

Memorandum

IDEAS Database Updates: Please NOTE the following updates as of 12/09/2016.

- Practice Registration screen - Local IRB continuing approval letter(s) are able to be uploaded
- Case Registration screen includes Data Change Request button
- PET Assessment screen includes reminder to physician

Helpful Improvements:

- Patient consent dates older than 30 days may be allowed in the database.
- The drop-down menu of available PET facilities will include the physical address of the PET facility.

Referring Physician Practices with Local IRB Approval:

IDEAS Practice Administrators at sites with local IRB oversight must upload ALL regulatory documents to include continuing approval letters, approved informed consent templates, and amendment approvals via the database portal. The sites with Schulman IRB oversight will NOT need to upload documents.

Will your site be obtaining local or central IRB approval? *

PLEASE NOTE: Please check one of the two radio buttons below to indicate whether your site will use a local Institutional Review Board (at site's cost) or if the site will use the central IRB (Schulman Associates) for which the site will not be charged. While you may return at any time to update or upload the actual IRB approval letter (if you choose "local") be advised that in order for the initial site REGISTRATION to be submitted, you will need to check local or central IRB.

Central IRB Approval (refer to Schulman Associates at www.sairb.com)

Local IRB Approval

Once local IRB approval has been obtained, please upload the Initial IRB approval letter and Initial IRB stamped-approved informed consent. Amendment and Continuing Review approval letters and associated informed consent documents must also be uploaded here. If your site has multiple IRB stamped-approved versions of the informed consent, please upload here by selecting the *Additional Informed Consent* option.

IRB Approval Date	IRB Expiration Date	Documents	Version Date	Approved	
04/21/2016	04/21/2017	Initial Approval		Yes	
11/21/2016	11/21/2017	Initial Informed Consent		Yes	
		Continuing Review - year 1			 
		Additional Informed Consent	10/27/2016	No	 
		Amendment 1			 



Once local IRB approval has been obtained, please upload the Initial IRB approval letter and Initial Informed Consent. Older sites that have the Initial documents previously uploaded will have this information added. Amendment and Continuing Review approval letters and associated informed consent documents must also be uploaded using this feature. If your site has multiple IRB stamped-approved versions of the informed consent, please upload here by selecting the *Additional Informed Consent* option and also indicate the Informed Consent *version date* as applicable.

Add IRB Document

IRB Document may be uploaded here. Allowed file extension: pdf, max file size: 10Mb

Upload IRB Document file Browse ...

Documents: Additional Informed Consent

Version Date: 10/27/2016

Add Cancel

The IRB Approval Date and the IRB Expiration Date will be populated upon ACR review of the uploaded documents. Once approved, the site will not be able to delete the document.

If the wrong document is uploaded then you must *delete* the document and *add* the correct document via “Add IRB Document” option. The “Download” button is used only to open the document that has been previously uploaded.

Data Change Request button on Case Registration Form:

All data corrections should be requested using the “Submit Data Change” button on the corresponding form. The “Submit Data Change” button is now available on the Case Registration form. Simply open the form requiring a data changes and click on the “Submit Data Change” button on left menu panel to detail the corrections for that form. The IDEAS Staff will contact the site if any additional clarification is needed.

Case Registration | PET Completion | PET Report | PET Assessment

Case Registration: This record has been submitted.

PET Completion: 13

PET Report

PET Assessment

My Requests

Submit Data Change

Case Registration

This form is to be completed with each new referral.

Eligibility Confirmation Form

This form is to be completed with each new referral.

I certify that all of the following are correct:

Criteria	Answer
1. The patient is 65 years of age or older.	<input checked="" type="radio"/> Yes <input type="radio"/> No

PET Assessment Form Instructions:

A reminder text has been added to ensure that the physician completing the PET Assessment form is the same individual as the interpreting physician.

Case Registration | PET Completion | PET Report | **PET Assessment**

Case Registration: This record has not been submitted.

PET Completion: 13

PET Report

This PET Assessment Form **MUST be completed by the physician who interpreted this patient's brain amyloid PET study.**

PET Assessment

My Requests

Amyloid PET Assessment Form

The radiologist/nuclear medicine physician who interprets the amyloid PET will be required to complete the online Amyloid PET Assessment Form within 7 days of the scan.