HID Web App Experiment, Subject, Visit, Clinical Assessment Management Tutorial

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March 16, 2005

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Chapter 1

General overview of the data management section of the HID web app

In order to be able to alter data, you need a user account with data maintenance privileges. Once you get a user account with data maintenance privileges and the url for your site's HID web app with data maintenance privileges from your administrator, you can login to the application (See Figure 1.1).

After login, you should see a welcome screen like in Figure 1.2 (Welcome screens are one of the candidates for site specific customization). At the header and footer of the screen you will see links to BIRN web site, NIH, NCRR and DHHS). Also in the header you will see the ID of the database you are currently connected.

The screen has a menu on the left-side of the screen for the application. For Experiment, study group maintenance and subject enrollment *Experiment* menu item is used. Pressing the magnifying glass icon brings you to the Experiment selection screen (See Figure 1.3, pressing the plus icon brings you to the new experiment addition screen (See Figure 1.4).

For subject , visit, segment and clinical assessment management *Subject* menu item is used. When you press the magnifying glass icon, you will see the *subject find/select* screen (See Figure 1.5), pressing the plus icon brings you to the subject addition screen (See Figure 1.8).

Also please note, there will be a change in the data hierarchy, namely addition of study between visit and a segment, which require the data maintenance described here to change in some parts. The tutorial will be updated when this change is implemented.

1.1   Experiment Management

1.1.1   Add a new experiment

To add a new experiment, press the plus button in the Experiment section of the left menu. In the new experiment screen, provide the mandatory experiment name, select the contact person from the available contacts dropdown, provide (optional) experiment description and press the *Add* button (See Figure 1.4).

1.1.2 Maintaining an existing experiment

First you click the magnifying glass icon in the Experiment section of the left menu, to go to the Experiment Selection screen in Figure 1.3. Then, doubleclick on the experiment name you want to maintain in the list of available experiments . You should see the experiment management screen (See Figure 1.9). In this screen you will see the subjects currently enrolled to the experiment including their study groups. Here you can enroll new subjects, change an enrolled subjects study group or add a new study group.

1.1.2.1 Adding a new study group

When you press *Add Study Group* button in the experiment management page, you will arrive to the *study group addition* screen as shown in Figure 1.6. Here you select the research group type from the dropdown list, provide the name of the new study group. Optionally, also provide a description an press the *Add* button when done.

1.1.2.2 Enrolling a new subject

To enroll a new subject, press the *Enroll* button. In the subject enrollment screen (see Figure 1.7), select the subject from the available subjects list, then select the study group the subject will be in and press *Enroll* button.

1.2 Subject/Visit/Segment Management

1.2.1 Adding a new subject

To add a new subject, press the plus button in the subject section of the left menu. In the New subject screen (see Figure 1.8), press the *Create SubjectID* button to create a new BIRN ID for your subject. Optionally, you can also provide a name and/or a birth date.

1.2.2 Maintaining an existing subject

To maintain an existing subject, press the magnifying glass button in the subject section of the left menu to arrive to subject find/select screen (see Figure 1.5) and doubleclick on the subject ID in the *Select a Subject* list, to go to the Subject Management screen (See Figure 1.10)

1.2.2.1 Adding a new visit

In the subject management screen (see Figure 1.10), press the *New Visit* button. In the *Visit Management* screen (see Figure 1.11), provide the mandatory *Visit Date*, *Visit Time*, *Segment Date*, *Segment Time* and *Protocol* values. The *Visit Date* and *Segment Date* must be the same, violation of this will result in a validation error. The *Name* field is added in the last BIRN schema change and related to addition of study concept between visit and segment concept. Since the study concept semantics are not fully implemented, you can leave it blank for the time being. Then, click the *Add* button.

1.2.2.2 Editing an existing visit

In the subject management screen (see Figure 1.10), from the *Visit Date* dropdown list select the visit you want to edit and press the *Edit* button. Now, you should see the Visit Management screen (see Figure 1.12, where you edit the visit parameters. Press the *Update* button when done.

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1.2.2.3 Adding a new segment

In the subject management screen (see Figure 1.10), press the *Manage* button in the *Segments* section, to arrive to the subject segment management screen (see Figure 1.13). Here press the *New Segment* button. In the Segment Management screen, change the default value for the mandatory *Time* value to match the time of the visit segment you want to add, Change the protocol, and (optionally) provide a name and a description and press *Add Segment* button.

1.2.2.4 Editing an existing segment

In the subject management screen (see Figure 1.10), press the *Manage* button in the *Segments* section, to arrive to the subject segment management screen (see Figure 1.13). Here, press the *Edit* button in the *Segments* section to arrive to the Segment Edit screen (See Figure 1.15), where you can edit the parameters of the segment and press the *Edit* button to make the changes permamnent.
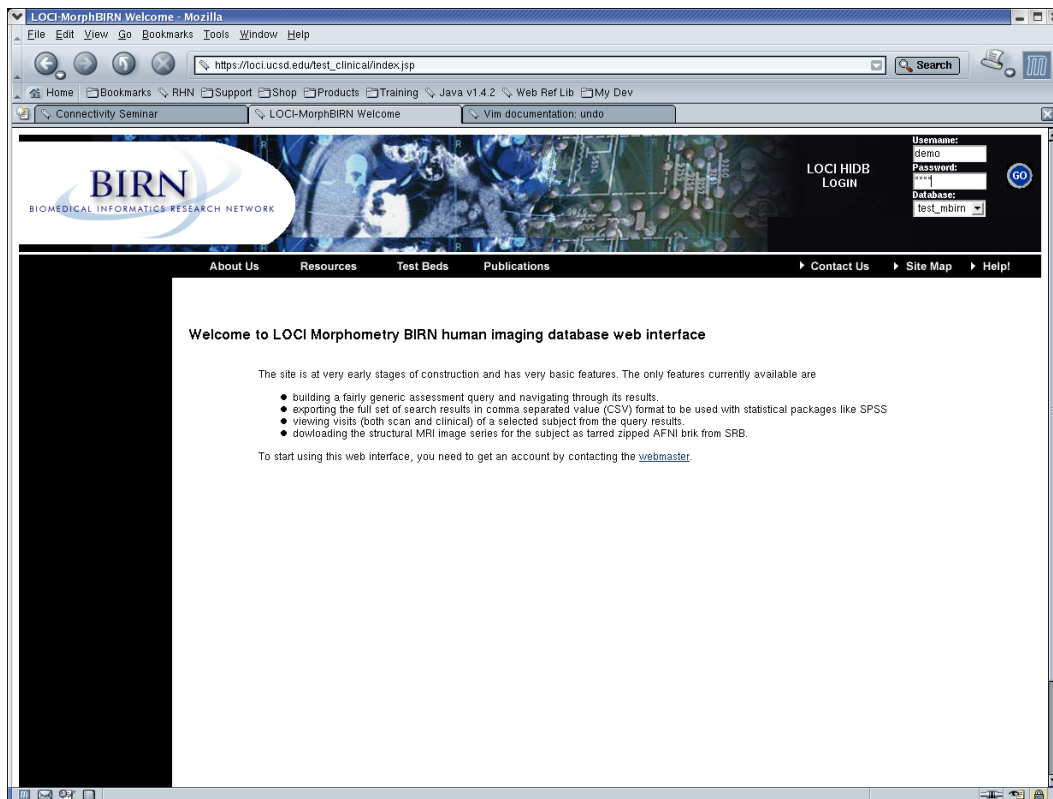
Figure 1.1: HID web app login
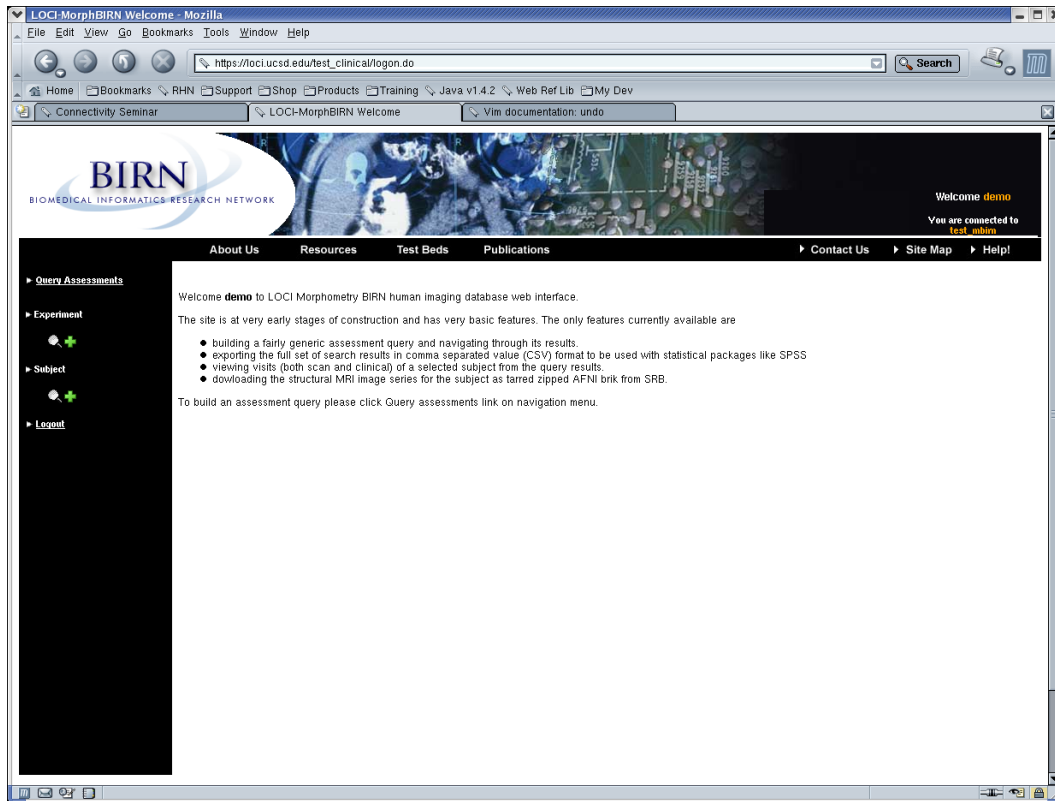
Figure 1.2: HID web app welcome page
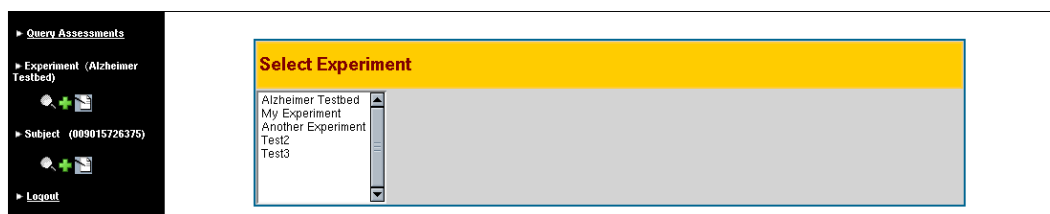
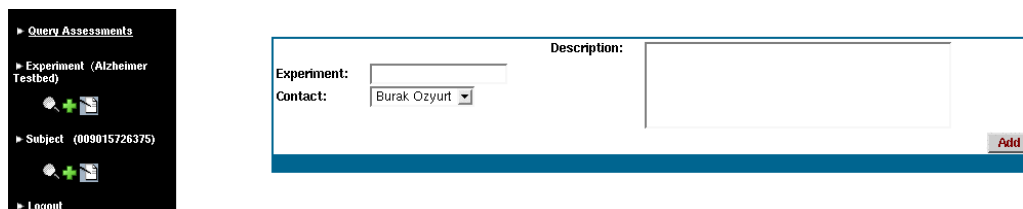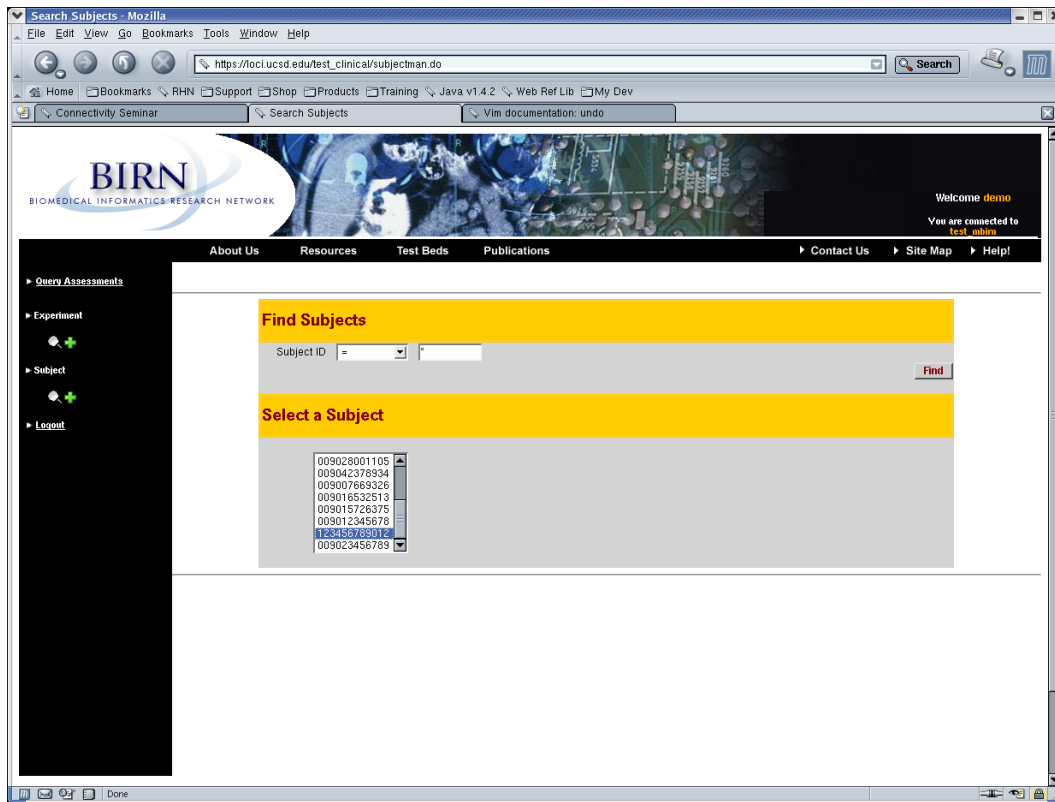Figure 1.3: Select Experiment screen

Figure 1.4: New Experiment screen
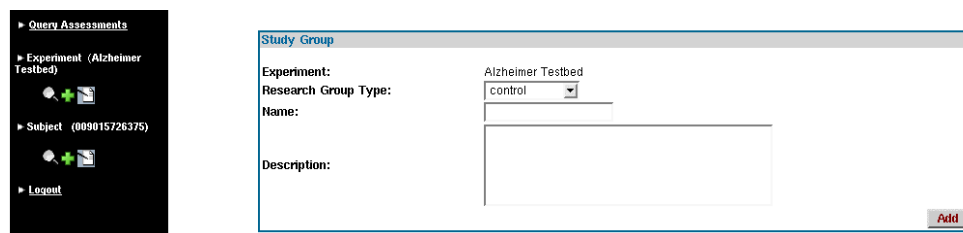
Figure 1.5: Find/Select Subject screen

Figure 1.6: New Study Group section

Figure 1.7: Enroll subject
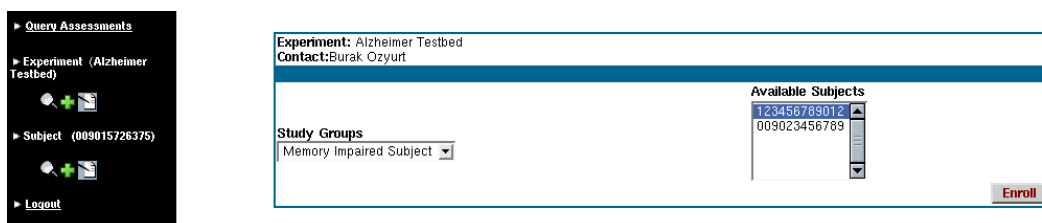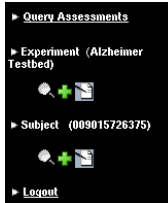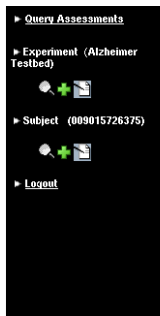
Figure 1.8: New Subject screen

Figure 1.9: Experiment management screen

Figure 1.10: Subject management screen

Figure 1.11: Visit management screen

Figure 1.12: Editing a visit

Figure 1.13: Segment management

Figure 1.14: Adding a new segment

Figure 1.15: Editing a segment

Chapter 2

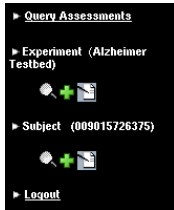# A walkthrough example

2.1 Preparing a new subject

- Create a new subject (see Figure 1.8).

- After new subject addition (see Figure 2.1), the subject will not be associated to any experiment. The next step will be to enroll the new subject to an experiment.

- To enroll the subject, first click on the magnifying glass button in the Experiment section of the left menu and then doubleclick on the experiment name you want the subject enrolled. You will see a screen like in Figure 2.2), where you need to press the *Enroll* button.

- In the subject enrollment screen (see Figure 2.3), select the newly created subject from the available subjects list, then select the study group the subject will be in and press *Enroll* button.

- In the experiment management screen (see Figure 2.4), you will see the subject in the *Enrolled Subjects* list.

- The next step is to have a visit and a segment for the newly enrolled subject. You either directly jump to the subject visit management screen by doubleclicking on the subject ID in the *Enrolled Subjects* list or click on the magnifying glass button in the Subject section of the left menu, and doubleclick on the subject ID in the *Select a Subject* list (see Figure 2.5).

- In the subject management screen (see Figure 2.6), press the *New Visit* button.

- In the *Visit Management* screen (see Figure 2.7), provide the mandatory *Visit Date*, *Visit Time*, *Segment Date*, *Segment Time* and *Protocol* values. The *Visit Date* and *Segment Date* must be the same, violation of this will result in a validation error. The *Name* field is added in the last BIRN schema change and related to addition of study concept between visit and segment concept. Since the study concept semantics are not fully implemented, you can leave it blank for the time being. Then, click the *Add* button.

- After that, you will see the first visit and its first segment for the newly created subject in the subject management screen (see Figure 2.8). Now, you are ready for adding clinical assessments to visit segments.

2.2 Adding a clinical assessment to the new subject

- Once you have a visit and a segment, Press *Manage* button in the subject management screen (see Figure 2.8), to go to the Segment Management screen (see Figure 2.9), where besides editing existing segments, adding new segments, you can also add new assessments done at the particular segment of the clinical (or sometimes scan) visit. Also from this screen you can edit existing clinical assessments. To add a new assessment, select the assessment type you want from the dropdown list just before the *Add Assessment* button and press the *Add Assessment* button

- You will arrive to the cover page of the selected assessment (see Figure 2.10) In this page there are always be 5 mandatory fields, namely;

  - Date - the date, in mm/dd/yyyy format, the assessment is done (which is same as the date of the segment).
  - Time - the time, in hh:mm military time format i.e. 13:45 and 01:45 are 12 hours apart.
  - informant ID - the BIRN ID for the informant
  - Informant Relation - the relation of the informant to the subject. Since the informant ID must be a valid BIRN ID for an entry in the database, practically you can only select *self*. The ability to correctly use other type of informant relation will not be available till a resolution how to proceed with Informant entries to the database.
  - Clinical Rater -

  Once completed entering the mandatory fields and any other fields in the cover page, press the *Next* button to go to the first page of the assessment. Please note that, you can just do data entry for a few pages of an assessment and continue in a later HID web app session. After each assessment page, the data entered so far is saved to the database.

- Now, you will be in the first page of the assessment (see Figure 2.11). The assessment will be laid out very similar to the paper form of the assessment. You can navigate between pages of the assessment using the *Previous* and *Next* buttons in the bottom portion of each page.

- In case you have questions left unanswered like the question 11 in Figure 2.12, click on the small notepad icon located on the left upper corner of the question, to popup the *Notes* window where you select the reason while the question is not answered and press the *Close* button in the popup window.

- In the last page of the assessment (see Figure 2.13), you will have a *Submit* button instead of a *Next* button. Pressing this button, will save the last page to the database and show the saved results for the last page. Currently there is no visual clue after the last page is submitted.

- Once the assessment is finished, you can click the Edit (notepad like) button in the Subject section of the left menu and in the shown subject management menu select the visit you want to view from the Visit Date dropdown, press the manage button to go to the segment management screen and select the segment you have just added a new assessment from the Segment Date dropdown. You should something similar to Figure 2.14. You can start editing the assessment (if you want) by clicking the *Edit* button next to it.
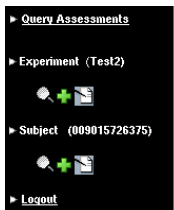
Figure 2.1: After new subject addition

Figure 2.2: Prepare subject -Step 1

Figure 2.3: Prepare subject -Step 2

Figure 2.4: Prepare subject -Step 3
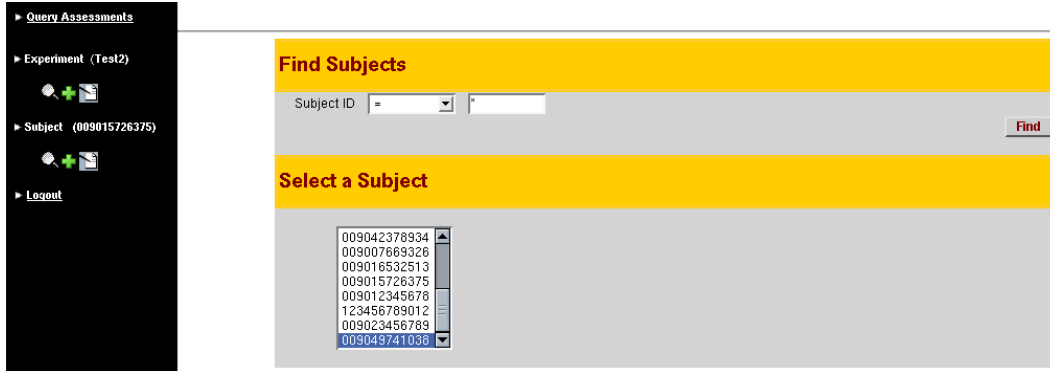
Figure 2.5: Prepare subject -Step 4
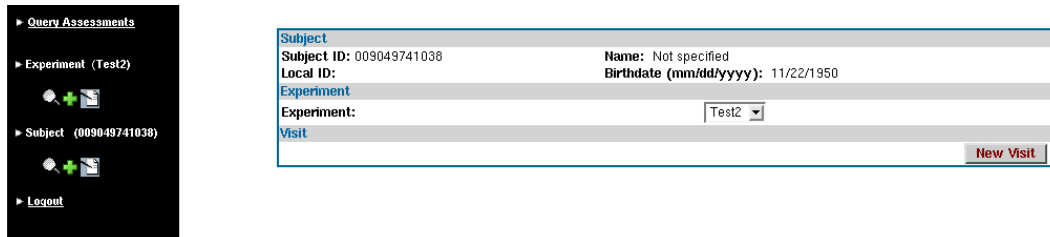
Figure 2.6: Prepare subject -Step 5

Figure 2.7: Prepare subject -Step 6

Figure 2.8: Prepare subject -Step 7

Figure 2.9: Adding a new assessment -Step 1

SIMPSON ANGUS RATING SCALE	
ID	
MONTH # (baseline visit=00)	
TYPE Proband/Subject 1	
DATE (mm/dd/yyyy)	03/11/2005
TIME (hh:mm)	12:45
Informant ID	009049741038
Informant Relation	self
CLINICAL RATER	STAGING

STATUS	
(at intake) Normal Control	◉ 0
Neuroleptic Naive	○ 1
Neuroleptic Non-Naive	○ 2
Almost Neuroleptic Naive	○ 3
Totally Psychoactive Drug Naive	○ 4
Other	○ 5

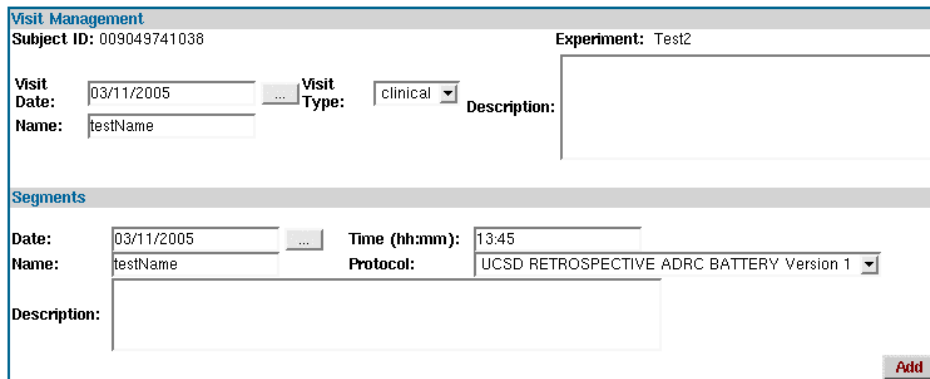| MEDICATION	
No Medication	◉ 0
Medication	○ 1

SOURCES	
Interviewer	○ No
	◉ Yes
Staff	◉ No
	○ Yes
Family	○ No
	○ Yes
Friends	◉ No
	○ Yes
Other	

Figure 2.10: Adding a new assessment - Step 2

SIMPSON ANGUS RATING SCALE

▤ 1. GAIT

The patient is examined as he walks into the examining room; his gait, the swing of his arms, his general posture, all form the basis for an overall score for this item. This is rated as follows:

Normal	○ 0
Diminution in swing while the patient is walking	◉ 1
Marked diminution in swing with obvious rigidity in the arm	○ 2
Stiff gait with arms held rigidly before the abdomen.	○ 3
Stooped shuffling gait with propulsion and retropulsion.	○ 4

▤ 2. ARM DROPPING

The patient and the examiner both raise their arms to shoulder height and let them fall to their sides. In a normal subject a stout slap is heard as the arms hit the sides. In the patient with extreme Parkinson's syndrome the arms fall very slowly.

Normal, free fall with loud slap and rebound.	◉ 0
Fall slowed slightly with less audible contact and little rebound.	○ 1
Fall slowed, no rebound	○ 2
Marked slowing, no slap at all	○ 3
Arms fall as though against resistance; as though through glue	○ 4

▤ 3. SHOULDER SHAKING

The subject's arms are bent at a right angle at the elbow and are taken one at a time by the examiner who grasps one hand and also clasps the other around the patient's elbow. The subject's upper arm is pushed to and fro and the humerus is externally rotated. The degree of resistance from normal to extreme rigidity is scored as follows:

Normal	○ 0
Slight Stiffness and resistance.	○ 1
Moderate stiffness and resistance.	◉ 2
Marked rigidity with difficulty in passive movement.	○ 3
Extreme stiffness and rigidity with almost a frozen shoulder.	○ 4

▤ 4. ELBOW RIGIDITY

The elbow joints are separately bent at right angles and passively extended and flexed, with the subject's biceps observed and simultaneously palpated. The resistance to this procedure is rated. (The presence of cogwheel rigidity is noted separately.) Scoring is from 0 to 4, as in the Shoulder Shaking test.

Normal	○ 0
Slight stiffness and resistance.	◉ 1
Moderate stiffness and resistance.	○ 2
Marked rigidity with difficulty in passive movement.	○ 3
Extreme stiffness and rigidity with almost a frozen shoulder.	○ 4

5. COGWHEELING

Cogwheeling is directly felt while each major joint of the upper extremity is being moved in flexion/extension, and pronation/supination.

	Not Present	Very Mild/Ques	Definitely Present
▤ Right	◉ 0	○ 1	○ 2
▤ Left	○ 0	◉ 1	○ 2
▤ Overall	○ 0	◉ 1	○ 2

Previous   Next

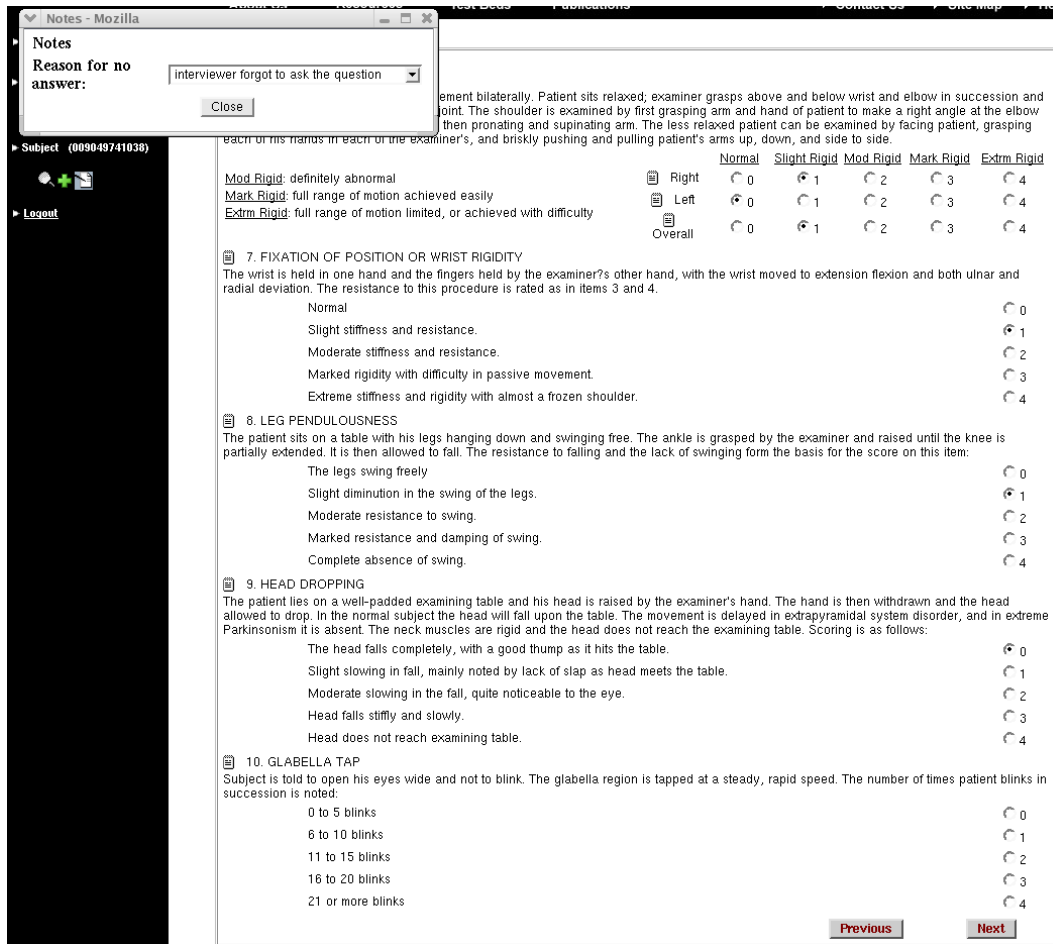Figure 2.11: Adding a new assessment - Step 3
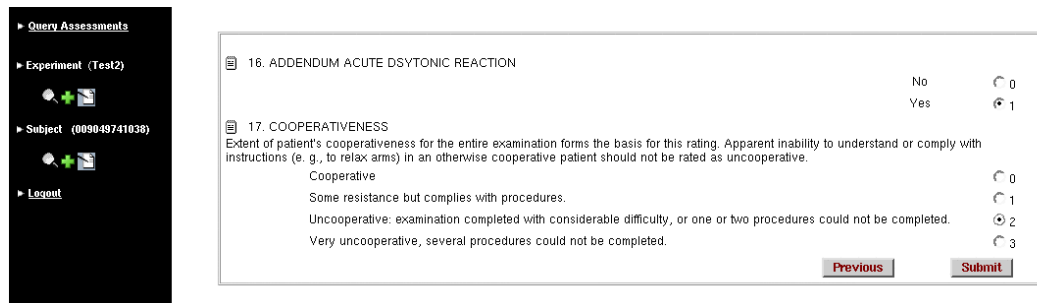
Figure 2.12: Adding a new assessment - Step 4

Figure 2.13: Adding a new assessment - Step 5

Subject

Subject ID: 009049741038

Experiment: Test2

Visit: 03/11/2005

Segments

New Segment

Segment: 03/11/2005 13:45

Segment ID: 1
Date: 03/11/2005   Time: 13:45   Protocol: UCSD RETROSPECTIVE ADRC BATTERY 1
Name: testName

Description: Edit

Assessments

Abnormal Involuntary Movement Scale   Add Assessment

Simpson Angus Rating Scale   Edit

Addendum Acute Dsytonic Reaction	Akathisia	Akinesia	Arm Dropping	Balance	Cogwheeling Left	Cogwheeling Overall	Cogwheeling Right	Cooperativeness	Elbow Rigidty
1	3	2	0	1	1	1	0	2	1

Family	Fixation of Position or wrist rigidty	Friends	GAIT	Glabella Tap	Head Dropping	Interview	Leg Pendulousness	Medication	Other
-10000	1	0	1	-10000	0	1	1	0	0

RATER1	RATER2	Reliability	Rigidity of major joints Left	Rigidity of major joints Overall	Rigidity of major joints Right	Salivation	Shoulder Shaking	Staff	Status
		2	0	1	1	1	2	0	0

Tremor Left	Tremor Overall	Tremor Right
2	0	1

Figure 2.14: Adding a new assessment -Step 6