

NEW
iDEAS

**Imaging Dementia—Evidence
For Amyloid Scanning**

***Case Registration and Data Entry for
Referring Dementia Practices***



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User Role Information

- A user may have multiple roles in the study portal.
 - *All practices must have an assigned Practice Administrator, Dementia Specialist and a Practice Finance User

Practice Administrator*	Dementia Specialist*	Practice Finance User*	Practice Registrar
<ul style="list-style-type: none"> - Automatically assigned to the person who initially submits the pre-registration form. - Has complete administrative functionality in the New IDEAS portal. - Responsible for administrative duties associated with site registration and adding practice staff profile accounts. - Has view access to all case report forms and edit/submission access to all forms <i>except</i> pre- and post-PET form. 	<ul style="list-style-type: none"> - Has view, edit and submission access to all case report forms. - Only user role that has edit and submission access to pre- and post-PET forms. 	<ul style="list-style-type: none"> - Only user role that has access to the practice's finance portal" - Responsible for submission of banking information - Does not have any access to patient case report forms 	<ul style="list-style-type: none"> - Has view access to all case report forms and edit/submission access to all forms <i>except</i> pre- and post-PET form.

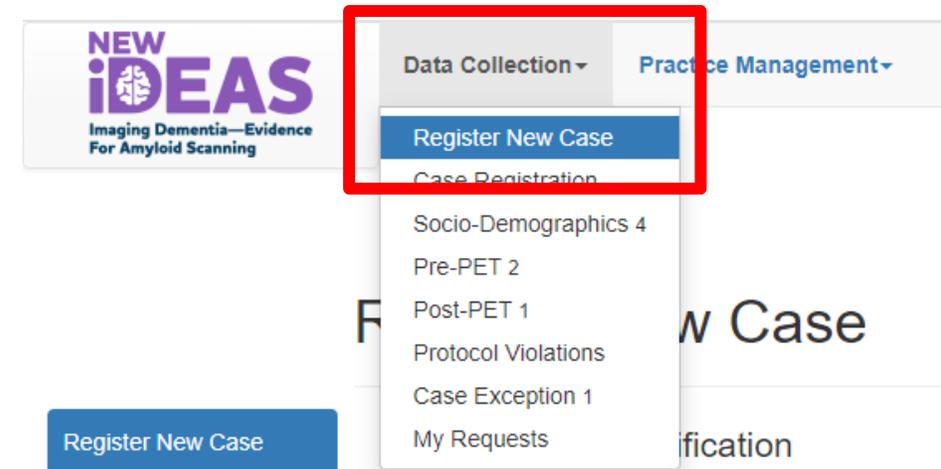
Visit 1: Clinical Assessment—Pre-PET Visit

Form/Assessment:	Must be completed by:	Requirements:
Case Registration Form	Administrator, Registrar OR Dementia Specialist	Must be completed <u>after</u> patient consent
Socio-demographic electronic Case Report Form	Administrator, Registrar OR Dementia Specialist	Must be completed <u>within 7</u> <u>days</u> of case registration AND collected via patient self- reporting interview
Pre-PET electronic Case Report Form (Clinical Assessment)	Dementia Specialist <u>ONLY</u>	Must be completed <u>within 7</u> <u>days</u> of case registration

Visit 1: Case Registration Online

Completed by the referring dementia specialist (or an authorized designee who has obtained the registrar role enabling access to the database)

1. Login to New IDEAS Portal, <https://app.ideas-study.org/>.
2. Under “Data Collection” select “Register New Case”.
3. Complete Cohort Identification and Eligibility Confirmation. Review and Click “Confirm.”
4. A unique 5-digit study case number for that patient will be issued.
5. A confirmation e-mail will be sent to the dementia specialist practice and the PET facility.



Case Registration Example: Cohort Identification

Register New Case

Cohort Identification

Date Of Birth 

Patient's self-reported identification of their gender

- Male
- Female
- Transgender Male
- Transgender Female
- None of these fully describe me
- Prefer not to answer

Patient's self-reported identification of their race (Select all that apply)

- American Indian or Alaska Native (For example: Aztec, Blackfeet Tribe, Mayan, Navajo Nation, Nome Eskimo Community)
- Asian or Asian American (For example: Asian Indian, Chinese, Filipino, Japanese, Korean, Pakistani, Vietnamese)
- Black, African American, or African (For example: African American, Ethiopian, Haitian, Jamaican, Nigerian, Somali)
- Hispanic, Latino, or Spanish (For example: Colombian, Cuban, Dominican, Mexican or Mexican American, Puerto Rican, Salvadoran)
- Middle Eastern or North African (For example: Algerian, Egyptian, Iranian, Lebanese, Moroccan, Syrian)
- Native Hawaiian or other Pacific Islander (For example: Chamorro, Fijian, Marshallese, Native Hawaiian, Tongan)
- White or European (For example: English, European, French, German, Irish, Italian, Polish)
- None of these fully describe me
- Prefer not to answer



The participant's self-identification of their race will be collected as part of the registration process to verify availability within defined cohorts.

Case Registration Example: Eligibility Confirmation

Eligibility Confirmation

This form is to be completed with each new referral.

All inclusion and exclusion criteria must be confirmed by the referring dementia specialist and/or the participant's medical records, prior to registration. I certify that all of the following are correct:

Criteria	Answer
1. The patient is a Medicare beneficiary	<input type="radio"/> Yes <input type="radio"/> No
2. The patient meets clinical criteria for Mild Cognitive Impairment (MCI) or Dementia as defined by the 2018 National Institute on Aging – Alzheimer's Association Research Framework.	<input type="radio"/> Yes <input type="radio"/> No
3. The patient has had a brain MRI and/or CT within 24 months prior to enrollment.	<input type="radio"/> Yes <input type="radio"/> No
4. The patient has had a clinical laboratory assessment (including CBC, standard blood chemistry profile, TSH, vitamin B12) within 12 months prior to enrollment.	<input type="radio"/> Yes <input type="radio"/> No
5. The patient is expected to be able to tolerate amyloid PET imaging as required by protocol, to be performed at a participating PET facility.	<input type="radio"/> Yes <input type="radio"/> No
6. The patient is English or Spanish speaking (for purposes of informed consent).	<input type="radio"/> Yes <input type="radio"/> No
7. Neuropsychiatric syndrome can be classified into "clinically typical" or "clinically atypical" categories. (Refer to section 4.1.2 of protocol for guidance)	<input type="radio"/> Yes <input type="radio"/> No
8. The patient has signed consent to participate in New IDEAS Study. Consent may be by proxy.	<input type="radio"/> Yes <input type="radio"/> No

Inclusion and Exclusion criteria must be confirmed by the referring dementia specialist and/or the participant's medical records **prior to registration.**



Case Registration Example: Consent Confirmation

- The patient consent form must be completed **BEFORE** case registration is completed.
- The fully executed informed consent form (pdf only) must be uploaded to complete the Case Registration Form.



8. The patient has signed consent to participate in New IDEAS Study. Consent may be by proxy. Yes No

Consent provided by: Patient Proxy

In what language was the consent form completed? English Spanish

Date consent signed: 

Case Registration Example: Optional Component Verification

Indicate if the patient has consented to the following **optional** New IDEAS study components.

Optional Component Verification: Image archive, biorepository, and additional research studies:

The patient has consented to collection and archiving of his or her de-identified amyloid PET images for use in future research.

Yes No

The patient has consented to collection and archiving of his or her de-identified blood samples for use in future research.

Yes No

The New IDEAS Study is collaborating with additional research studies investigating amyloid, cognitive decline, Alzheimer's disease and other types of dementia and the patient is willing to be contacted about other research studies for which he or she may be a candidate.

Yes No

Confirm

Click “**Confirm**” to finish case registration for patient.

Case Registration Example: Finish Case Registration for Eligible Patients

- **After a patient is registered AND is eligible to participate**, the Dementia Specialist or Practice Administrator will be prompted to enter the following information:
 - Patient Information (Name, Address, Phone Number, Email, SSN, Medicare ID)
 - Upload the fully executed Patient Consent Form (PDF format only , Max File Size 10Mb)
 - PET Facility where Amyloid PET has been scheduled
 - Person responsible for data on form.
- Form must be submitted prior to completion of the sociodemographic form and pre-PET assessment.

Case Registration Example: Incomplete Forms

Incomplete forms will appear as a number behind the form in the in the portal form list.

In this example, there is 1 incomplete Case Registration Form for practice 6988.

Case Registration 1

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Data Collection Practice Management Dementia Specialist

6988 - Test Practice practice

Case #50019 , 01/26/2021

Case Registration Socio-Demographics Pre-PET Comments (0) Protocol Violations

Register New Case

Case Registration 1 This record has not been submitted.

Socio-Demographics 4

Pre-PET 2

Post-PET 1

Protocol Violations

Case Exception 1

My Requests

Save My Work

Case Registration

This form is to be completed with each new referral.

Cohort Identification

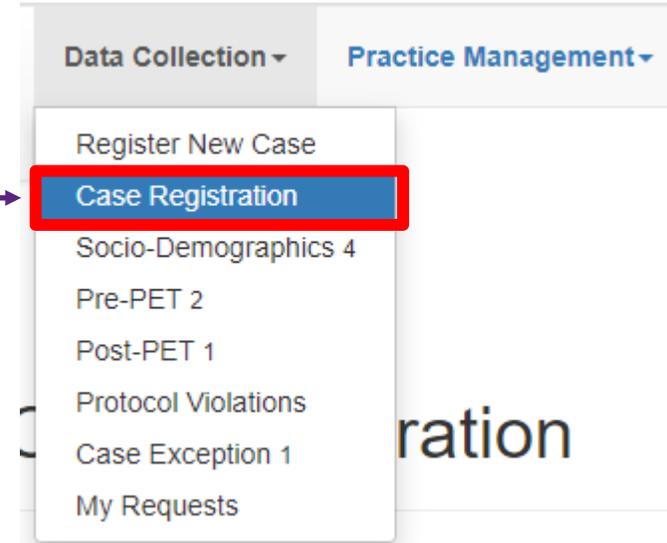
Date Of Birth 01/26/2021

Patient's self-reported identification of their gender

- Male
- Female
- Transgender Male
- Transgender Female
- None of these fully describe me

Case Status Overview

View list of registered cases under “Data Collection.”
Select “Case Registration.”



Unique 5-digit study case identifier.
Click on this Case # to see patient form status.

Case #	Stage	Status	Patient	Registration	Forms
50015	Case Registration	OPEN	John Doe	11/09/2020	Case Socio-Demo Pre Post

A **green box** indicates the form has been completed.
A **blue box** indicates the form is available but has not been completed.
A **white box** indicates that the form is not available yet.

Socio-Demographic Form Example

Case #	Stage	Status	Patient	Registration	Forms
50012	Case Registration	OPEN	John Doe	10/26/2020	Case Socio-Demo

A **green box** indicates the form has been completed and the case is registered. A **blue box** indicates the form is available but has not been completed.

Socio-demographic form completed by authorized site staff during **interview** with participant.

All responses to Socio-Demographic form are **self-reported by the participant**.

Must be submitted **within 7 days of registration date**.

Case #50012 John Doe, 10/26/2020

Case Registration

Socio-Demographics

Case Exception

Comments (0)

Protocol Violations

This record has not been submitted.

Socio-Demographics Form

This form is intended to capture socio-demographics data of your patient. This form must be submitted within 7 days of the case registration date. [Data elements below must be collected by authorized site staff during interview with participant.](#) All responses must be self-reported by the participant.

1. Please specify marital status:

- Married
- Living with partner
- Widowed
- Divorced
- Separated
- Never married
- Prefer not to answer

2. Please specify living arrangements:

- Patient lives alone
- Patient lives at home with...

Pre-PET Case Report Form Example

Case #	Stage	Status	Patient	Registration	Forms
50015	Case Registration	OPEN	John Doe	11/09/2020	Case Socio-Demo Pre Post

A **blue box** indicates the Pre-PET Form is available but has not been completed. A **white box** indicates the Post-PET form is not available yet.

Case Registration Socio-Demographics Pre-PET Comments (0) Protocol Violations

*by Nov 15, 2020
65 days overdue*

This record has not been submitted.

PRE-PET CLINICAL ASSESSMENT FORM

This form is intended to capture medical history data on your patient, as well as your diagnosis and management plan prior to amyloid PET. The management plan section asks that you describe your plan as if amyloid PET Imaging were not available to your patient. This form must be submitted within 7 days of the patient's Pre-PET clinic visit.

Pre-PET Visit Status:

Was the Pre-PET visit completed?

Yes, I certify that the Pre-PET visit was completed. The Pre-PET form can be submitted.

No, the Pre-PET visit was not completed. I confirm that the Pre-PET form cannot be submitted.

Pre-PET form must be completed by **the Dementia Specialist within 7 days after case registration.**

Describe your management plan as if amyloid PET Imaging **were not available** to your patient.

Visit 2: Amyloid PET Scan

- The PET facility will receive an e-mail notification when the Pre-PET eCRF has been completed.
- The Amyloid PET Scan must be completed **within 60 Days after** Pre-PET electronic Case Report Form Completion.
 - No data entry is required by the dementia practice at this study time point.

Example Case: Patient 50011 has been registered, a Socio-Demographic form has been completed and the Pre-PET form has been completed. Patient is awaiting scan.

Case #	Stage	Status	Patient	Registration	Forms
50011	Pre-PET Completed	INCOMPLETE	John Doe	10/26/2020	Case Socio-Demo Pre

Visit 3: Post-PET Office Visit

- Must be completed **90 ± 30 Days** after amyloid PET scan.
- **Document actual patient management** as reflected by management changes that have been implemented into patient care.

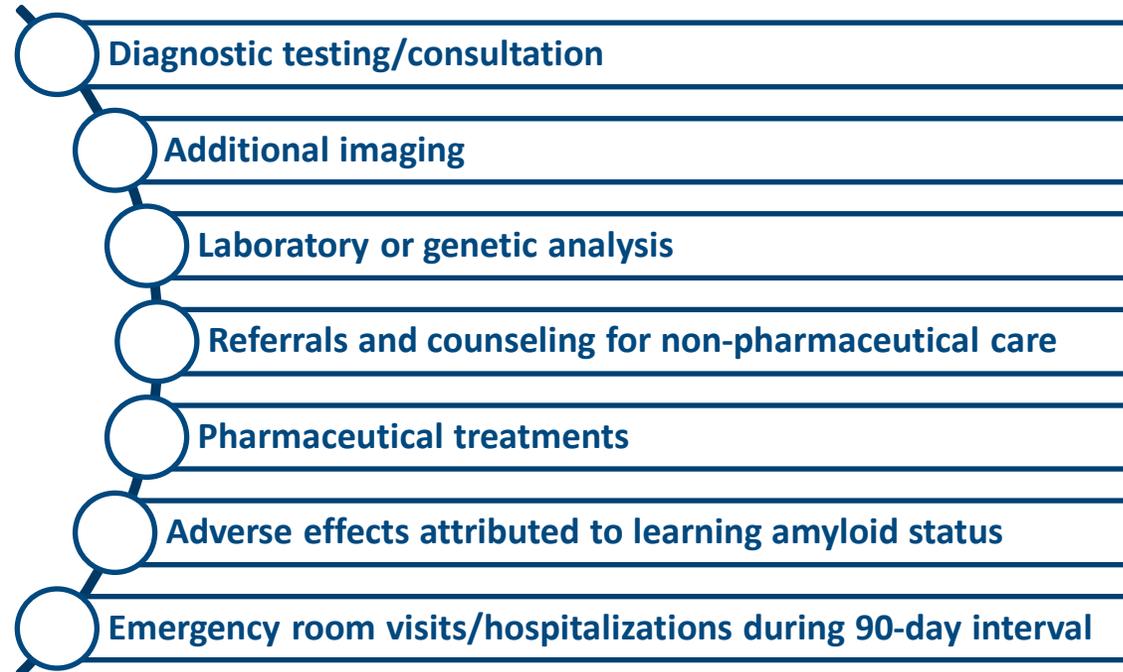
Form/Action Item:	Completed by:	Requirements:
90-day (from day of PET scan) clinical office follow-up	Referring Dementia Specialist*	May occur within a window of 60-120 days post-PET scan date. In office visit (preferred)
Post-PET eCRF	Same Dementia Specialist who completed Pre-PET eCRF	Due within 30 days after 90-day visit.

*Under no circumstances is the dementia specialist permitted to delegate the post-PET contact (in person visit or telephone) to other staff or to another physician.

Post-PET Form Example

The referring Dementia Expert will document:

- Follow-up Visit Status
- Differential Diagnosis
- Management Plan



50018 PET Completed

OPEN

patient_name 11/16/2020
patient_lname

Case Socio-Demo Pre Post

The **blue box** indicates that the Post-PET form is available but has not been completed.

Data Change Request Form

- Click on the Case # of interest.
- Select the completed form you have a data change request for.
- Detail your requested data changes in the comment box.
- Click “Send.” An email will be sent to ACR New IDEAS staff for review.

[Register New Case](#)

[Case Registration](#) **1**

[Socio-Demographics](#) **4**

[Pre-PET](#)

[Post-PET](#)

[Protocol Violations](#)

[Case Exception](#) **1**

[My Requests](#)

View All requests
by clicking “My
Requests”

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[Register New Case](#)

[Case Registration](#) **1**

[Socio-Demographics](#) **4**

[Pre-PET](#)

[Post-PET](#)

[Protocol Violations](#)

[Case Exception](#) **1**

[My Requests](#)

[Submit Data Change](#)

Case #50011 John Doe, 10/26/2020

[Case Registration](#)

[Socio-Demographics](#)

[Pre-PET](#)

This record has been submitted.

Socio-Demographics Form

This form is intended to capture socio-demographics data of your patient elements below must be collected by authorized site staff during interview

1. Please specify marital status:

- Married
- Living with partner
- Widowed
- Divorced
- Separated
- Never married

Please submit your requested data change for this form

Site #: 6988

Case #: 50011

Form: Socio-Demographics

User: Practice Admin (00uup0wtph95juouK0h7)

Detail your requested data change(s) below. You will be contacted if clarification of your request is needed:

[Send](#)

[Close](#)

Protocol Violation Form

- Protocol Violations can be viewed via the “Protocol Violations” tab.
- Protocol Violations are initiated by the New IDEAS Study Team and must be acknowledged by Dementia Practice.

Protocol Violations

Register New Case

Case Registration **1**

Socio-Demographics **4**

Pre-PET **2**

Post-PET **1**

Protocol Violations

Case Exception **1**

My Requests

+ Filter Protocol Violation Status: Need Response x

Protocol Id	Protocol Violation Status	Protocol Violation Date	Submission Date	Case #	Case status
There are no items to display					

Case Comments Section

- Communication about patient cases should only be communicated through the New IDEAS portal, never by email.
 - Select “Case Registration”
 - Click on the Case # of interest.
 - Select “Comments” tab.
 - Write patient comment and submit by selecting “Comment for everyone.”

Case #50012 John Doe, 10/26/2020

Register New Case

Case Registration 1

Socio-Demographics 4

Pre-PET 2

Post-PET 1

Case #

50012

Case Registration Socio-Demographics Case Exception **Comments (0)** Protocol Violations

Comment:

Comment for everyone

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