.

- Once the patient has been positioned foam pads can be placed alongside the head for additional support. Velcro straps and/or tape should also be used to secure the head position. Vacuum bean bags can also be used in this process.

- If using a dedicated PET system it is helpful to perform a short emission or transmission scan to determine optimal axial position.

- The patients should be offered a "panic button" or be reassured that someone is watching or able to hear them at all times.

- **Proper positioning of the subject to get the entire head in the field of view is critical to the success of the project.**

- **Checking the patient positioning and readjusting (if possible) the position of the subjects' head should be done often throughout the study.**

Ambient Conditions

Florbetapir F 18 Scans**:**

Standardization of the environment during the 50 minute uptake period following Florbetapir F 18 administration is not essential.

Phantom Naming Convention

DOD ADNI Phantom Naming Convention (entered during LONI upload):
For the upload to LONI, phantom scans should follow the naming convention:

XXX_P_YYYY
X=Site#/ P=Phantom/Y=Phantom#

For example, each phantom scan from site 006 should be coded:

006_P_9999

Participant Naming Convention

It is ***VERY*** important that each site follow standard file identification so that all scans can be easily identified. The file ID will be assigned by the Clinical Study Coordinator at the clinical site prior to the PET visit.

For subject scans, the naming convention will NOT include a site identifier, rather only the 7-digit subject ID will be used when uploading scans to LONI.

In the ADCS EDC web portal, the SCRNO will equal SSSSSSS
[S = seven digits subject ID]

The seven digit subject ID will automatically append CS at the end of the ID to identify this is a clinic site participant

For example, a scan from a study participant referred to site 007 would be coded:

0001204 - CS

However, when the scan is uploaded to LONI only the 7-digit subject ID portion of the ID should be used. Additionally please ensure in the series description, the type of scan is identified as Florbetapir F 18. Also ensure the header information is complete for each and every scan.

De-identification

As part of the upload process to LONI, all the information entered into the scanner will be removed and replaced with the information entered during the LONI upload procedure. For this reason, you are encouraged to enter the phantom/participant scan information into the scanner following standard local practice. However if your site permits, you can use the above naming convention as the subject ID that is entered in the scanner as well**.**

Documentation

The study coordinator must ensure the PET Technologist has a copy of the Florbetapir F 18 PET Scan Information Forms prior to each scan session. Be sure to complete the metadata sheet ***as the study is being acquired.*** A process should be established for transferring this form back to the study coordinator. The study coordinator will then need to ensure the appropriate data is entered online within 24 hours of the scan.

Assessments and Endpoints for Florbetapir F 18 Scan :

The following assessments will be performed for all participants:

- Informed consent for DOD ADNI study;
- A 370 MBq (10 mCi +/- 10%) bolus injection of Florbetapir F 18 will be administered (saline should not be added to the dose prior to administration) and 20 minute continuous brain PET imaging will begin approximately 50 minutes post-injection. The images will be reconstructed immediately after the 20 minute scan, and if motion artifact is detected, another 20 minute continuous scan will be acquired.
- During the imaging session subjects will be observed continuously for signs of adverse events or serious adverse events.
- The injection site will be observed for excessive inflammation or damage to the surrounding tissue.
- Either a physician or a person designated by the physician, appropriate by training and experience, should be present during the Florbetapir F 18 injection and present to approve the discharge of the subject from the PET suite.

Follow-up post AV45 administration:

In the event of a sterility failure during the Florbetapir F 18 synthesis:

Avid will have the following plans for notification and follow-up of a possible sterility failure:

- Avid will notify the investigator immediately when the sterility test of a dose of Florbetapir F 18 injection shows growth (possible failure).
- Avid will conduct a sterility test failure investigation (which may take up to two weeks).
- Avid will notify the investigator of the outcome of the sterility test failure investigation (confirmed sterility failure and microbial identification or invalidated first test with a negative retest).

Avid recommends diligent monitoring of subjects who have received a dose having a possible failing or confirmed to have a failing sterility test result. The investigator should exercise appropriate medical judgment regarding treatment for possible or actual infection.

Florbetapir F 18**:**

- Have the patient use the restroom and empty their bladder.
- Allow them to lie comfortably in a bed or reclining chair in a room. Supply them with blankets/pillows as needed to maximize their comfort.
- Inspect the radiopharmaceutical dose solution prior to administration and do not use it if it contains particulate matter or is discolored.
- **Using aseptic technique and radiation shielding, draw 370 MBq (10 mCi +/- 10%)** of Florbetapir F 18 and assay with a dose calibrator. ***Record the assay time to the nearest minute.*** Do not q.s. (add saline) to the dose prior to administration. Adding saline could potentially lead to precipitation out of solution form.
- Inject the AV-45 through a short intravenous catheter (approx. 1.5 inches or less) as a single intravenous bolus. Follow the injection with an intravenous flush of 0.9% sterile sodium chloride. ***Record the injection time to the nearest minute.*** The IV line can be discontinued at this time.
- Re-assay the dose syringe and record the time of the residual assay. Record the amount and if the residual activity is 0.1 mCi or greater, correct the amount of the injected dose for the residual activity.
- Allow the subject to rest comfortably in the room for approximately 30 minutes for the incorporation of Florbetapir F 18 into the brain.
- At the end of the 30 minute incorporation period, have the patient use the restroom and empty their bladder.
- Position and secure the subject in the scanner using methods previously described. **Alignment marks should be put on the subject using the laser system, which can then be subsequently used to check alignment and reposition the subject as necessary.**
- Acquire a ***dynamic***, 3D scan consisting of four-5 minute fames. Acquisition must start 50 minutes post injection.
- **It is crucial that the subject's position is checked several times throughout the 20 min PET** scan. A good idea is to check the patient's marks **using** the laser system at the **end** of each 5 min scan frame. The subject's position should be returned as closely as possible to the original position **just at the beginning of the next scan** frame.

- All images will need to be corrected using measured attenuation.
  - PET Only Scanners
    - Acquire an attenuation correction scan using rod sources for 5-6 minutes after the acquisition of the emission scan. **Again it is absolutely crucial that the subject is repositioned "on their marks" prior to acquiring the transmission scan. The single most common reason for unusable PET scans is motion between the emission and transmission scans.**
    - Segmentation and re-projection routines will be applied for attenuation correction.
  - PET/CT Scanners
    - Standard CT acquisition parameters
    - The patient must undergo the CT scan starting at an appropriate time post injection to assure that the emission scan will begin at 50 min. Be sure to prepare the subject so that you are ready to press "start" for the PET scan at 50 minutes.

- Upon completion the subject can be removed from the scanner and encouraged to void. The subject should also be instructed to drink plenty of fluids and void frequently throughout the day to help reduce radiation exposure.

- Either a physician or a person designated by the physician, appropriate by training and experience, should be present to approve the discharge of the subject from the PET suite.

- Reconstruct images using parameters specific to the system used for scanning. (See Appendix A in this document).

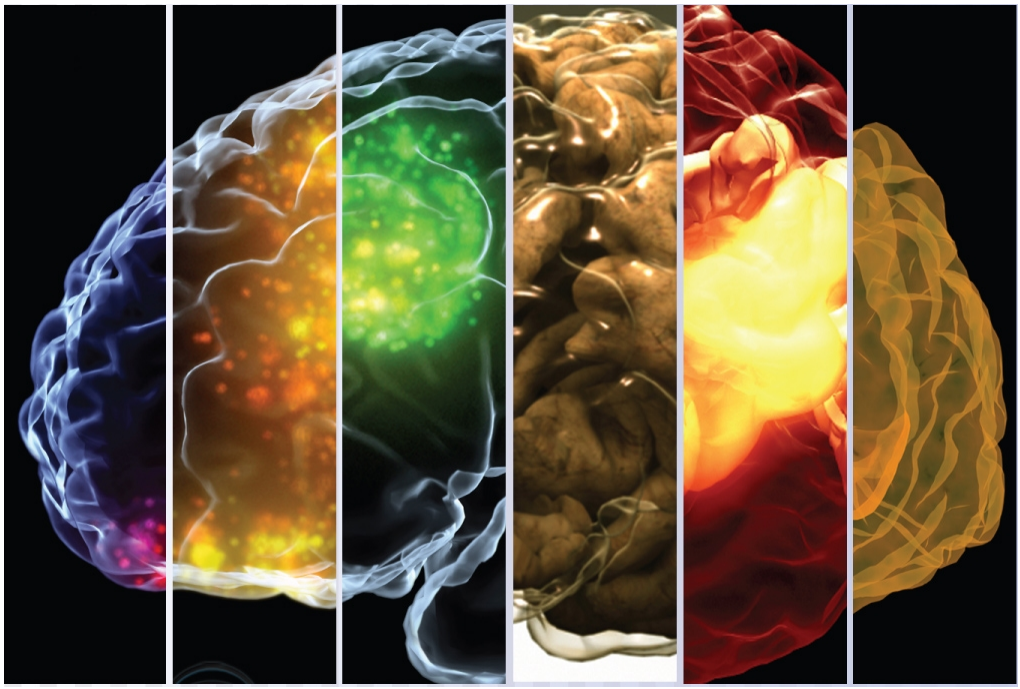
- Upon completion of the reconstruction, review all the images to assess for artifacts and motion.

- Archive **ALL** raw and processed study data including copies of the normalization and blank scans. It is necessary to archive and store raw and processed data at the imaging site for the duration of the project (approximately 2 years).

- Transfer image data to the Laboratory of Neuroimaging (LONI) at UCLA. Please upload only the fully corrected image set.

IMPORTANT: Data uploads to LONI should be performed as soon as the images have been acquired & reconstructed as it will be important to promptly QC the data to identify if the scan needs to be repeated. The timeframe should be 1-2 business days from acquisition.

Appendix A – LONI



Uploading PET data to the Laboratory of Neuro Imaging (LONI)

Image Data Archive Instructions

CONTENTS:

A - Image Data Archive Overview

B - System Requirements

C - User Registration

D - IDA Log in

E - Archive Process Overview

F - Archive Instructions

G - Archiving Data in Batch

A - IMAGE DATA ARCHIVE OVERVIEW

The LONI Image Data Archive (IDA) provides an integrated environment for safely archiving, querying and visualizing neuroimaging data utilizing a web-browser interface. The archive protects data from unauthorized access while providing the ability to share data among collaborative investigators.

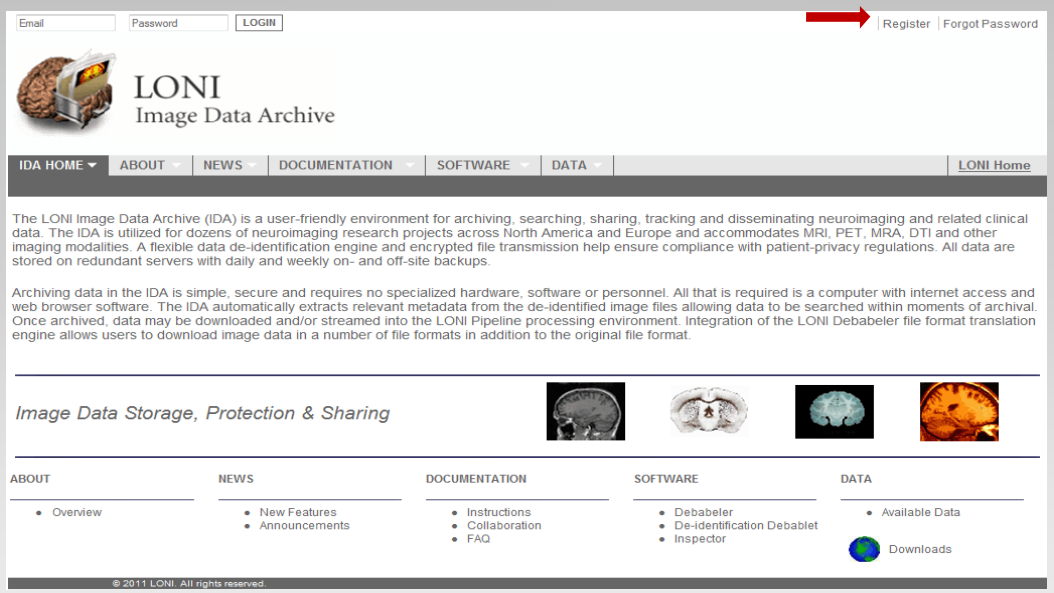
For questions or problems with the IDA please send email to adni@loni.ucla.edu

B - SYSTEM REQUIREMENTS

The IDA system requires a computer with Internet access, newer web browser software (IE, Netscape, Mozilla, Safari), Java Plug-in (Oracle/Sun version 1.5 or higher), and a valid user account.

C - USER REGISTRATION

If you do not have a user account, Click Register on the Image Data Archive Log-In page. **https://ida.loni.ucla.edu.**

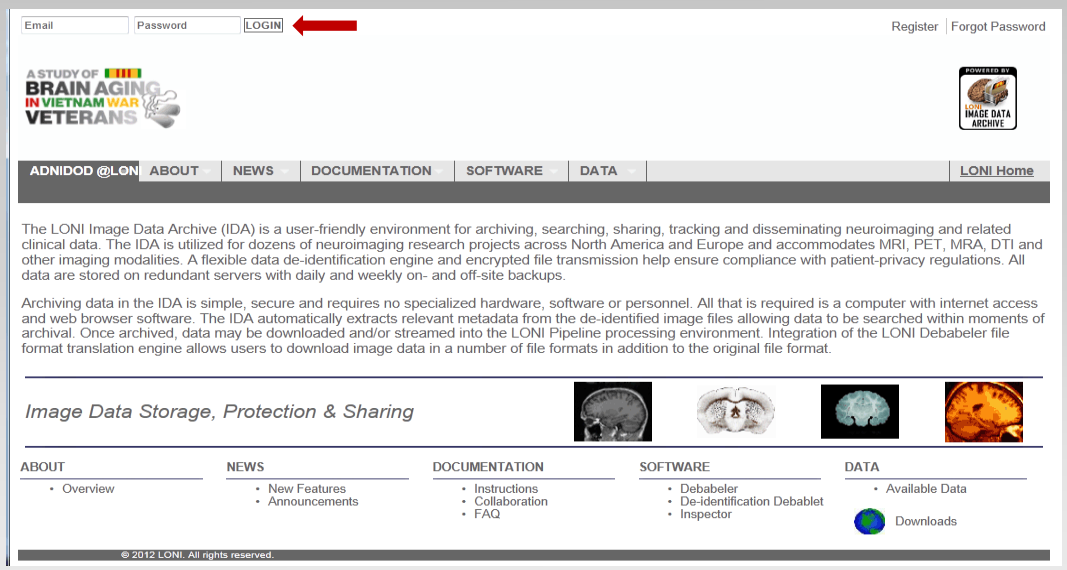


Complete the form to create a new account then click the REGISTER button.

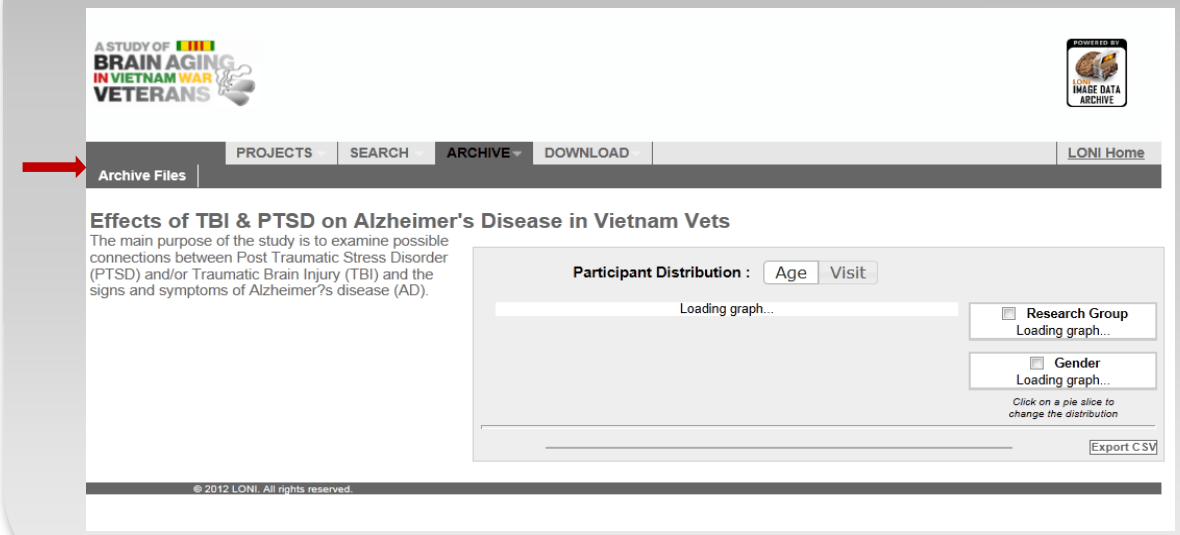
Once the registration process is complete, a confirmation email will be sent with a temporary password and login instructions.

D – IDA LOG IN

On the Log-in page at https://ida.loni.ucla.edu/login.jsp?project=ADNIDOD, provide your email address and then click Login. New users, please refer to the user registration section for instructions on how to register for a user account.



Select Archive Files from the ARCHIVE menu.



E – ARCHIVE PROCESS OVERVIEW

There are two steps in the archive process: de-identification and file transmission. The de-identification step removes or replaces potentially identifying subject information from image headers.

During the file transmission step, the de-identified files are securely transmitted to LONI and stored in the data archive.

SYSTEM REQUIREMENTS

The IDA system requires a computer with Internet access, newer web browser software (IE, Netscape, Mozilla, Safari), Java Plug-in (Oracle/Sun version 1.5 or higher), and a valid user account.

PROCESS

Following user authentication, the user chooses the data to be archived by selecting the directory where the data are located and chooses a directory where the de-identified files will be written. Next, a Java applet de-identifies the files, inserting the user-supplied subject identifier and removing or replacing other potentially identifying information. The user is given the opportunity to validate the de-identification results, prior to transmitting the images. Once the results of the de-identification process have been validated, the files are transmitted from the user's local computer to LONI. Upon arrival at LONI, the data are stored in a fault-tolerant storage area network and the database is populated with relevant metadata attributes.

The archive log in page is available from IDA Home page https://ida.loni.ucla.edu/login.jsp?project=ADNIDOD. Enter your email address and password then click the Sign-In button. New users, please refer to the user registration section for instructions on how to register as a user.

F - ARCHIVE INSTRUCTIONS

Use the Single Archive process to upload one or more files from a single subject.

PREREQUISITES

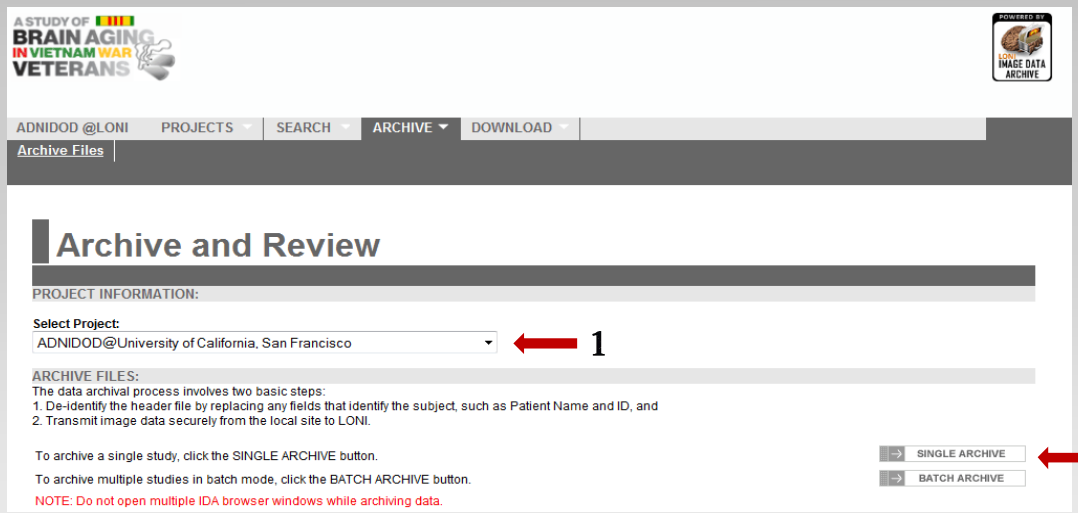
- Place all image files for each subject within a single directory (source directory), which may contain subdirectories. The source directory must not contain multiple image formats.
- Create an empty directory where the de-identified files will be written (target directory).

NOTE

- The browser window must remain open during the entire upload process. Closing the browser window cancels the upload.

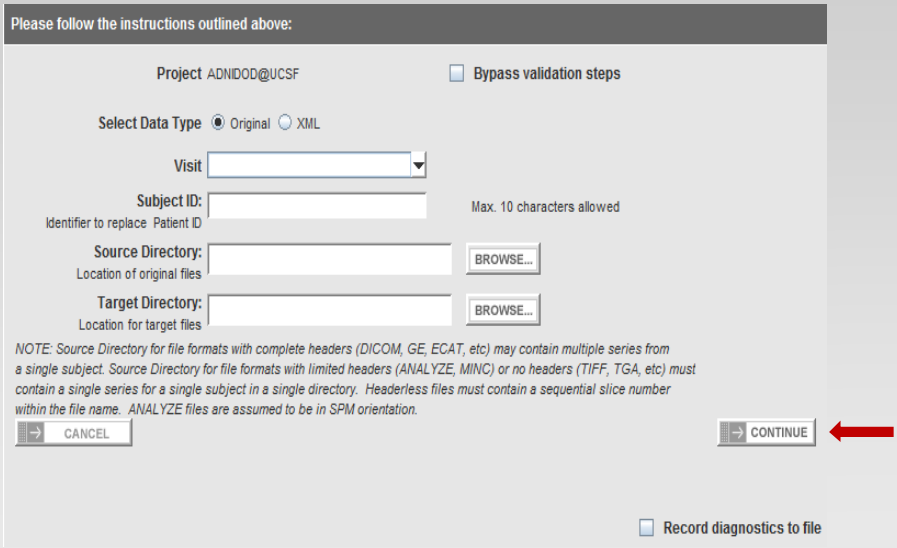
Choose Archive Files from the Archive menu.

- Select your Project/Site from the drop down menu (1).
- Click SINGLE ARCHIVE (2).



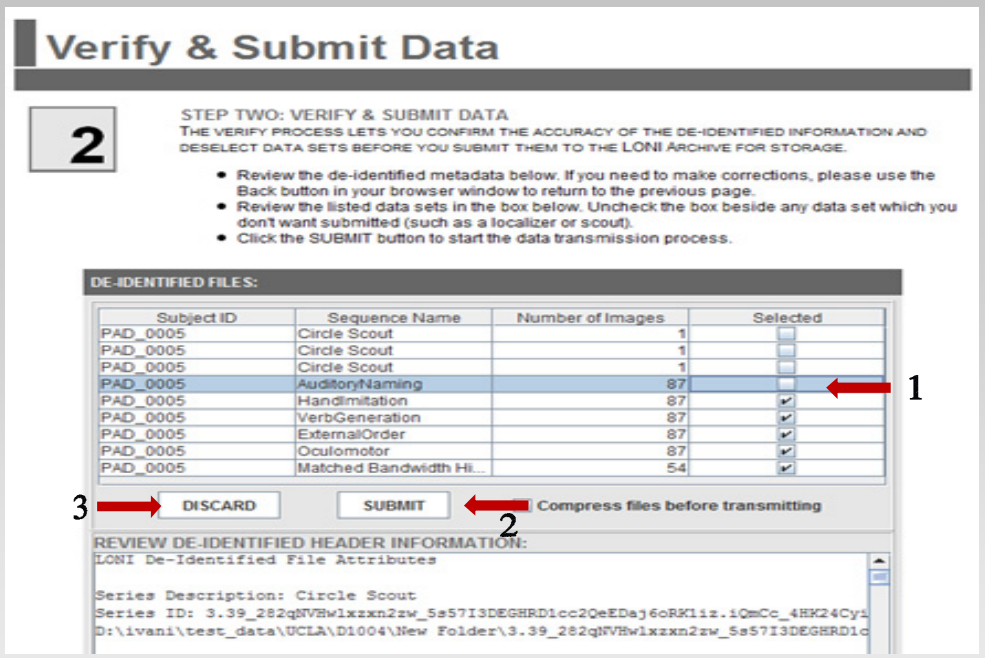
1. On the De-Identify page:

   - Select a Visit.
   - Provide a Subject ID.
   - Click Source Directory - Browse to find the directory which contains the file(s) to be uploaded or provide the directory path then click Select Source File Directory.
   - Repeat the process to select a Target Directory to contain the de-identified files.
   - To upload files without validating de-identification results, check the Bypass Validation Steps box (not recommended for first time users).
   - Click CONTINUE to begin the de-identification process.
   - To automatically record any issues during the archive process, check the box near Record diagnostics to file. You will be prompted to provide a location to store the diagnostics file. Note: this is an optional step.



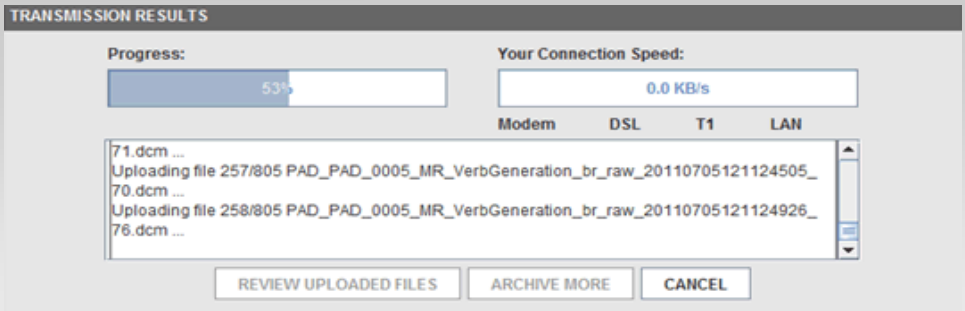
- When the de-identification step is complete, a list of de-identified files is shown along with the de-identified header information.

- To remove any images, uncheck the Selected box beside the image (1).
- Click SUBMIT to transmit the de-identified images (2).
- Choosing Discard cancels the upload and returns to the previous page (3).



- The progress bar shows the status of the file transmission step.

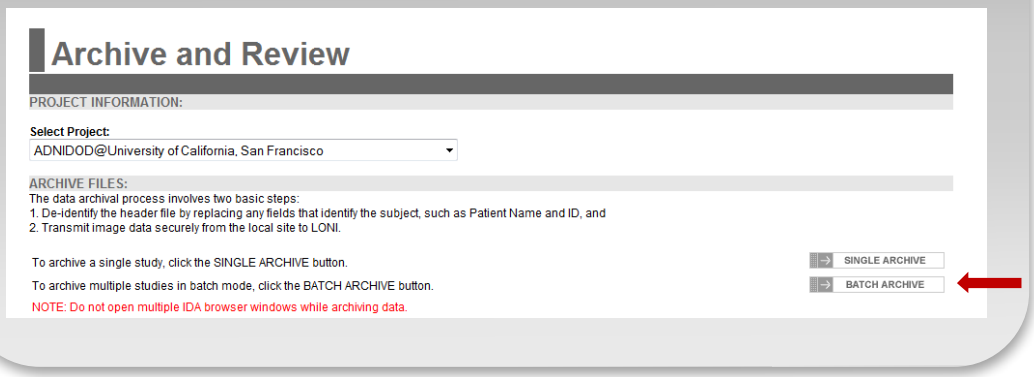
- Once the file transmission is complete, click REVIEW UPLOADED FILES to view the results of the archiving process
  .
- Or click ARCHIVE MORE to upload more files.



G. ARCHIVING DATA IN BATCH

The Batch Archive process is similar to Single Archive, except that multiple subjects and image series can be submitted in a batch. Batches can be of the same or different file formats and modalities. However, users cannot review the results of the de-identification process prior to the batch upload

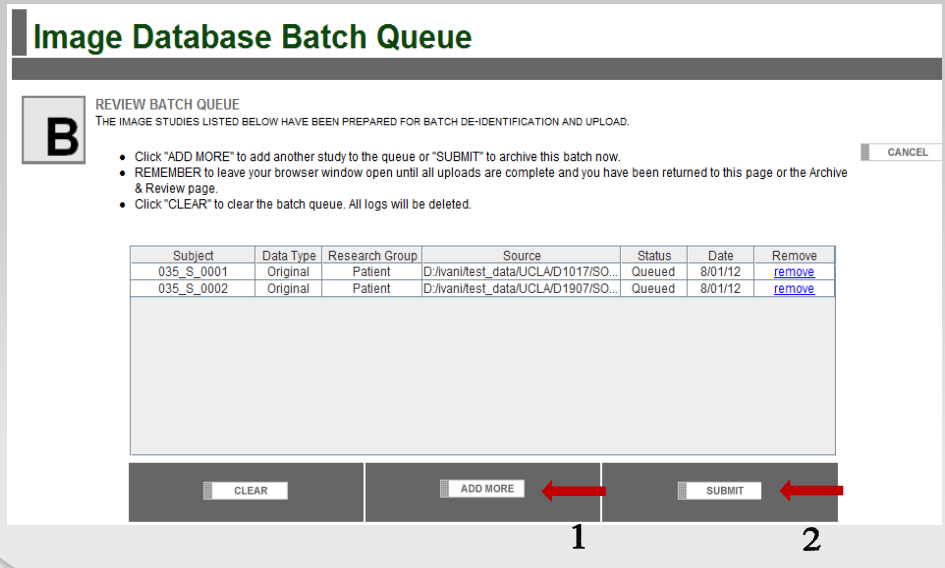
Click BATCH ARCHIVE on the Archive and Review page.



Follow the instructions on the Single Archive section.

On the Batch Queue page, click ADD MORE(1) to add more studies. Repeat this process for each series or subject to be archived.

Click SUBMIT(2) to de-identify and upload all files.



DETAILS:

- Once files are archived, click Review Uploaded Files to view a list of all the successfully archived images. Or click Archive More to upload more files

Appendix B – Scanner Specific Reconstruction Parameters

GE Discovery STE slice PET/CT scanners

Acquisition Parameters:

Radiotracer:
AV-45: **9.0-11.0 mCi**

Scan start time post-injection:
AV-45: **50 min**

CT scan:
Low mAs scan acquired shortly before emission. Leave enough time to start emission acquisition promptly at min.

Scans and scan duration:
AV-45: **20 min, four × 5-min** frames

Randoms Correction:
Singles (not real-time subtraction)

Reconstruction Parameters:

Iterative (fully 3D Iter; not 3D FORE IR)**:**
4 iterations; 20 subsets

Grid: **128 × 128**

FOV: **256 mm** (results in voxel size of 2.0 mm)

Slice Thickness: **3.27 mm**

Smoothing
Filter: **NONE or 0.0** (for all filter options: loop filter, post-filter and z-axis filter)

All corrections '**On**'

Questions: e-mail Robert Koeppe (koeppe@umich.edu)

GE Discovery 600 and 690 PET/CT scanners

Acquisition Parameters:

Radiotracer:
AV-45: **9.0-11.0 mCi**

Scan start time post-injection:
AV-45: **50 min**

CT scan:
Low mAs scan acquired shortly before emission. Leave enough time to start emission acquisition promptly at min.

Scans and scan duration:
AV-45: **20 min, four × 5-min** frames

Randoms Correction:
Singles (not real-time subtraction)

Reconstruction Parameters:

Iterative (fully 3D Iter; not 3D FORE IR)**:**
4 iterations; 32 subsets

Grid: **128 × 128**

FOV: **256 mm** (results in voxel size of 2.0 mm)

Slice Thickness: **3.27 mm**

Smoothing
Filter: **NONE or 0.0** (for all filter options: loop filter, post-filter and z-axis filter)

All corrections '**On**'

Questions: e-mail Robert Koeppe (koeppe@umich.edu)

GE Discovery ST - 47 slice PET/CT scanners

Acquisition Parameters:

Radiotracer:

AV-45: **9.0-11.0 mCi**

Scan start time post-injection:

AV-45: **50 min**

CT scan:

Low mAs scan acquired shortly before emission. Leave enough time to start emission acquisition promptly at min.

Scans and scan duration:

AV-45: **20 min, four × 5-min** frames

Randoms Correction:

Singles (not real-time subtraction)

Reconstruction Parameters:

Iterative if available (fully 3D Iter; not 3D FORE IR) Only if fully iterative is not available, as in some older systems, is it ok to use 3D FORE IR.

4 iterations; 21 subsets

Grid: **128 × 128**

FOV: **256 mm** (results in voxel size of 2.0 mm)

Slice Thickness: **3.27 mm**

Smoothing Filter: **NONE or 0.0** (for all filter options: loop filter, post-filter and z-axis filter)

All corrections '**On**'

Questions: e-mail Robert Koeppe (koeppe@umich.edu)

GE Discovery RX - 47 slice (LYSO) PET/CT scanners

Acquisition Parameters:

Radiotracer:
AV-45: **9.0-11.0 mCi**

Scan start time post-injection:
AV-45: **50 min**

CT scan:
Low mAs scan acquired shortly before emission. Leave enough time to start emission acquisition promptly at min.

Scans and scan duration:
AV-45: **20 min, four × 5-min** frames

Randoms Correction:
Singles (not real-time subtraction)

Reconstruction Parameters:

Primary Reconstruction Method: **Iterative** (3D Iter; not 3D FORE IR)**:**
4 iterations; 21 subsets

Grid: **128 × 128**

FOV: **256 mm** (results in voxel size of 2.0 mm)

Slice Thickness: **3.27 mm**

Smoothing
Filter: **NONE or 0.0** (for all filter options: loop filter, post-filter and z-axis filter)

All corrections '**On**'

Questions: e-mail Robert Koeppe (koeppe@umich.edu)

GE Discovery LS - 35 slice (PET/CT) scanners

Acquisition Parameters:

Radiotracer:
AV-45: **9.0-11.0 mCi**

Scan start time post-injection:
AV-45: **50 min**

CT scan:
Low mAs scan acquired shortly before emission. Leave enough time to start emission acquisition promptly at min.

Scans and scan duration:
AV-45: **20 min, four × 5-min** frames

Randoms Correction:
Singles (not real-time subtraction)

Reconstruction Parameters:

4 iterations; 21 subsets

Grid: **128 × 128**

FOV: **256 mm** (results in voxel size of 2.0 mm)

Slice Thickness: **4.25 mm**

Smoothing
Filter: **NONE or 0.0** (for all filter options: loop filter, post-filter and z-axis filter)

All corrections '**On**'

Questions: e-mail Robert Koeppe (koeppe@umich.edu)

GE Advance - 35 slice PET scanners

Acquisition Parameters:

Radiotracer:
AV-45: **9.0-11.0 mCi**

Scan start time post-injection:
AV-45: **50 min**

Transmission scan:
Five or six min 2-D scan acquired immediately **post**-emission scan; process with **segmentation**.

Scans and scan duration:
AV-45: **20 min, four × 5-min** frames

Randoms Correction:
Singles (not real-time subtraction, unless singles correction not available)

Reconstruction Parameters:

Primary Reconstruction Method: **FORE Iterative:**
4 iterations; 21 subsets

Grid: **128 × 128**

FOV: **256 mm** (results in voxel size of 2.0 mm)

Slice Thickness: **4.25 mm**

Smoothing
Filter: **NONE or 0.0** (for all filter options: loop filter, post-filter and z-axis filter)

All corrections '**On**'

Questions: e-mail Robert Koeppe (koeppe@umich.edu)

Philips Gemini TF - 90 slice PET/CT scanners

Acquisition Parameters:

Radiotracer:
AV-45: **9.0-11.0 mCi**

Scan start time post-injection:
AV-45: **50 min**

CT scan:
Low mAs scan acquired shortly before emission. Leave enough time to start emission acquisition promptly at min.

Acquisition Protocol: **Brain Protocol**

20 min, four × 5-min frames

Reconstruction Parameters:

Iterative: LOR 3D Ramla (*** Note: if only older software versions are available, 3D Ramla reconstruction is acceptable)

Grid: **128 × 128**

FOV: **256 mm** (results in voxel size of 2.0 mm)

Slice Thickness: **2.0 mm**

Smoothing: Set SMOOTH parameter to '**SHARP**'

All other parameters should be set to defaults for the "**Brain**" protocol

All corrections '**On**'

For LOR 3D Ramla reconstruction: The attenuation field should indicate "CTAC-SG" and the scatter field should indication "SS-Simul"

Questions: e-mail Robert Koeppe (koeppe@umich.edu)

Philips Gemini and Gemini GXL - 90 slice PET/CT scanners

Acquisition Parameters:

Radiotracer:

AV-45: **9.0-11.0 mCi**

Scan start time post-injection:

AV-45: **50 min**

CT scan:

Low mAs scan acquired shortly before emission. Leave enough time to start emission acquisition promptly at min.

Acquisition Protocol: **Brain Protocol**

20 min, four × 5-min frames

Reconstruction Parameters:

Iterative: LOR 3D Ramla (*** Note: if only older software versions are available, 3D Ramla reconstruction is acceptable)

Grid: **128 × 128**

FOV: **256 mm** (results in voxel size of 2.0 mm)

Slice Thickness: **2.0 mm**

Smoothing: Set SMOOTH parameter to '**SHARP**' , or if not available, set lambda = 0.008

All other parameters should be set to defaults for the "**Brain**" protocol

All corrections '**On**'

For LOR 3D Ramla reconstruction: The attenuation field should indicate "CT-SEG" and the scatter field should indication "SS-Simul"

For 3D Ramla reconstruction: Attenuation and scatter fields should indicate "NonUni-BGSub"

Questions: e-mail Robert Koeppe (koeppe@umich.edu)

Philips Allegro - 90 slice PET scanners

Acquisition Parameters:

Radiotracer:
AV-45: **9.0-11.0 mCi**

Scan start time post-injection:
AV-45: **50 min**

Transmission scan:
5 min 2-D scan post-emission scan. Process with segmentation and re-projection

Acquisition Protocol: **Brain Protocol**

20 min, four × 5-min frames

Reconstruction Parameters:

Iterative: LOR 3D Ramla (*** Note: if only older software versions are available, 3D Ramla reconstruction is acceptable)

Grid: **128 × 128**

FOV: **256 mm** (results in voxel size of 2.0 mm)

Slice Thickness: **2.0 mm**

Smoothing: Set SMOOTH parameter to **SHARP**' , or if not available, set lambda = 0.008

All other parameters should be set to defaults for the "**Brain**" protocol

All corrections '**On**'

For LOR 3D Ramla reconstruction: The attenuation field should indicate "CT-SEG" and the scatter field should indication "SS-Simul"

For 3D Ramla reconstruction: Attenuation and scatter fields should indicate "NonUni-BGSub"

Questions: e-mail Robert Koeppe (koeppe@umich.edu)

Siemens ECAT Exact HR+ (BGO) 63-slice scanners

Acquisition Parameters:

Radiotracer:
AV-45: **9.0-11.0 mCi**

Scan start time post-injection:
AV-45: **50 min**

Transmission scan:
5 min 2-D scan post-emission scan. Process with segmentation and re-projection

Acquisition Protocol: **Brain Protocol**

20 min, four × 5-min frames

Reconstruction Parameters:

Method: **Iterative:** (FORE / OSEM-2D)
4 iterations; 16 subsets

Grid: **128 × 128**

Brain Mode: **ON**

Zoom: **2.0**

Smoothing
Filter: **NONE** (software version 7.2 says **'All Pass (Ramp)'**)
Axial filtering: **NONE** (software version 7.2 says **'Off'**)

All corrections '**On**'

Questions: e-mail Robert Koeppe (koeppe@umich.edu)

Siemens HRRT 207-slice scanners

Acquisition Parameters:

Radiotracer:
AV-45: **9.0-11.0 mCi**

Scan start time post-injection:
AV-45: **50 min**

Transmission scan:
5 min 2-D scan post-emission scan. Process with segmentation and re-projection

Acquisition Protocol: **Brain Protocol**

20 min, four × 5-min frames

Reconstruction Parameters:

Method: **Iterative:** (OSEM-3D)
6 iterations; 16 subsets

Grid: **256 × 256 × 207**

Voxel size: **1.219 mm^3**

Smoothing **2mm** Gaussian

All corrections '**On**'

Questions: e-mail Robert Koeppe (koeppe@umich.edu)

Siemens BioGraph mCT - 81 or 109 (TrueV) slice PET/CT scanners

Acquisition Parameters:

Radiotracer:
AV-45: **9.0-11.0 mCi**

Scan start time post-injection:
AV-45: **50 min**

CT scan:
Low mAs scan acquired shortly before emission. Leave enough time to start emission acquisition promptly at min.

Acquisition Protocol: **Brain Protocol**

20 min, four × 5-min frames

Reconstruction Parameters:

Method: **Iterative: OSEM-3D**
4 iterations; 24 subsets

Grid: **400 × 400**

Zoom: **2.0** (results in voxel size of ~1.018 mm)

Smoothing
Filter: **NONE** (or '0.0')

Match CT: '**Off' or 'No'** (results in PET slice thickness of ~2.027 mm)

All corrections '**On**'

Questions: e-mail Robert Koeppe (koeppe@umich.edu)

Siemens BioGraph TruePoint - 81 or 109 (TrueV) slice PET/CT scanners (Model 1093/1094)

Acquisition Parameters:

Radiotracer:

AV-45: **9.0-11.0 mCi**

Scan start time post-injection:

AV-45: **50 min**

CT scan:

Low mAs scan acquired shortly before emission. Leave enough time to start emission acquisition promptly at min.

Acquisition Protocol: **Brain Protocol**

20 min, four × 5-min frames

Reconstruction Parameters:

Method: **Iterative: FORE / OSEM-2D**
4 iterations; 16 subsets (or **14** subsets if 16 is not an option with your software)

Grid: **336 × 336**
Note: if the software version you are running still allows "**TRIM**" to be set, then reconstruction can be set to a **168 × 168** matrix with TRIM '**ON**'

Zoom: **2.0** (results in voxel size of ~1.015 mm; or ~2.03 mm for the 168 × 168 grid)

Smoothing Filter: **NONE** (or '0.0')

Match CT: '**Off' or 'No'** (results in PET slice thickness of ~2.027 mm)

All corrections '**On**'

Questions: e-mail Robert Koeppe (koeppe@umich.edu)

Siemens BioGraph "HiRes" - 81 slice PET/CT scanners (Model 1080)

Acquisition Parameters:

Radiotracer:

AV-45: **9.0-11.0 mCi**

Scan start time post-injection:

AV-45: **50 min**

CT scan:

Low mAs scan acquired shortly before emission. Leave enough time to start emission acquisition promptly at min.

Scans and scan duration:

LIST-MODE: If your scanner has list-mode capability:

20 min, four × 5-min frames

NO LIST-MODE: If your scanner does not have list-mode capability:

20 min: two **scans: 10-min each**

*** Note that reduce motion artifacts, two separate emission scans will be acquired as closely together as possible. The first is to be started at 50 min. Do not repeat CT scan.

Reconstruction Parameters,

Method: **Iterative: FORE / OSEM-2D**
4 iterations; 16 subsets (or **14** subsets if 16 is not an option with your software)

Grid: **168 × 168**

TRIM: **'On'**

Zoom: **2.0** (results in voxel size of ~2.031 mm)

Smoothing
Filter: **NONE** (or '0.0')

Match CT Slice location: '**Off' or 'No'** (results in PET slice thickness of ~2.000 mm)

All corrections '**On**'

Questions: e-mail Robert Koeppe (koeppe@umich.edu)

Siemens BioGraph (LSO) 47-slice PET/CT scanners
(also sold as **CTI Reveal**)

Acquisition Parameters:

Radiotracer:

AV-45: **9.0-11.0 mCi**

Scan start time post-injection:

AV-45: **50 min**

CT scan:

Low mAs scan acquired shortly before emission. Leave enough time to start emission acquisition promptly at min.

Scans and scan duration:

Two scans: 10-min each

*** Note that reduce motion artifacts, two separate emission scans will be acquired as closely together as possible. The first is to be started at 30 (FDG) or 50 (AV-45) min. If your scanner software version does not allow a repeat emission acquisition unless you perform a second CT scan, please contact Robert Koeppe (see below) prior to scanning

Reconstruction Parameters,

Method: **Iterative:** (FORE / OSEM-2D)
6 iterations; 16 subsets (or **14** subsets if 16 is not an option)

Grid: **128 × 128**

TRIM: **ON**

Zoom: **2.0**

Smoothing Filter: **NONE** (or '0.0')

All corrections '**On**'

If your scanner software version has on option for "**Match CT Slice location**", this must be left '**OFF**' (e.g. box is unchecked)

Questions: e-mail Robert Koeppe (koeppe@umich.edu)

Appendix C – Example Florbetapir F 18 PET Scan Information Form

Version 1

Alzheimer's Disease Cooperative Study

ADCS

Florbetapir F 18 PET Scan Information

Page 1 of 5

Visit:

DOD ADNI PARTICIPANT NUMBER | SITE ID | EXAMINER INITIALS | EXAMINATION DATE (MONTH – DAY – YEAR)

To be completed by Study Coordinator:

Study Coordinator Name: _____

Telephone #: _____

DOD ADNI Participant Initials: ☐☐☐

Scheduled Date: ☐☐ ☐☐ ☐☐☐☐ (MONTH DAY YEAR)

Was scan conducted? ☐ Yes ☐ No

Reason why the scan was not conducted:

- ☐ Illness
- ☐ Participant unavailable
- ☐ Participant unwilling
- ☐ Administrative problems
- ☐ Software/scanner error
- ☐ Withdrawn consent
- ☐ Not called for by the protocol
- ☐ Other (specify) _____

If no, was radiotracer administered? ☐ Yes ☐ No

Scan Date: ☐☐ ☐☐ ☐☐☐☐ (MONTH DAY YEAR) **Technologist Initials** ☐☐☐

Select one of the following scanner vendors and models:

☐ GE:
- ☐ Advance
- ☐ Discovery LS
- ☐ Discovery ST
- ☐ Discovery RX
- ☐ Discovery STE/VCT
- ☐ Discovery 600
- ☐ Discovery 690

☐ Siemens:
- ☐ ACCEL/EXACT
- ☐ Biograph (Model 1023/1024)
- ☐ Biograph HiRes (Model 1080)
- ☐ BioGraph TruePoint (Model 1093/1094)
- ☐ BioGraph mCT
- ☐ HR+
- ☐ HRRT

☐ Philips:
- ☐ Allegro
- ☐ Gemini
- ☐ Gemini - GXL
- ☐ Gemini - TF

DOD ADNI Specific 86 Instrument last modified 02/9/11

Alzheimer's Disease Cooperative Study

ADCS

Florbetapir F 18 PET Scan Information

Visit:

DOD ADNI PARTICIPANT NUMBER	SITE ID	EXAMINER INITIALS	EXAMINATION DATE
			MONTH — DAY — YEAR

Time of today's Scanner QC (*Enter '00' for seconds portion of the time if seconds are unavailable.)*

: : **HH:MM:SS**

Time of Florbetapir F 18 dose assay (*Enter '00' for seconds portion of the time if seconds are unavailable.)*

: : **HH:MM:SS**

Florbetapir F 18 dose assay [*Corrected for Residual Activity (Proper dose is 9 - 11 mCi)*]

mCi

Florbetapir F 18 Volume

mL

Time of Florbetapir F 18 injection (*Enter '00' for seconds portion of the time if seconds are unavailable.)*

: : **HH:MM:SS**

Emission Scan Start Time: *Enter '00' for seconds portion of the time if seconds are unavailable.*

: : **HH:MM:SS**

Target start time is 50 min Florbetapir F 18 post-injection. Provide an explanation if start time is not between **48** and **52** min post-injection.

_____

_____

_____

_____

Alzheimer's Disease Cooperative Study

ADCS

Florbetapir F 18 PET Scan Information

Visit:

DOD ADNI PARTICIPANT NUMBER	SITE ID	EXAMINER INITIALS	EXAMINATION DATE
			MONTH – DAY – YEAR

SECTION II. SCAN PROTOCOL INFORMATION

Any variations from protocol during Florbetapir F 18 uptake?

☐ Yes
☐ No

If Yes, describe: _____

Predefined Acquisition Protocol ID: _____

Which framing rate was used?

☐ 4 frames, 5 min/frame (4 x 300s)
☐ 2 scans, 10 min each (2 x 600s) (only for BioGraph scanners without list-mode)
☐ 1 frame, 20 min (1x1200s) (Only for the oldest BioGraph scanners; Models 1023 or 1024)

If any deviations, describe: _____

Subject motion problems:

☐ Yes
☐ No

If Yes, decribe: _____

Scanner malfunction

☐ Yes
☐ No

If Yes, describe: _____

Other protocol variations:

☐ Yes
☐ No

If Yes, describe: _____

SECTION III. SCAN RECONSTRUCTION

Check which of the following reconstructions was used:

☐ FORE/2D - OSEM (Siemens)
☐ OSEM3D (Siemens) (If HRRT scanners using OP, please select OSEM3D)
☐ 3D Iterative (GE)
☐ FORE/Iterative (GE)
☐ 3D or LOR Ramla (Philips)
☐ 3D Back-projection (GE)

Alzheimer's Disease Cooperative Study

ADCS

Florbetapir F 18 PET Scan Information

Visit:

DOD ADNI PARTICIPANT NUMBER	SITE ID	EXAMINER INITIALS	EXAMINATION DATE
			MONTH – DAY – YEAR

If FORE/2D-OSEM, OSEM3D, or 3D Iterative, or FORE Iterative (GE):

Subsets:

- ☐ 12
- ☐ 14
- ☐ 16
- ☐ 20
- ☐ 21
- ☐ 24
- ☐ 32
- ☐ Other

If Other, specify: _____

Iterations:

- ☐ 4
- ☐ 6
- ☐ Other

If Other, specify: _____

If 3D or LOR Ramla, please complete either:

Lambda = _____ (relaxation parameter)

OR

Was "Smooth" parameter set to "Sharp"?

☐ Check here to confirm

If 3D Back-Projection, Ramp filter?

☐ Check here to confirm

If FORE/2D - OSEM select one of the following

- ☐ Brain mode "ON" for PET-only Siemens scanners
- ☐ TRIM "ON" for PET/CT Siemens scanners (older software versions)
- ☐ TRIM not available for PET/CT Siemens scanners (new software versions)

If TRIM not available, must reconstruct with a zoom of 2.0 into a 336x336 grid for BioGraph TruePoint or 400x400 grid for BioGraph mCT

No post-process smoothing:

☐ Check here to confirm

Attenuation Correction:

- ☐ CT
- ☐ Ge - 68 + Segmentation
- ☐ Cs - 137 + Segmentation

Alzheimer's Disease Cooperative Study

ADCS

Florbetapir F 18 PET Scan Information

Visit:

DOD ADNI PARTICIPANT NUMBER	SITE ID	EXAMINER INITIALS	EXAMINATION DATE
			MONTH – DAY – YEAR

SECTION IV. DATA TRANSFER AND ARCHIVE:

Was data transferred to LONI within 24 hours of scan?

Data must be transmitted to LONI within 24 hours of the PET scan. If your site is unable to complete the transfer with 24 hours please indicate the problem in the "Comments" section below.

☐ Yes
☐ No

Transfer Date: ☐☐ (Month) ☐☐ (Day) ☐☐☐☐ (Year)

Comments:

_____

_____

_____

Was all raw PET data archived locally to be able to do complete reconstruction of PET Scan if needed?

If No, please explain under comments

☐ Yes
☐ No

Archive Medium: _____

Comments:

_____

_____

_____

SECTION V. LUMBAR PUNCTURE DATA:

Was a Lumbar Puncture completed prior to the Florbetapir F 18 scan?

☐ Yes
☐ No

If Yes, what was the interval between LP and Florbetapir F 18?

☐ Less than 6 hours
☐ 6-12 hours
☐ 13-24 hours
☐ 25-48 hours
☐ 49-72 hours
☐ More than 72 hours