

# COEUS



## IRB

# MODULE

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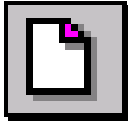
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# Short Cut Identification Sheet

## For IRB Module Only



**Protocol Button:** Opens the protocol screen, users can create a new protocol, create an amendment and create a renewal. You can also create notes here for a particular protocol at any point of the protocol history.



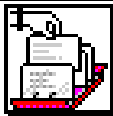
**Add Protocol Button:** This button creates a new record within the Protocol and Committee screens



**Protocol Summary Button:** Users can view the summary for a particular protocol. This is good for quick reference for such things as who is PI and expiration date.



**Protocol Details Button:** Allows users to view, only, the entire protocol record.



**Protocol Submission Button:** Opens a screen where users will see all protocols that have been submitted for IRB review and where all comments for the decisions made on a specific protocol will be entered. Also allows users to assign IRB reviewers to a particular protocol.



**Protocol Submission Details:** Allows users to view the summary of a particular protocols submission details. For example, this will let you check if the protocol go for an expedited or full review and who are the reviewers.

# Short Cut Identification Sheet

## For IRB Module Only



**Schedule Button:** Open the window where you would assign a protocol to a particular IRB committee and allows you to assign reviewers as well as assigning the protocol to a particular meeting.



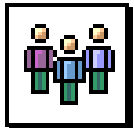
**Save Button:** Saves any changes made to a particular record.



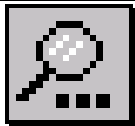
**Save As Button:** Use to save a query as an Excel report.



**Edit Button:** Allows user to edit a particular record in any screen.



**Committee Button:** Opens window to allow for the creation and modification of IRB committees.



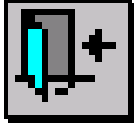
**Search Button:** Users can use this button to search with in any screen.



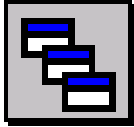
**Maintain Sponsor Button:** Allows for the creation and modification of sponsors.



**Rolodex Button:** Allows users to search for a particular agency and locate contact information for the same.



**Exit Button:** Use this button to exit out of the application



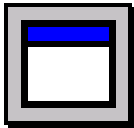
**Cascade Button:** Use this window to view the windows you have open in a cascade fashion.



**Tile Button:** Use this button to layout the windows you have open in a horizontal tile fashion.



**Vertical Tile Button:** Use this button to layout open windows in a vertical tile fashion.




**Layer Button:** Use this to place all the open windows one right on top of another in a “layered” fashion.

# Searching How To's

\*For all search options you can use the asterisk \* symbol as a wild card.

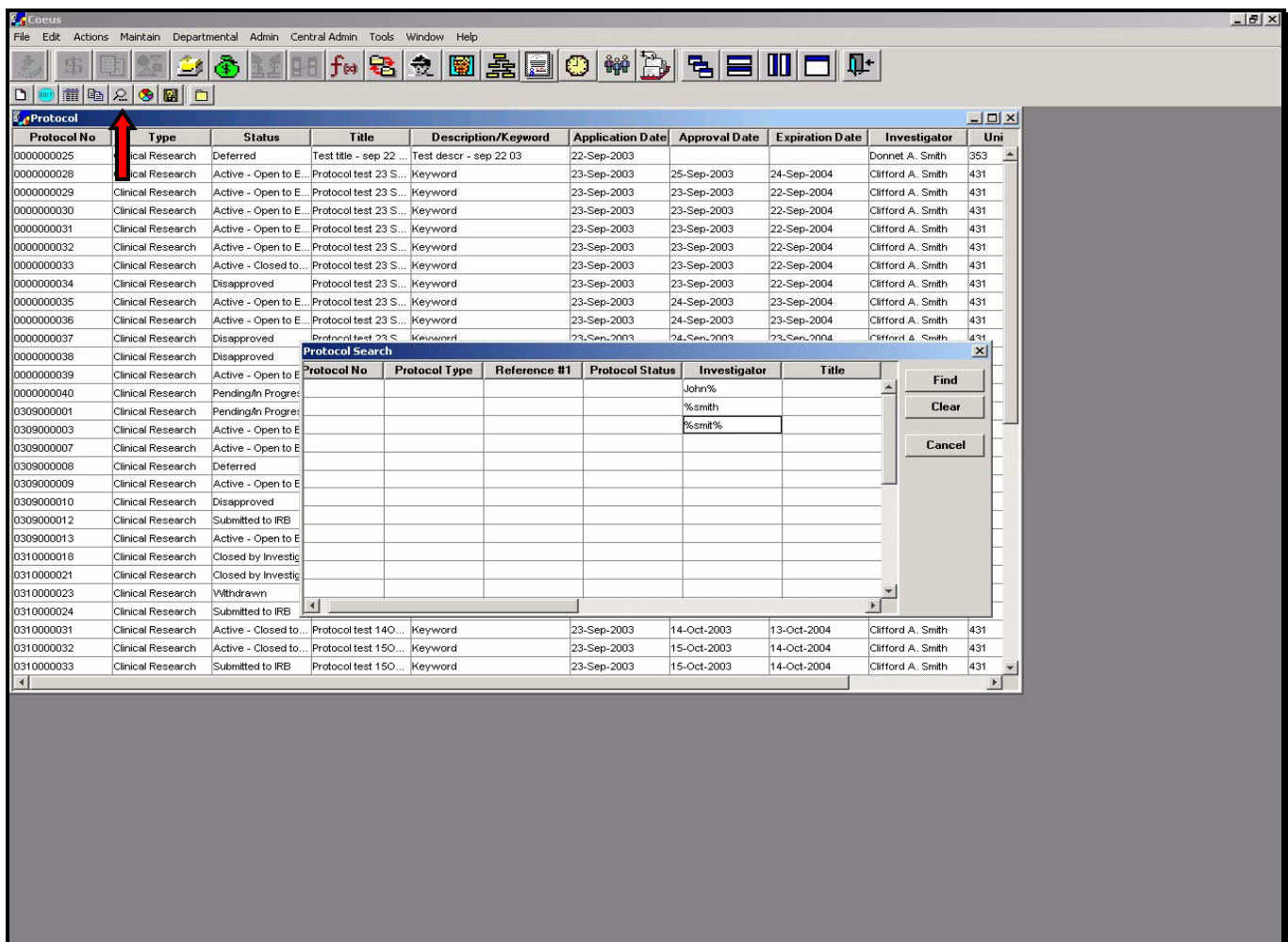
## 1. How to Search for PI Name, Protocol Number, & Title: EXAMPLE JOHN SMITH



Hit the Search Button  and when the window opens click in the Investigator field.

You can search by first or last name, and by part of a name.

For searching by First Name you will need to type the following: **“John\*”** this will generate a list of all the Johns that have protocols entered in the database. The wild card symbol is placed after the first name to indicate that it is “OK” for the database to pull a “John” with any text AFTER the first name. Like wise, if you’d like to look up an investigator by last name you would type **“\*Smith”**. This will pull all of the Smiths that were entered into the database. Here the wild card was used BEFORE the last name to tell the database that it can pull all records with any text before the word “Smith”. In order to search by a partial name you would type **“\*Smit\*”** this will pull a list with any name that has “Smit” in it.




The screenshot shows the Lotus database application interface. A search window titled "Protocol Search" is open, displaying a table with columns: Protocol No, Protocol Type, Reference #1, Protocol Status, Investigator, and Title. The search criteria entered in the Investigator field is "John%". The main window displays a list of protocol records with columns: Protocol No, Type, Status, Title, Description/Keyword, Application Date, Approval Date, Expiration Date, Investigator, and Uni.

Protocol No	Type	Status	Title	Description/Keyword	Application Date	Approval Date	Expiration Date	Investigator	Uni
0000000025	Clinical Research	Deferred	Test title - sep 22 ...	Test descr - sep 22 03	22-Sep-2003			Donnet A. Smith	353
0000000028	Clinical Research	Active - Open to E...	Protocol test 23 S...	Keyword	23-Sep-2003	25-Sep-2003	24-Sep-2004	Clifford A. Smith	431
0000000029	Clinical Research	Active - Open to E...	Protocol test 23 S...	Keyword	23-Sep-2003	23-Sep-2003	22-Sep-2004	Clifford A. Smith	431
0000000030	Clinical Research	Active - Open to E...	Protocol test 23 S...	Keyword	23-Sep-2003	23-Sep-2003	22-Sep-2004	Clifford A. Smith	431
0000000031	Clinical Research	Active - Open to E...	Protocol test 23 S...	Keyword	23-Sep-2003	23-Sep-2003	22-Sep-2004	Clifford A. Smith	431
0000000032	Clinical Research	Active - Open to E...	Protocol test 23 S...	Keyword	23-Sep-2003	23-Sep-2003	22-Sep-2004	Clifford A. Smith	431
0000000033	Clinical Research	Active - Closed to...	Protocol test 23 S...	Keyword	23-Sep-2003	23-Sep-2003	22-Sep-2004	Clifford A. Smith	431
0000000034	Clinical Research	Disapproved	Protocol test 23 S...	Keyword	23-Sep-2003	23-Sep-2003	22-Sep-2004	Clifford A. Smith	431
0000000035	Clinical Research	Active - Open to E...	Protocol test 23 S...	Keyword	23-Sep-2003	24-Sep-2003	23-Sep-2004	Clifford A. Smith	431
0000000036	Clinical Research	Active - Open to E...	Protocol test 23 S...	Keyword	23-Sep-2003	24-Sep-2003	23-Sep-2004	Clifford A. Smith	431
0000000037	Clinical Research	Disapproved	Protocol test 23 S...	Keyword	23-Sep-2003	24-Sep-2003	23-Sep-2004	Clifford A. Smith	431
0000000038	Clinical Research	Disapproved							
0000000039	Clinical Research	Active - Open to E...						John%	
0000000040	Clinical Research	Pending/In Progres...						%smith	
0309000001	Clinical Research	Pending/In Progres...						%smit%	
0309000003	Clinical Research	Active - Open to E...							
0309000007	Clinical Research	Active - Open to E...							
0309000008	Clinical Research	Deferred							
0309000009	Clinical Research	Active - Open to E...							
0309000010	Clinical Research	Disapproved							
0309000012	Clinical Research	Submitted to IRB							
0309000013	Clinical Research	Active - Open to E...							
0310000018	Clinical Research	Closed by Investig...							
0310000021	Clinical Research	Closed by Investig...							
0310000023	Clinical Research	Withdrawn							
0310000024	Clinical Research	Submitted to IRB							
0310000031	Clinical Research	Active - Closed to...	Protocol test 140...	Keyword	23-Sep-2003	14-Oct-2003	13-Oct-2004	Clifford A. Smith	431
0310000032	Clinical Research	Active - Closed to...	Protocol test 150...	Keyword	23-Sep-2003	15-Oct-2003	14-Oct-2004	Clifford A. Smith	431
0310000033	Clinical Research	Submitted to IRB	Protocol test 150...	Keyword	23-Sep-2003	15-Oct-2003	14-Oct-2004	Clifford A. Smith	431

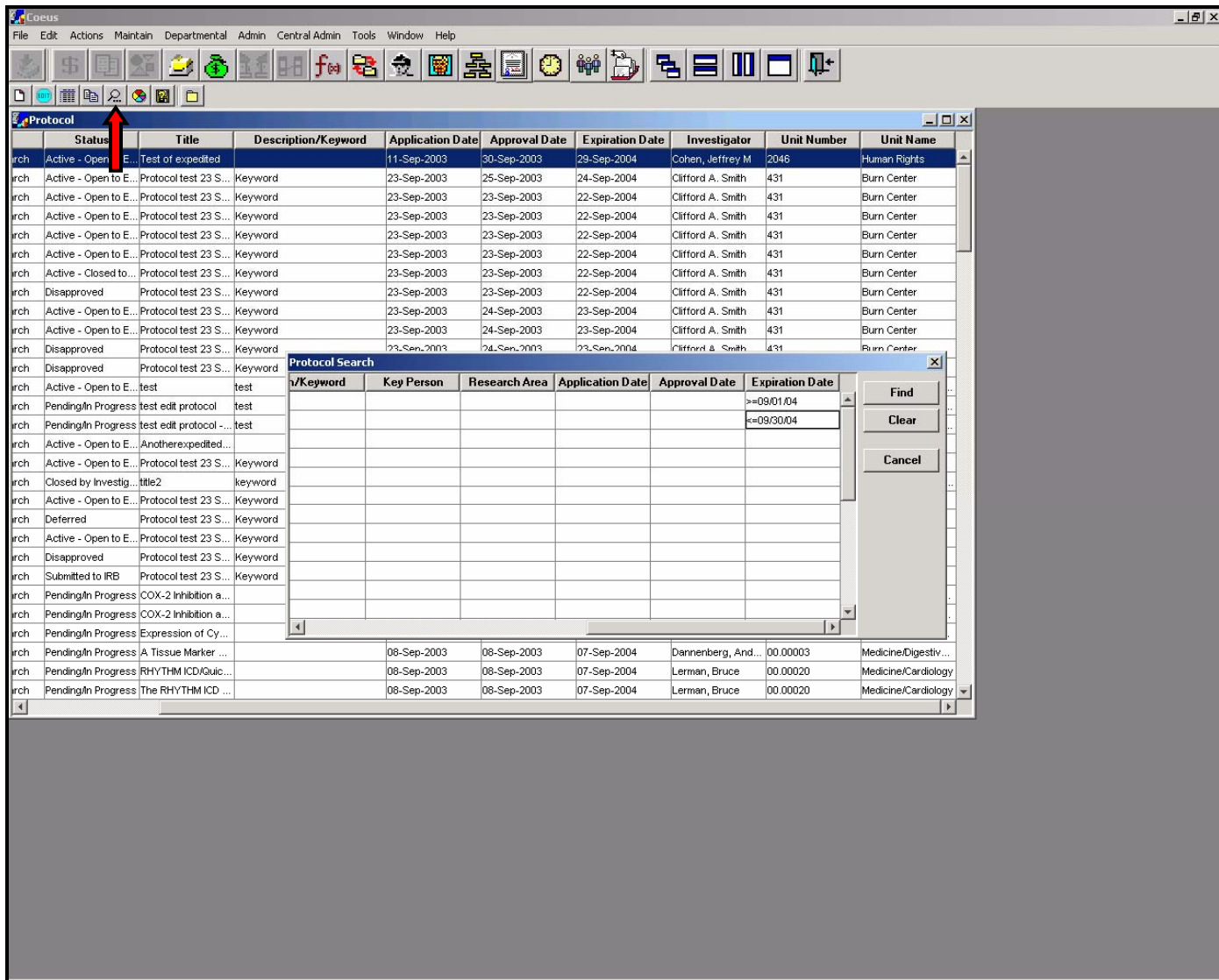
# Searching How To's

The same principle used in this example to search by Investigator name would be used to locate a record by either protocol number, title, description, keyword or any other field that is NOT a drop down menu.

## 2. How to Search by Date Range: EXAMPLE 9/01/04-9/30/04 by Expiration Date

The search option will open automatically when the Protocol Screen is opened for the first time. Or you can hit the Search Button  and click on either the Protocol Number, Approval or Expiration Date. For this example we will use the Expiration Date field.

In order to define the range you will need to type in the following statement within two cells of the search field. In the first cell you will type in the starting date “>=09/01/04”, then in the second cell you will type the end date as “and <=09/30/04”.



Protocol Number	Status	Title	Description/Keyword	Application Date	Approval Date	Expiration Date	Investigator	Unit Number	Unit Name
rch	Active - Open	E. Test of expedited		11-Sep-2003	30-Sep-2003	29-Sep-2004	Cohen, Jeffrey M	2046	Human Rights
rch	Active - Open to E...	Protocol test 23 S...	Keyword	23-Sep-2003	25-Sep-2003	24-Sep-2004	Clifford A. Smith	431	Burn Center
rch	Active - Open to E...	Protocol test 23 S...	Keyword	23-Sep-2003	23-Sep-2003	22-Sep-2004	Clifford A. Smith	431	Burn Center
rch	Active - Open to E...	Protocol test 23 S...	Keyword	23-Sep-2003	23-Sep-2003	22-Sep-2004	Clifford A. Smith	431	Burn Center
rch	Active - Open to E...	Protocol test 23 S...	Keyword	23-Sep-2003	23-Sep-2003	22-Sep-2004	Clifford A. Smith	431	Burn Center
rch	Active - Open to E...	Protocol test 23 S...	Keyword	23-Sep-2003	23-Sep-2003	22-Sep-2004	Clifford A. Smith	431	Burn Center
rch	Active - Closed to...	Protocol test 23 S...	Keyword	23-Sep-2003	23-Sep-2003	22-Sep-2004	Clifford A. Smith	431	Burn Center
rch	Disapproved	Protocol test 23 S...	Keyword	23-Sep-2003	23-Sep-2003	22-Sep-2004	Clifford A. Smith	431	Burn Center
rch	Active - Open to E...	Protocol test 23 S...	Keyword	23-Sep-2003	24-Sep-2003	23-Sep-2004	Clifford A. Smith	431	Burn Center
rch	Disapproved	Protocol test 23 S...	Keyword	23-Sep-2003	24-Sep-2003	23-Sep-2004	Clifford A. Smith	431	Burn Center
rch	Disapproved	Protocol test 23 S...	Keyword	23-Sep-2003	24-Sep-2003	23-Sep-2004	Clifford A. Smith	431	Burn Center
rch	Disapproved	Protocol test 23 S...	Keyword	23-Sep-2003	24-Sep-2003	23-Sep-2004	Clifford A. Smith	431	Burn Center
rch	Active - Open to E...	test	test						
rch	Pending/In Progress	test edit protocol	test						
rch	Pending/In Progress	test edit protocol -...	test						
rch	Active - Open to E...	Another expedited...							
rch	Active - Open to E...	Protocol test 23 S...	Keyword						
rch	Closed by Investig...	title2	keyword						
rch	Active - Open to E...	Protocol test 23 S...	Keyword						
rch	Deferred	Protocol test 23 S...	Keyword						
rch	Active - Open to E...	Protocol test 23 S...	Keyword						
rch	Disapproved	Protocol test 23 S...	Keyword						
rch	Submitted to IRB	Protocol test 23 S...	Keyword						
rch	Pending/In Progress	COX-2 Inhibition a...							
rch	Pending/In Progress	COX-2 Inhibition a...							
rch	Pending/In Progress	Expression of Cy...							
rch	Pending/In Progress	A Tissue Marker ...		08-Sep-2003	08-Sep-2003	07-Sep-2004	Dannenberg, And...	00.00003	Medicine/Digestiv...
rch	Pending/In Progress	RHYTHM ICD/Quic...		08-Sep-2003	08-Sep-2003	07-Sep-2004	Lerman, Bruce	00.00020	Medicine/Cardiology
rch	Pending/In Progress	The RHYTHM ICD ...		08-Sep-2003	08-Sep-2003	07-Sep-2004	Lerman, Bruce	00.00020	Medicine/Cardiology

# Searching How To's

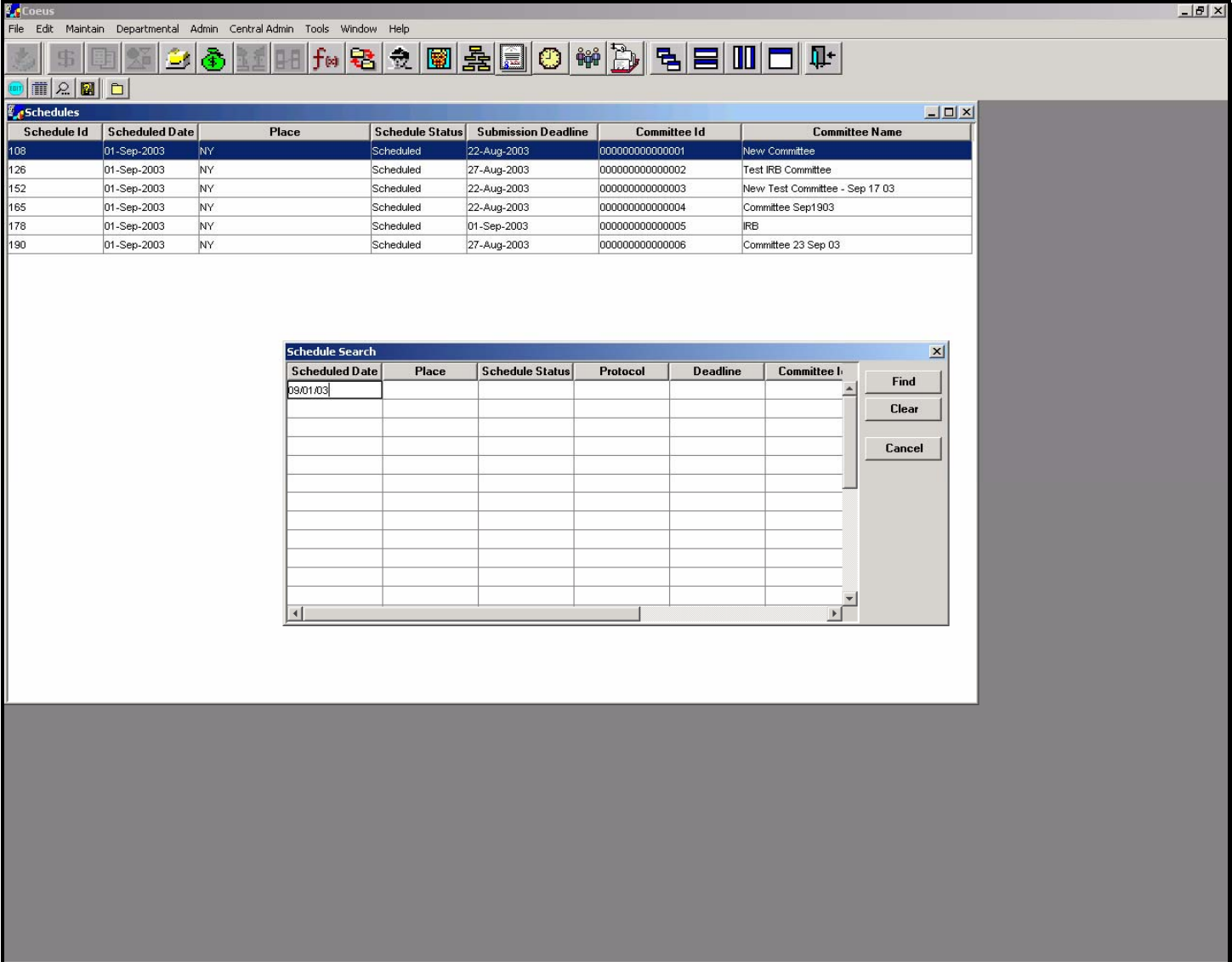
## 3. How to Search for Records that Have Been Submitted for Review: EXAMPLE 09/01/03 Meeting Date

This type of search will be done in the Schedule Screen. Again the search window will automatically open when this screen is launched for the first time, or you

can hit the Search Button .

In this example we are looking to find records which have been submitted for review at a particular meeting date; this case 9/01/03. One of the purposes for this type of search would be to generate an agenda.

You will need to enter the following meeting date **“09/01/03”** in the “Scheduled Date” field. All IRB Committees that have meetings scheduled for this date will be generated.



The screenshot displays the Coeus application interface. At the top, there is a menu bar (File, Edit, Maintain, Departmental, Admin, Central Admin, Tools, Window, Help) and a toolbar with various icons. The main window is titled "Schedules" and contains a table with the following data:


Schedule Id	Scheduled Date	Place	Schedule Status	Submission Deadline	Committee Id	Committee Name
108	01-Sep-2003	NY	Scheduled	22-Aug-2003	0000000000000001	New Committee
126	01-Sep-2003	NY	Scheduled	27-Aug-2003	0000000000000002	Test IRB Committee
152	01-Sep-2003	NY	Scheduled	22-Aug-2003	0000000000000003	New Test Committee - Sep 17 03
165	01-Sep-2003	NY	Scheduled	22-Aug-2003	0000000000000004	Committee Sep1903
178	01-Sep-2003	NY	Scheduled	01-Sep-2003	0000000000000005	IRB
190	01-Sep-2003	NY	Scheduled	27-Aug-2003	0000000000000006	Committee 23 Sep 03

Below the table, a "Schedule Search" dialog box is open. It has a table with the following columns: Scheduled Date, Place, Schedule Status, Protocol, Deadline, and Committee Id. The "Scheduled Date" field contains the text "09/01/03". To the right of the table are three buttons: "Find", "Clear", and "Cancel".

# Searching How To's

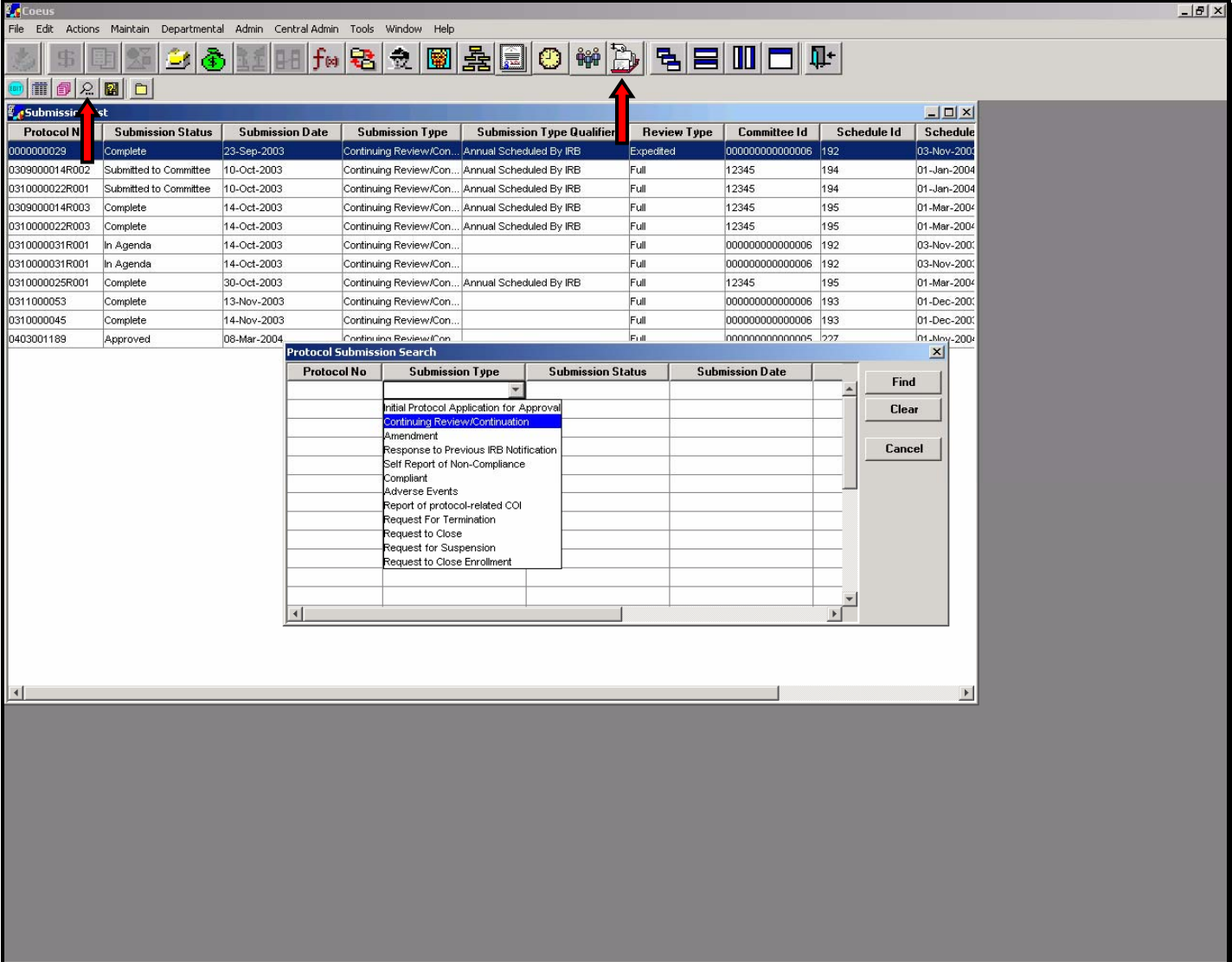
## 4. How to Search by Submission Type: EXAMPLE View a list of all Initial Protocol Applications records that have been submitted for review

This search will be done within the Protocol Submission List screen. The search window will open up automatically when you open up the Submission List screen or you

can hit the Search Button .

Select the "Submission Type" field and it will give you a drop down list with all of the different kinds of Submission types. In this example you will select "Initial Protocol Application" and then hit the "Find" button.

The database will generate a list of all the Initial Protocol Applications that have been submitted to the IRB. These same steps would be taken to look up Continuing Reviews or Amendments that have been submitted for review. The only change would be the Submission Type you select.



The screenshot shows the Coeus software interface. The main window displays a table of protocol submissions. A search window titled "Protocol Submission Search" is open, showing a dropdown menu for "Submission Type" with "Initial Protocol Application for Approval" selected. The search window also has fields for "Protocol No", "Submission Status", and "Submission Date", along with "Find", "Clear", and "Cancel" buttons.

Protocol No	Submission Status	Submission Date	Submission Type	Submission Type Qualifier	Review Type	Committee Id	Schedule Id	Schedule
000000029	Complete	23-Sep-2003	Continuing Review/Con...	Annual Scheduled By IRB	Expedited	000000000000006	192	03-Nov-2003
030900014R002	Submitted to Committee	10-Oct-2003	Continuing Review/Con...	Annual Scheduled By IRB	Full	12345	194	01-Jan-2004
031000022R001	Submitted to Committee	10-Oct-2003	Continuing Review/Con...	Annual Scheduled By IRB	Full	12345	194	01-Jan-2004
030900014R003	Complete	14-Oct-2003	Continuing Review/Con...	Annual Scheduled By IRB	Full	12345	195	01-Mar-2004
031000022R003	Complete	14-Oct-2003	Continuing Review/Con...	Annual Scheduled By IRB	Full	12345	195	01-Mar-2004
031000031R001	In Agenda	14-Oct-2003	Continuing Review/Con...		Full	000000000000006	192	03-Nov-2003
031000031R001	In Agenda	14-Oct-2003	Continuing Review/Con...		Full	000000000000006	192	03-Nov-2003
031000025R001	Complete	30-Oct-2003	Continuing Review/Con...	Annual Scheduled By IRB	Full	12345	195	01-Mar-2004
0311000053	Complete	13-Nov-2003	Continuing Review/Con...		Full	000000000000006	193	01-Dec-2003
0310000045	Complete	14-Nov-2003	Continuing Review/Con...		Full	000000000000006	193	01-Dec-2003
0403001189	Approved	08-Mar-2004	Continuing Review/Con...		Full	nnnnnnnnnnnnnnns	???	01-Nov-2003





# Running Reports



2. Once the necessary list has been generated, you will need to hit the Save As button. This action will automatically bring up the “Save Window”. From here, you will name the file, and let the database know where to save the report. In this example I called my file “Dr. Smith” and I choose to keep it on my Desktop.

3. At this point you have finished running the report. The database has saved the report as an Excel file.

The screenshot shows the Coeus software interface. The main window displays a table with the following columns: Protocol No, Type, Status, Title, Description/Keyword, Application Date, Approval Date, Expiration Date, Investigator, and Unit N. The table contains multiple rows of clinical research protocols. A red arrow points to the 'Save As' button in the toolbar. A 'Save' dialog box is open, showing the 'Save in' location as 'Desktop'. The dialog box includes a list of folders (My Documents, My Computer, My Network Places, Coeus-Cornell-DataMap) and a 'Files of type' dropdown set to 'XLS'. The 'File name' field is empty, and the 'Save' button is highlighted.

Protocol No	Type	Status	Title	Description/Keyword	Application Date	Approval Date	Expiration Date	Investigator	Unit N
0000000028	Clinical Research	Active - Open to E...	Protocol test 23 S...	Keyword	23-Sep-2003	25-Sep-2003	24-Sep-2004	Clifford A. Smith	431
0000000029	Clinical Research	Active - Open to E...	Protocol test 23 S...	Keyword	23-Sep-2003	23-Sep-2003	22-Sep-2004	Clifford A. Smith	431
0000000030	Clinical Research	Active - Open to E...	Protocol test 23 S...	Keyword	23-Sep-2003	23-Sep-2003	22-Sep-2004	Clifford A. Smith	431
0000000031	Clinical Research	Active - Open to E...	Protocol test 23 S...	Keyword	23-Sep-2003	23-Sep-2003	22-Sep-2004	Clifford A. Smith	431
0000000032	Clinical Research	Active - Open to E...	Protocol test 23 S...	Keyword	23-Sep-2003	23-Sep-2003	22-Sep-2004	Clifford A. Smith	431
0000000035	Clinical Research	Active - Open to E...	Protocol test 23 S...	Keyword	23-Sep-2003	24-Sep-2003	23-Sep-2004	Clifford A. Smith	431
0000000036	Clinical Research	Active - Open to E...	Protocol test 23 S...	Keyword	23-Sep-2003	24-Sep-2003	23-Sep-2004	Clifford A. Smith	431
0000000039	Clinical Research	Active - Open to E...	test	test	24-Sep-2003	24-Sep-2003	23-Sep-2004	Donnet A. Smith	353
0309000003	Clinical Research	Active - Open to E...	Protocol te					mith	431
0309000007	Clinical Research	Active - Open to E...	Protocol te					mith	431
0309000009	Clinical Research	Active - Open to E...	Protocol te					mith	431
0309000013	Clinical Research	Active - Open to E...	Protocol te					mith	431
0310000041	Clinical Research	Active - Open to E...	New title C					mith	353
0310000043	Clinical Research	Active - Open to E...	New title C					mith	353
0310000045	Clinical Research	Active - Open to E...	New title C					mith	353
0310000047	Clinical Research	Active - Open to E...	New title C					mith	353
0311000050	Clinical Research	Active - Open to E...	Title Nov06					mith	353
0311000051	Clinical Research	Active - Open to E...	Title Nov 0					mith	353
0311000052	Clinical Research	Active - Open to E...	New Proto					mith	353
0311000053	Clinical Research	Active - Open to E...	New Proto					mith	353
0402001178	Clinical Research	Active - Open to E...	New Proto					mith	353
0402001179	Clinical Research	Active - Open to E...	New Proto					mith	353
0402001181	Clinical Research	Active - Open to E...	New Proto					mith	353

# Protocol Screen Description

## Protocol Tab:

Field Name	Field Description	Field Notes
Protocol Number	Auto generated by clicking the save button; once all of the field have been completed.	
Protocol Type <b>(Required)</b>	Drop down list.	This value can be used to determine trends among various types of research.
Title <b>(Required)</b>	Self Explanatory	
Description/Keyword	For recording details that are not obvious from the title	Useful things to add here: <ul style="list-style-type: none"> <li>• Drug names</li> <li>• Names of illnesses</li> </ul>
Approval date	Auto generated once the status of a record has been modified to “Active Open to Enrollment”	
Expiration date	Auto generated once the status of a record has been modified to “Active Open to Enrollment”	
Reference Num 1	Used to track any other type of identifier.	Useful things to add here: <ul style="list-style-type: none"> <li>• Old protocol numbers</li> <li>• Columbia protocol numbers.</li> </ul>
Reference Num 2	Used to track any other type of identifier.	Useful things to add here: <ul style="list-style-type: none"> <li>• A contract or a grant number, if known.</li> </ul>
Organization Type	Drop down list records the type institutes that will be working on the project.	This section defaults to WMC, however it can be changed when required. Useful things to add here: <ul style="list-style-type: none"> <li>• Any cooperative organizations such as Columbia.</li> </ul>
Organization	Lists the name of the performing organizations	Defaults to WMC.

# Protocol Screen Description

## Investigator Tab:

Field Name	Field Description	Field Notes
Person Name <b>(Required)</b>	Records the name of the Primary Investigator.	Is automatically filled when a person has been selected from the Person or Rolodex directories.
PI	Box is automatically checked to flag for who is the PI.	Is automatically filled when a person has been selected from the Person or Rolodex directories.
Lead <b>(Required)</b>	Check this box if the unit/department that is listed for the PI is the performing department.	Additional unit/departments for each PI can be added
Number	The unique identifier for each department/unit.	Is auto generated when a person has been selected from the Person or Rolodex directories; or when a department/unit has been changed
Name	Name of the department.	Is auto generated when a person has been selected from the Person or Rolodex directories; or when a department/unit has been changed
OSP Administrator	N/A	Is auto generated when a person has been selected from the Person or Rolodex directories; or when a department/unit has been changed

# Protocol Screen Description

## Key Study Personnel:

Field Name	Field Description	Field Notes
Person Name	Records the name of the key personnel on the project.	Is automatically filled in when a person has been selected from the Person or Rolodex directories
Role	Self explanatory	Free text field. User can type in any text.
Affiliation	Drop down list to flag for Faculty, Non-Faculty or Affiliate	

## Correspondence Tab:

Field Name	Field Description	Field Notes
Type	Drop down list	Useful to identify the kind of contact that is recorded. For example, if you need to contact James Smith for any protocol detail and John Doe from a Sponsor agency, this tab allows for that information.
Name	Name of contact	Is automatically filled in when a person has been selected from the Person or Rolodex directories.
Comments	Self explanatory	

## Area of Research:

Field Name	Field Description	Field Notes
Code	Unique identifier for each department/unit	This is auto generated when a department/unit has been selected
Name <b>(Required)</b>	Name of unit/department	This is auto generated when a unit/department has been selected

# Protocol Screen Description

## Funding Source:

Field Name	Field Description	Field Notes
Type	Drop down list.	You choose, if none leave blank
Sponsor/Unit Number	Unique identifier for the Sponsor or Unit	Auto generated when Sponsor or Unit has been selected.
Name	Name of Sponsor or Unit	Auto generated when Sponsor or Unit has been selected.

## Actions Tab:

Field Name	Field Description	Field Notes
Description	Identifies the type of action that was taken on a protocol	Field is auto generated as protocol actions occur
Date	Self Explanatory	
Comments	Self Explanatory	

## Subjects Tab:

Field Name	Field Description	Field Notes
Description	Lists the type of subject used in the study	
Count	Number of subjects used in the study	

## Special Review:

Field Name	Field Description	Field Notes
Special Review	Drop down list	Useful to log any other kind of review the protocol requires.
Approval	Drop down list with statuses for the special review	
Protocol Number	Self Explanatory	Use for studies that need both IRB and IACUC protocols
Application Date	Self Explanatory	
Approval Date	Self Explanatory	
Special Review Comments	Self Explanatory	

# Protocol Screen Description

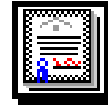
## Notes Tab:

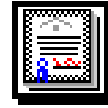
Field Name	Field Description	Field Notes
Comment	Self Explanatory	
By	Auto generates the user name of the person who created the note	
Time	Track dates and time of entry	
Restricted	Check box	Is used to make a note that the user does not want others to see. Will become useful once PIs begin to submit on-line.

## Amendments and Renewals:


Field Name	Field Description	Field Notes
Type	Either Amendment or Renewal	Auto generated when user selects to add and Amendment or Renewal
Version	Track the amendment or renewal number	
Status	Self Explanatory	
Created Date	Track the date the amendment or renewal was created	
Summary	A notes box for each amendment or renewal entry	

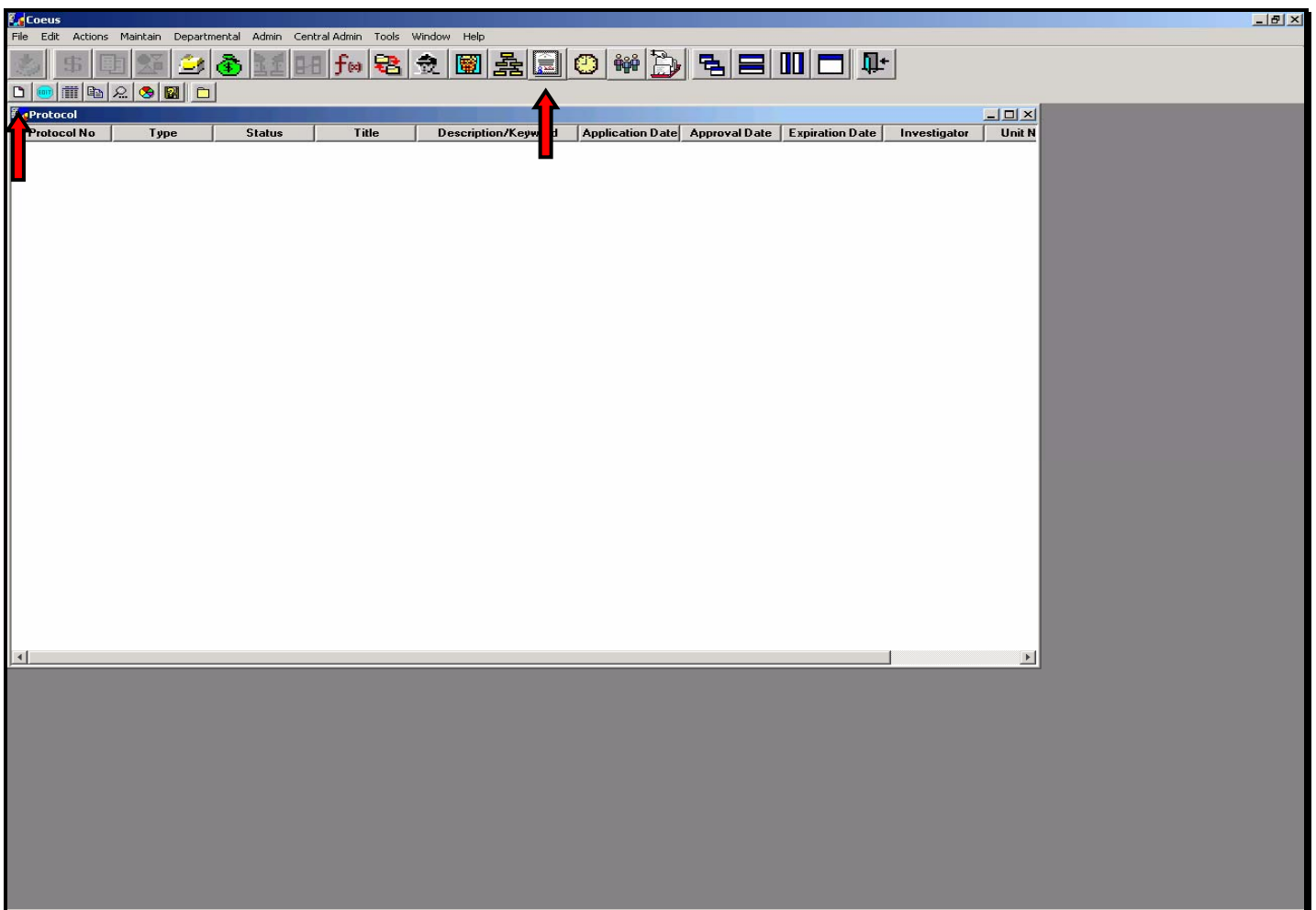
# How to Create a New Protocol Entry



1. Open the Protocol screen by hitting the *Protocol* Button  or by clicking on the *Maintain* menu and selecting *Protocol*. This action will automatically open the search window, if the screen is being opened for the first time; simply hit “Cancel” to continue



2. To create a new protocol you must click on the *Add Protocol* button  located on the upper left hand side of your screen. You can also go to the *Edit* menu and select the *Add* option. A window for a new protocol will open and you can begin to enter the information for a protocol, such as PI, Title, Keywords and so on.



# How to Create a New Protocol Entry

- 3. Protocol Tab:** This tab requires the user to enter the title of the protocol and the type of protocol that is being submitted. For example, a Clinical Research or Medical Record Review. It is important to note that this tab provides us with two fields called “Reference Number 1” and “Reference Number 2”. This is where the user can record any other Protocol numbers, like numbers provided from Columbia University or old Protocol numbers. This is a *key* field due to the fact that Coeus will automatically generate the protocol number. Under the “Organization” section of this tab, Coeus will automatically enter the WMC information. However, if another organization is the performing organization or if there is more than one institute that will work on the study, you can add that organization by hitting the *Add* button and locating the organization in the Organization search window.

The screenshot shows the Coeus software interface for creating a new protocol entry. The window title is "Coeus" and the menu bar includes File, Edit, Protocol Actions, Maintain, Departmental, Admin, Central Admin, Window, and Help. The toolbar contains various icons for navigation and actions. The main window is titled "Protocol Details" and has a tabbed interface with the following tabs: Protocol, Investigator, Key Study Personnel, Correspondents, Area of Research, Funding Source, Actions, Subjects, Special Review, Notes, and Amendments & Renewals. The "Protocol" tab is active, showing the following fields:

- Protocol Number:** [Empty text field]
- Type:** Clinical Research (dropdown menu)
- Status:** Pending/In Progress (dropdown menu)
- Billable:**
- Title:** Lose weight by eating chocolate (text field)
- Description/Keyword:** [Empty text field]
- Application Date:** 18-Mar-2004 (text field)
- Approval Date:** [Empty text field]
- Expiration Date:** [Empty text field]
- FDA Application No.:** [Empty text field]
- Reference Num 1:** [Empty text field]
- Reference Num 2:** [Empty text field]

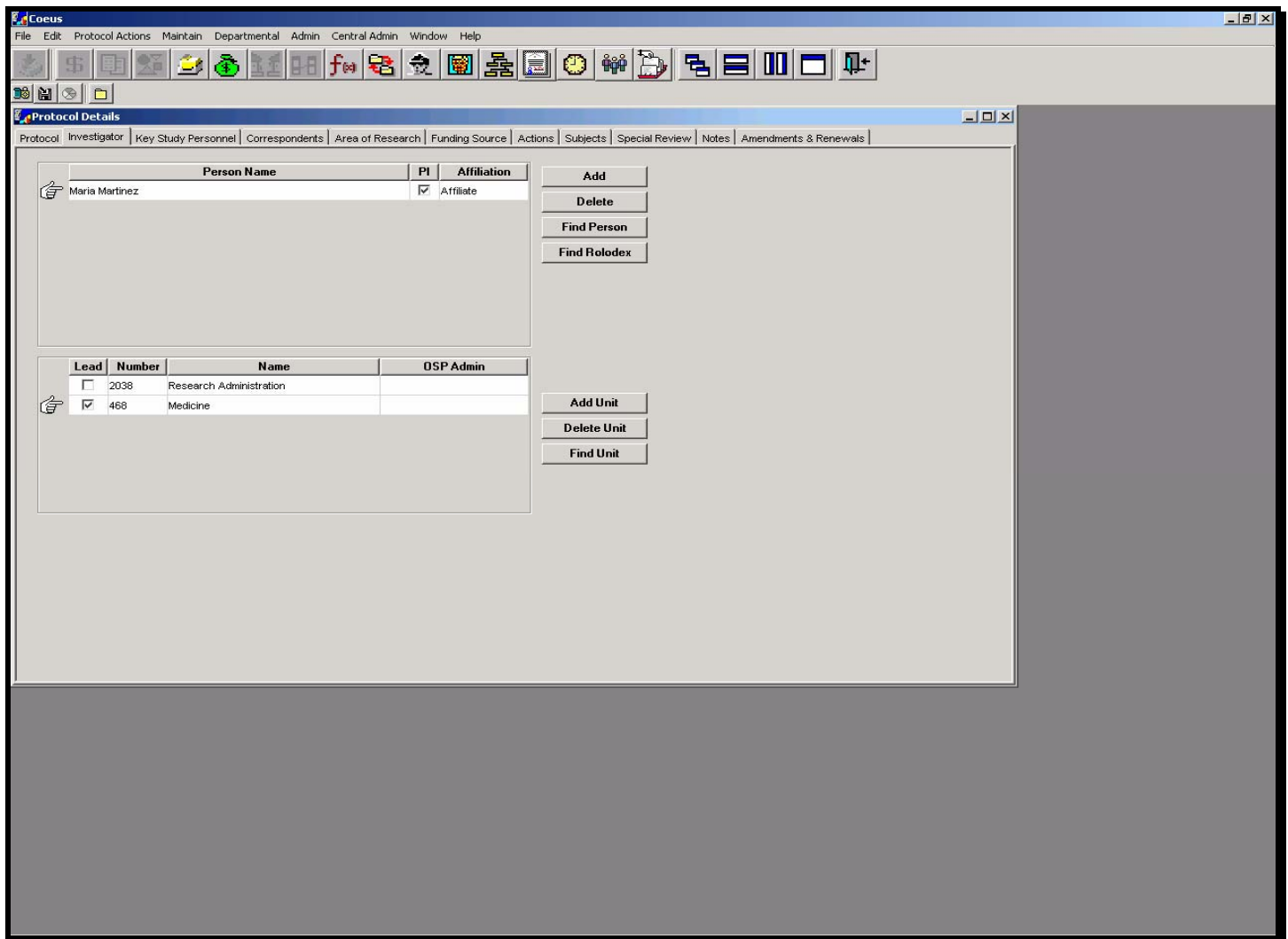
Below the protocol details is the "Protocol Organizations" section, which includes a table for organizations and an address field:

Type	Organization	Address
Performing Organization	RASP Office	my.org 123 maple street new york New York 12346, United States

Buttons for "Add", "Delete", "Find Addr", and "Clear Addr" are located to the right of the table.

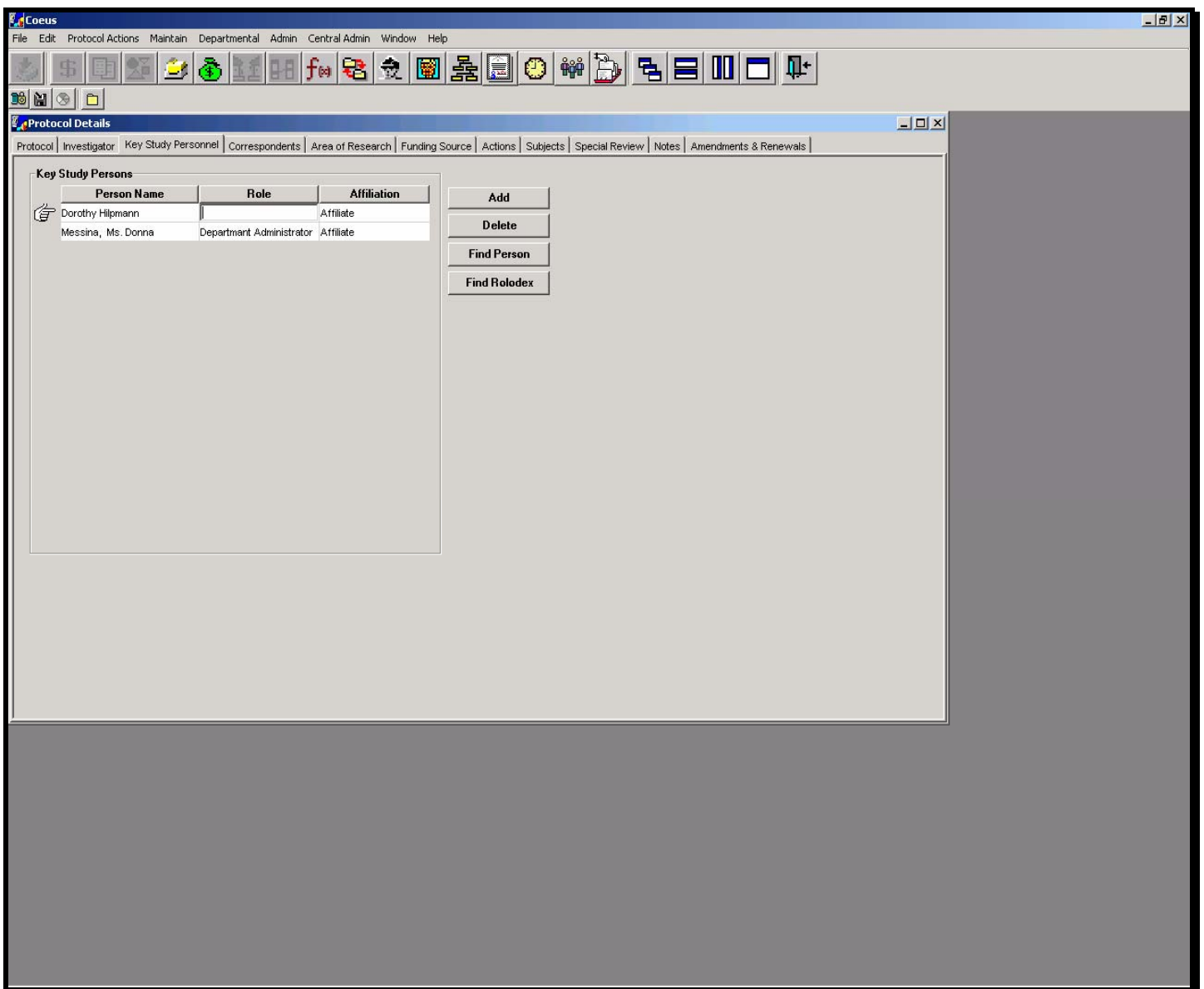
# How to Create a New Protocol Entry

- 4. Investigator Tab:** Here the user will record the information for the Primary Investigator. You will begin this section by hitting the “Find Person” button. This will pop open a search window, where you will type the Investigator name. Coeus will then generate that particular person or list of persons that have the same name. Highlight the person that will be the P.I. of the study and hit “OK”; Coeus will plug in the information onto the tab for you. Be sure to check off the lead unit box as it is a required field. Perhaps the PI works with more than one department; lead “Unit” represents the department where the PI primarily works. The user can add or remove units/departments by using the buttons on the right side of the unit listing.



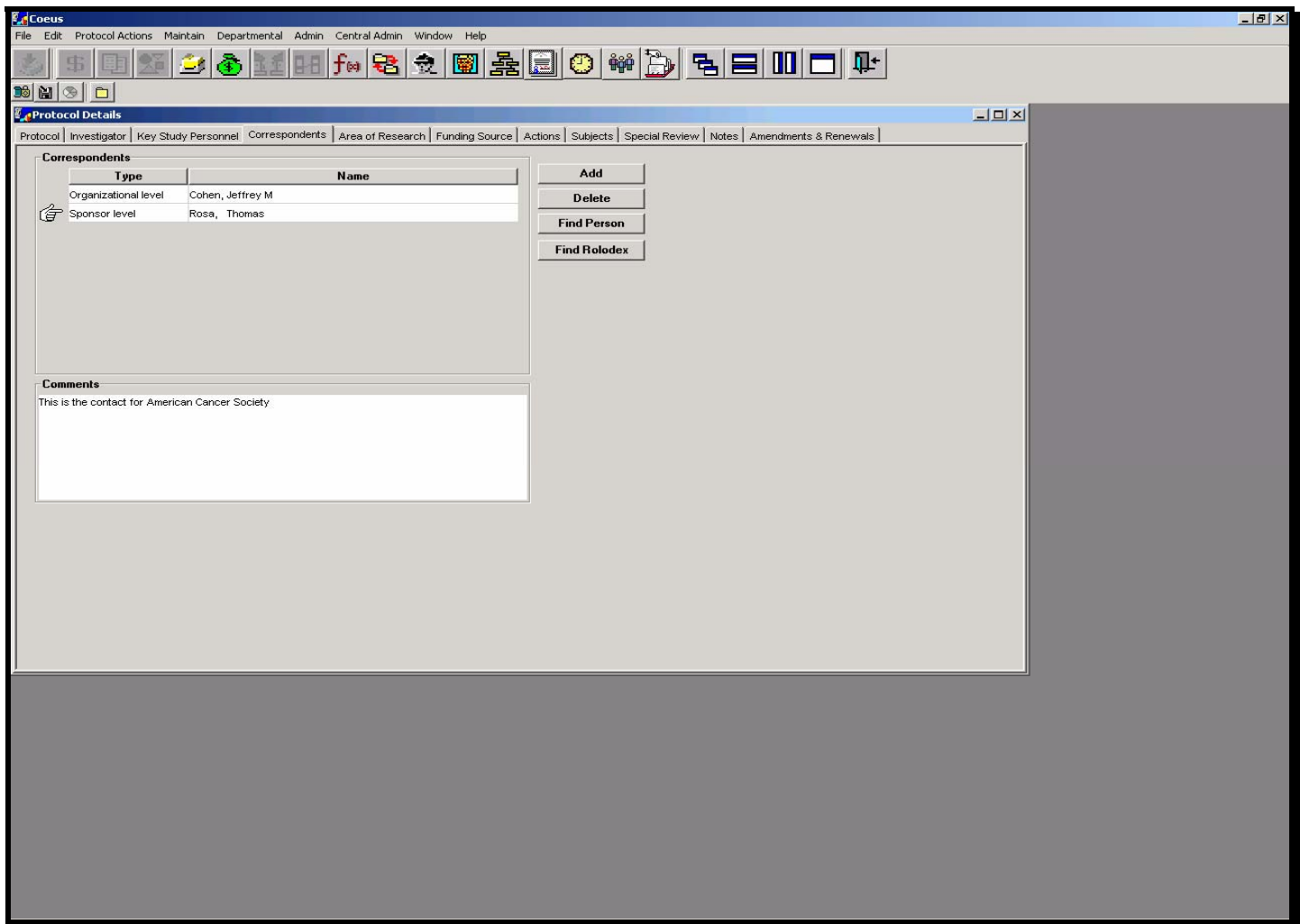
# How to Create a New Protocol Entry

- 5. Key Study Personnel Tab:** To begin this section, you will again start by hitting the *Find Person* button, and then typing in the name of the key personnel you need to enter. Coeus will generate the name, or list of names, that you are looking for. Highlight the name of the person you'd like to record and hit the *Ok* button. Coeus will plug in the name for you. Once the name has been entered you can click on the "Affiliation" field and select either affiliate, faculty, or non- faculty from the drop down list. In the "Role" field, free type any particular details that you would like to record.



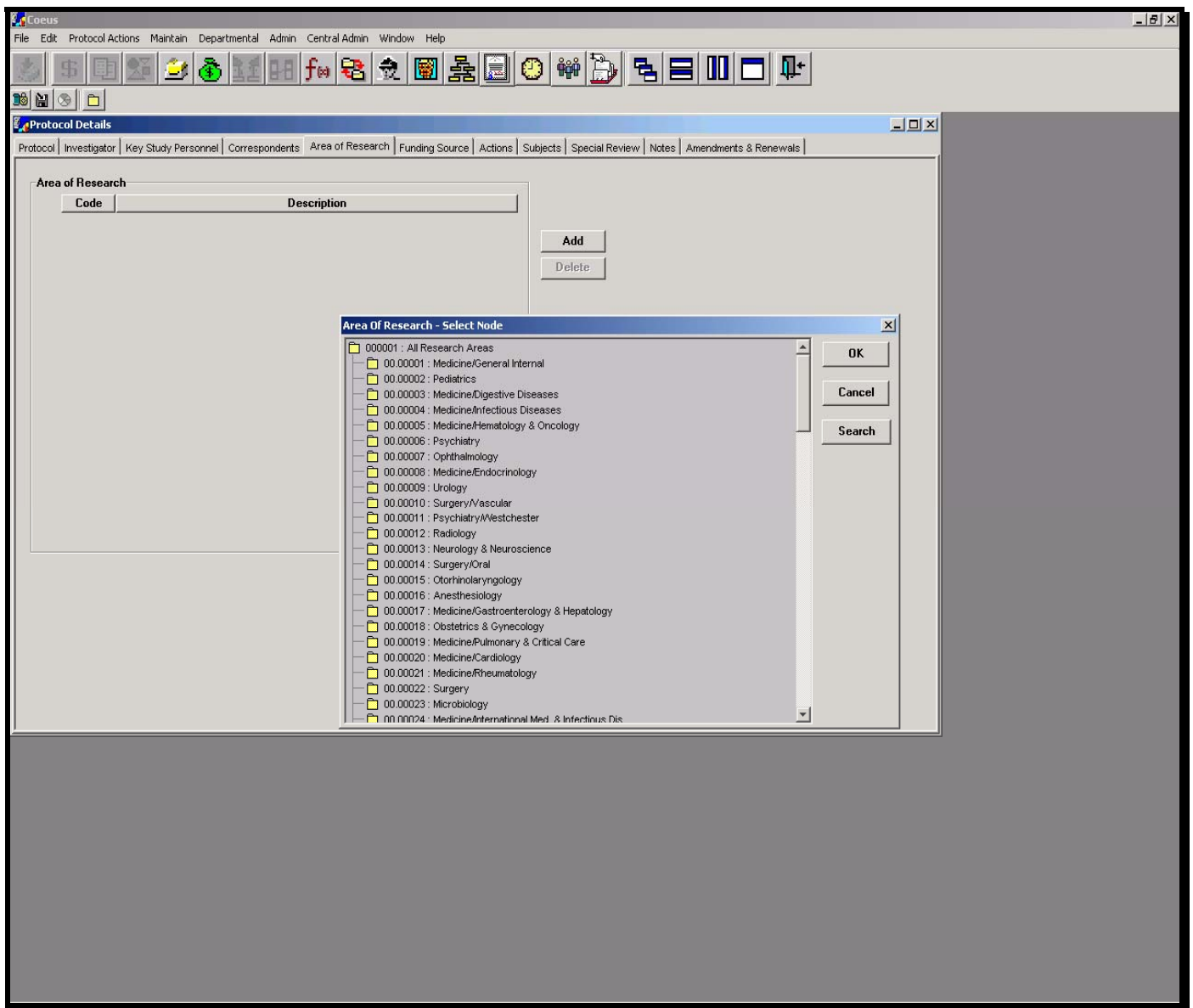
# How to Create a New Protocol Entry

6. **Correspondence Tab:** Here is where the user can record the contact names for various aspects of the protocol.
- Begin by hitting the *Find Person* button, if you will be entering a WMC Contact or by hitting the Find Rolodex button if you will be using a contact outside of WMC. Enter the name of the person you need, in either search window, highlight the name you need and hit *OK*.
  - Click on the “Type” field and select a type of correspondence from the drop down list, such as sponsor level or protocol level.
  - In the Comments box annotate any notes you would like to record about a particular contact, such as a coordinator of a project.



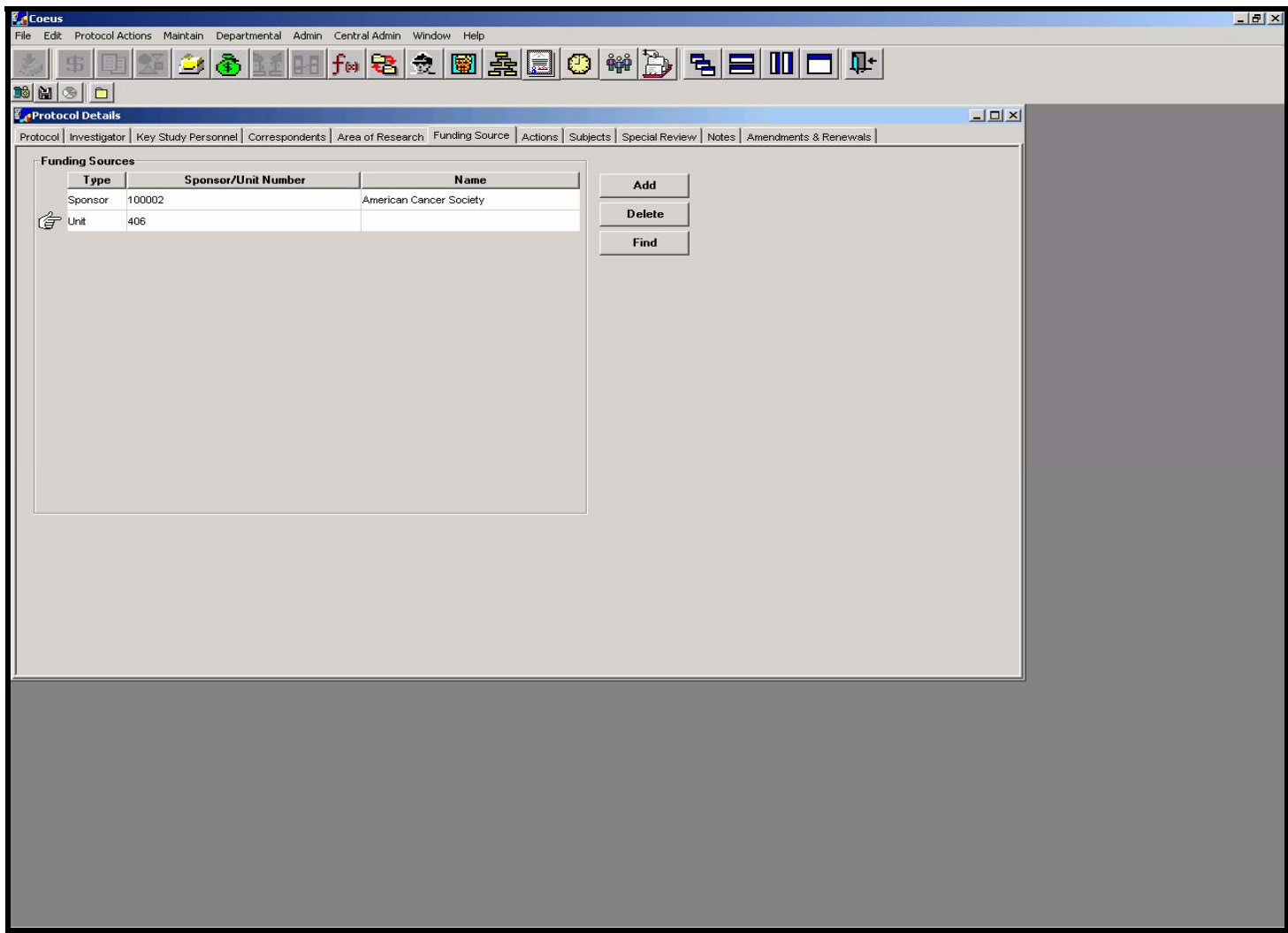
# How to Create a New Protocol Entry

- 7. Area of Research Tab:** The user will start off by hitting the *Add* button. This action will launch a window listing all of the WMC departments and their perspective divisions. Simply highlight the selection desired and hit *OK*, Coeus will fill in the selection into the tab. If the research study will work with more than one unit/department add additional units/departments by hitting the *Add* button and selecting additional units.



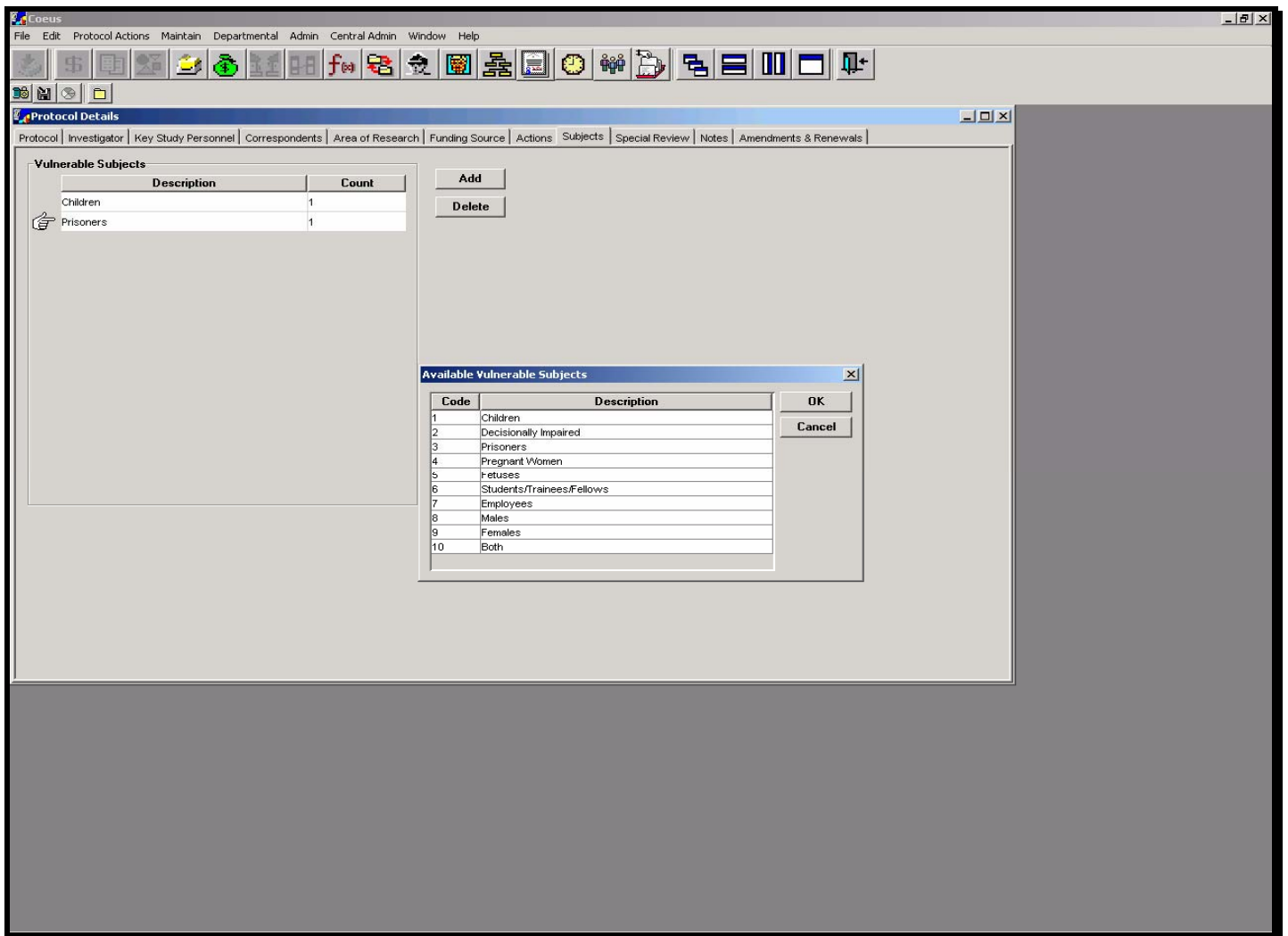
# How to Create a New Protocol Entry

- Funding Source Tab:** Begin by hitting the *Add* button. Select the type of Sponsor you would like to enter from the drop down list in the “Type” field. Then hit the *Find* Button and type in the name of the funding source you are recording. Please note that the type of search window that is launched depends on the type of funding source you have selected from the drop down list. Once you have generated the funding source you need, highlight your selection and hit *OK*. Coeus will add that information into the tab. Please note that if you select “Other” from the drop down list, you will be required to free type the funding source into the field.



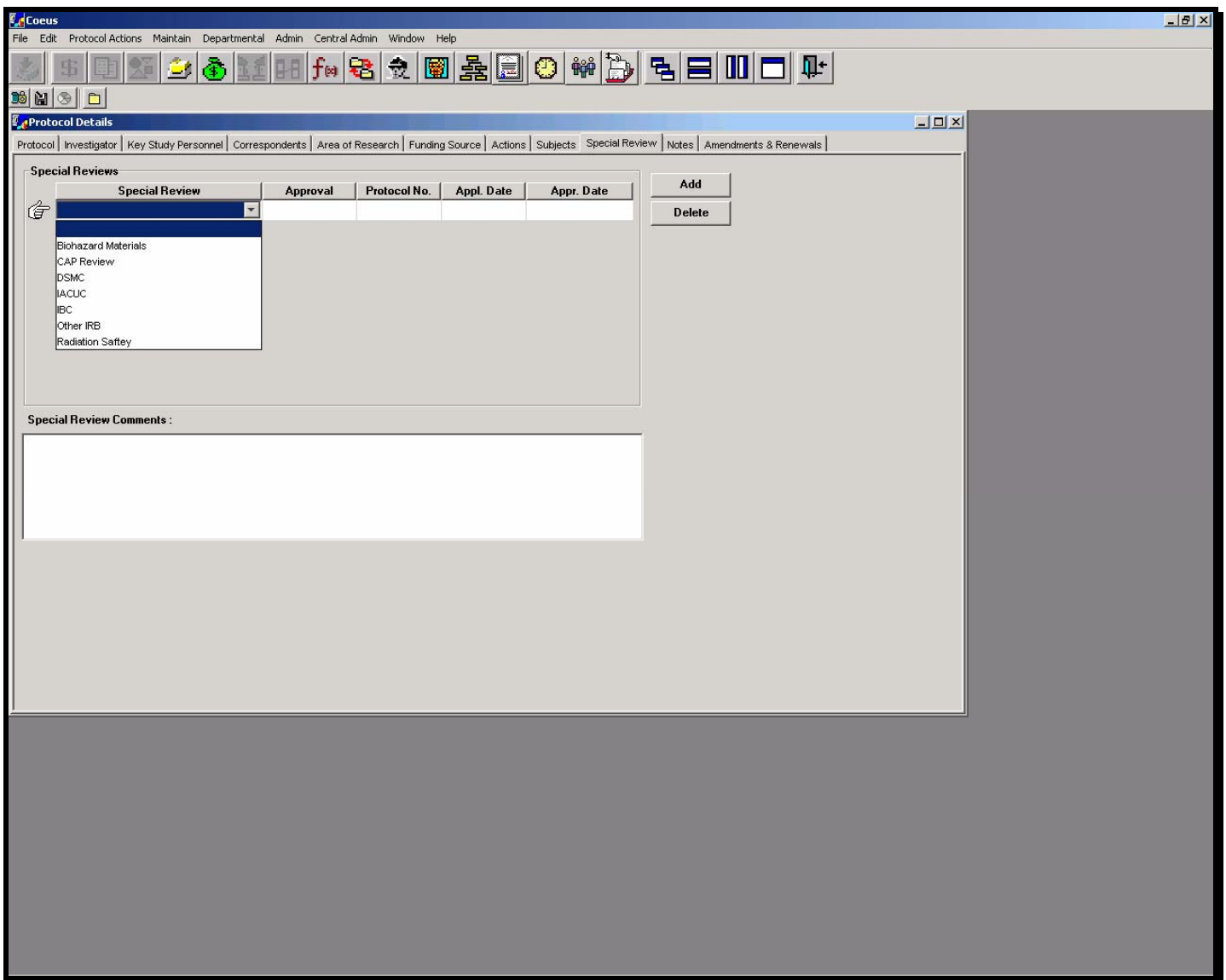
# How to Create a New Protocol Entry

9. **Action Tab:** This tab is NOT for data entry. It is where Coeus tracks protocols that have been submitted for review, and Amendments or Renewals that have been added to a protocol. As the life of the protocol evolves, Coeus will list all events that have occurred. This tab will be blank for a brand new protocol.
10. **Subjects Tab:** Begin by hitting the *Add* button. Once the button is hit, a window will open with a list of the various types of subjects. Highlight the desired type and hit *OK*; after Coeus has filled in the subject type click in the “Count” field and enter the number of subjects that will be used in the study. If more than one type of subject will be used in the study, hit the *Add* button again and again, until you have entered all of the needed information.



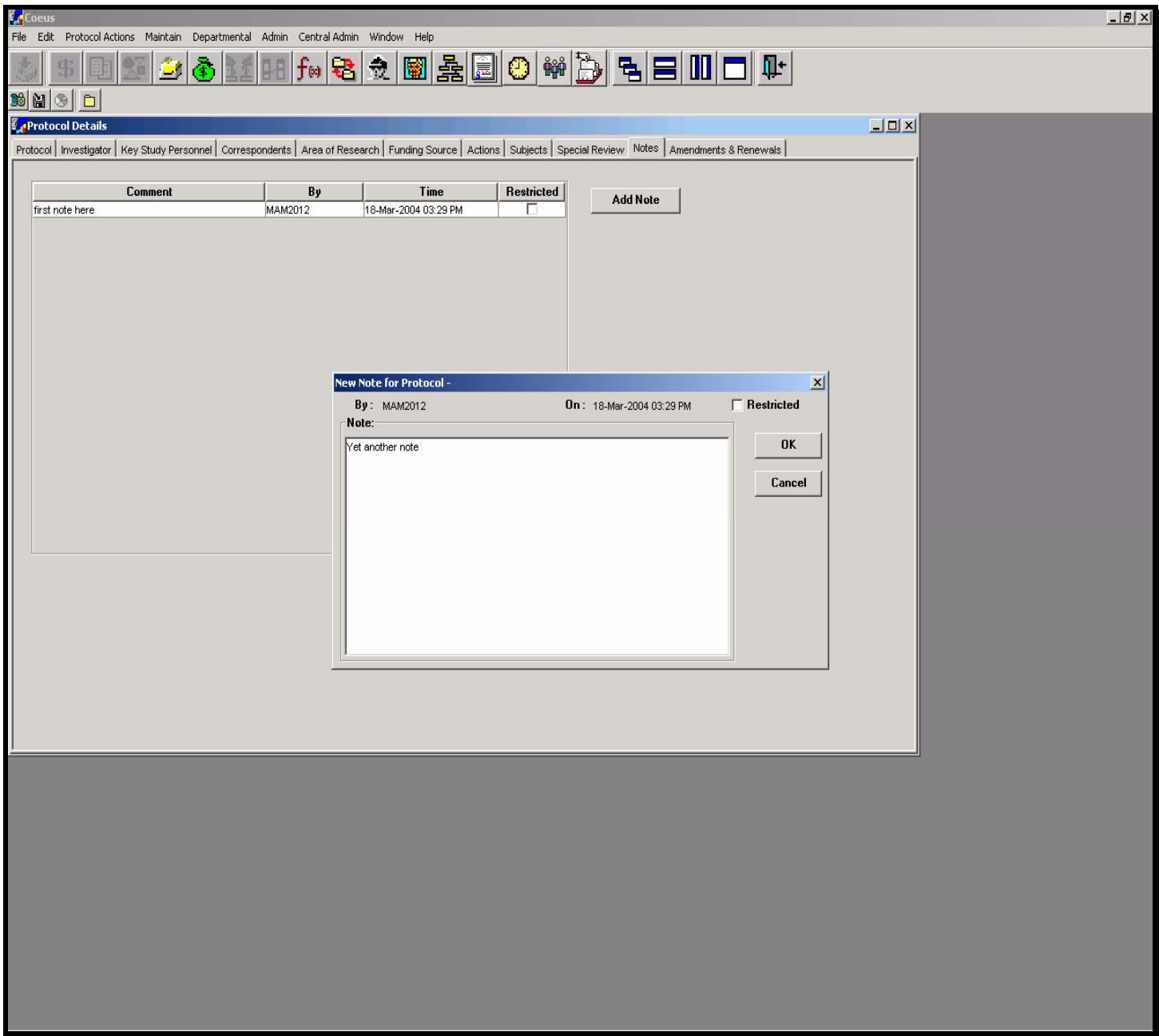
# How to Create a New Protocol Entry

**11. Special Review Tab:** This tab is used to record any review that needs to be approved before the protocol is approved. Such reviews could be IBC or an external IRB or a CAP review. Begin by hitting the *Add* button. Then in the “*Special Review*” field select the type of review that is required from the drop down list. Then records the approval status of that review and fill out the remaining fields within the appropriate information. Use the comments box to enter any notes for each particular review.




# How to Create a New Protocol Entry

- 12. Notes Tab:** This tab keeps a list of all notes on a particular protocol by the user name of the person who created the note and by date. Please note that by checking the “Restricted” box you will prevent other users from seeing the note you have created.




# How to Create a New Protocol Entry

**13. Amendments & Renewals:** This is where all Amendments and Renewals get created. That step will be done at a later point.

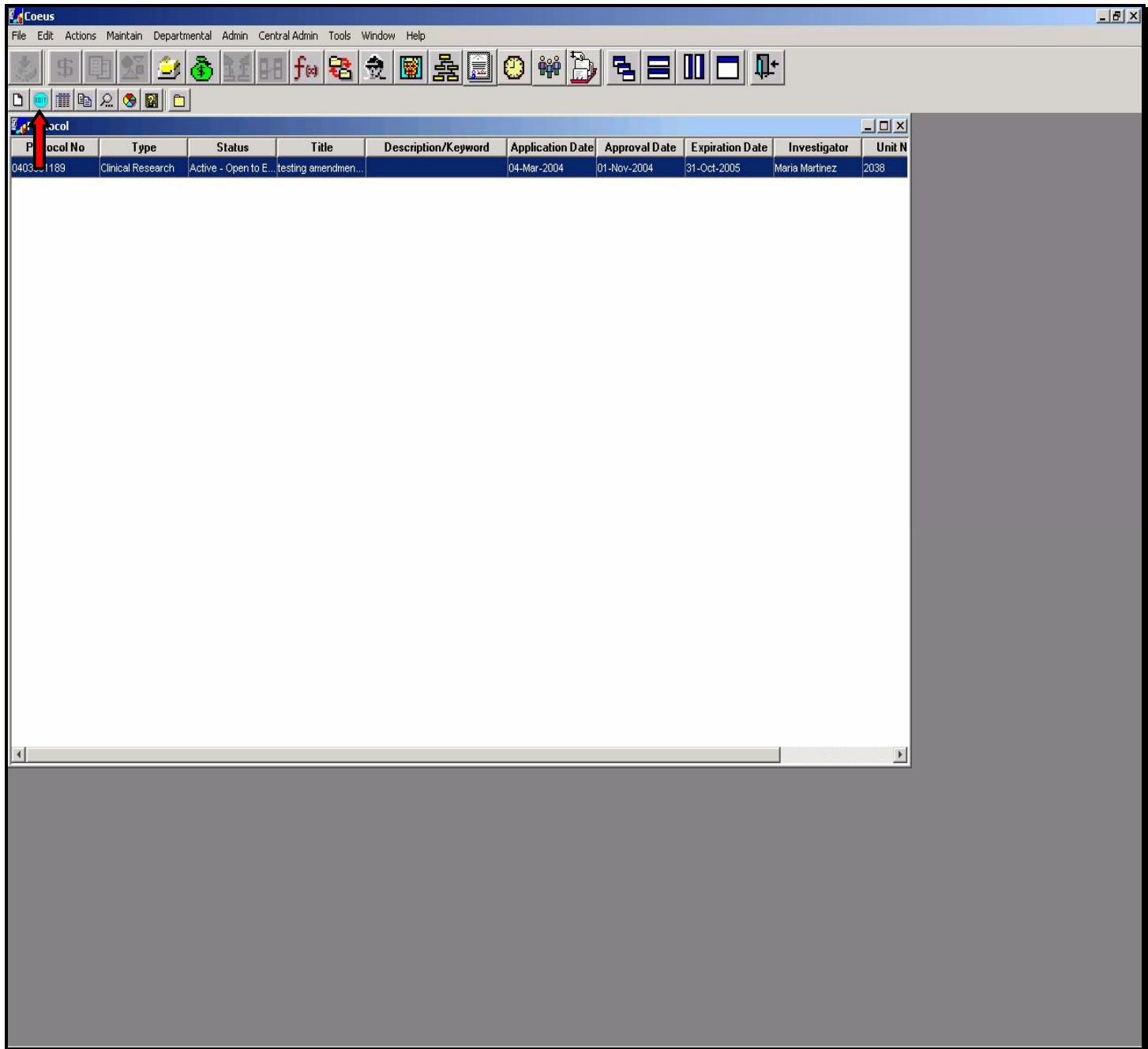
**14.** Once finished, you must save the record by hitting the *Save* button . If you try to close the window without saving the record, Coeus will prompt you to save the entry.

# How to Submit A Protocol For Review

1. To submit a protocol to the IRB you must first locate the protocol you would like

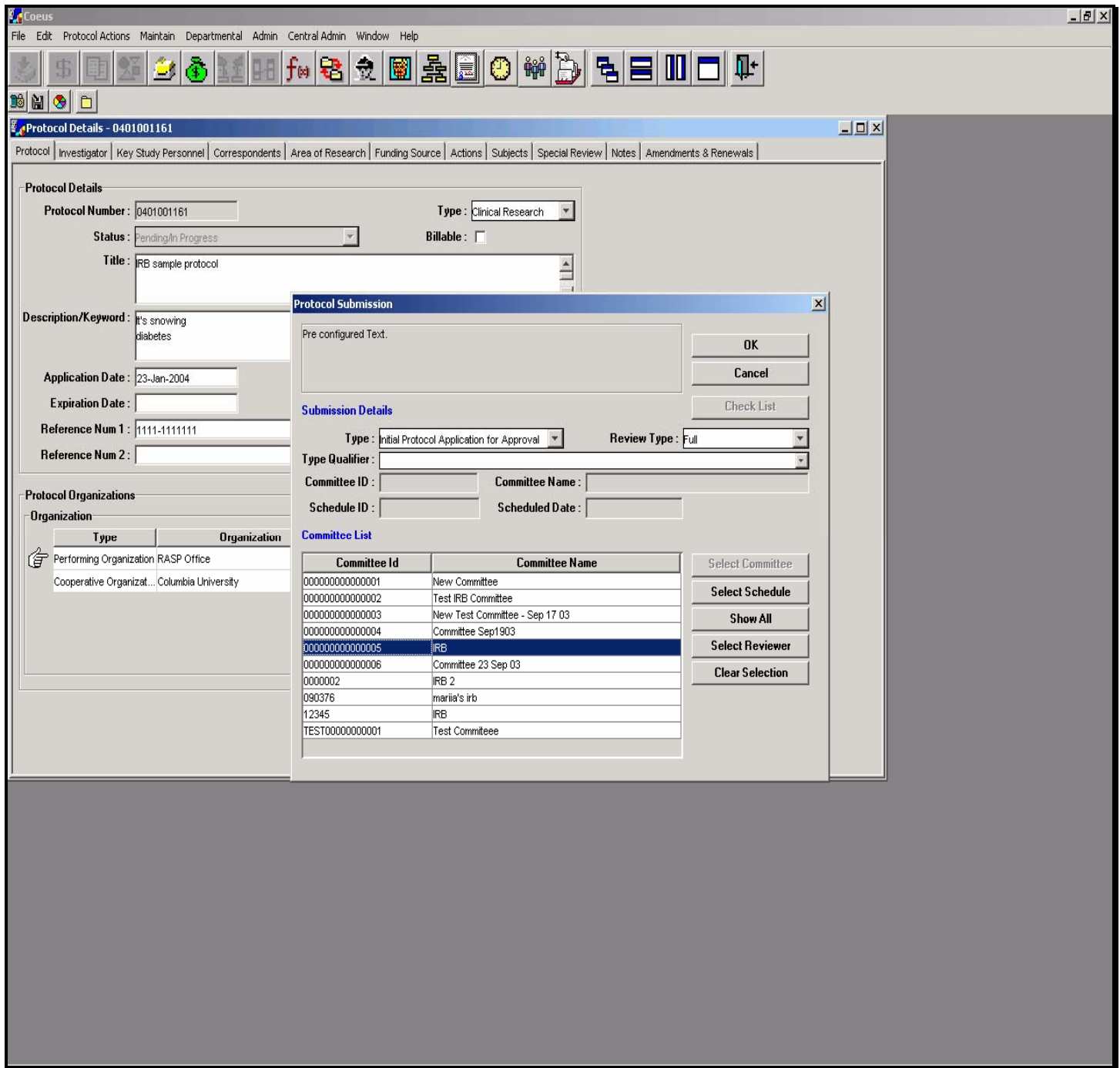
to submit by using the search function  (see “Searching How Tos).

2. Then open the record in *Edit* mode. Due this by clicking on the *Edit* button



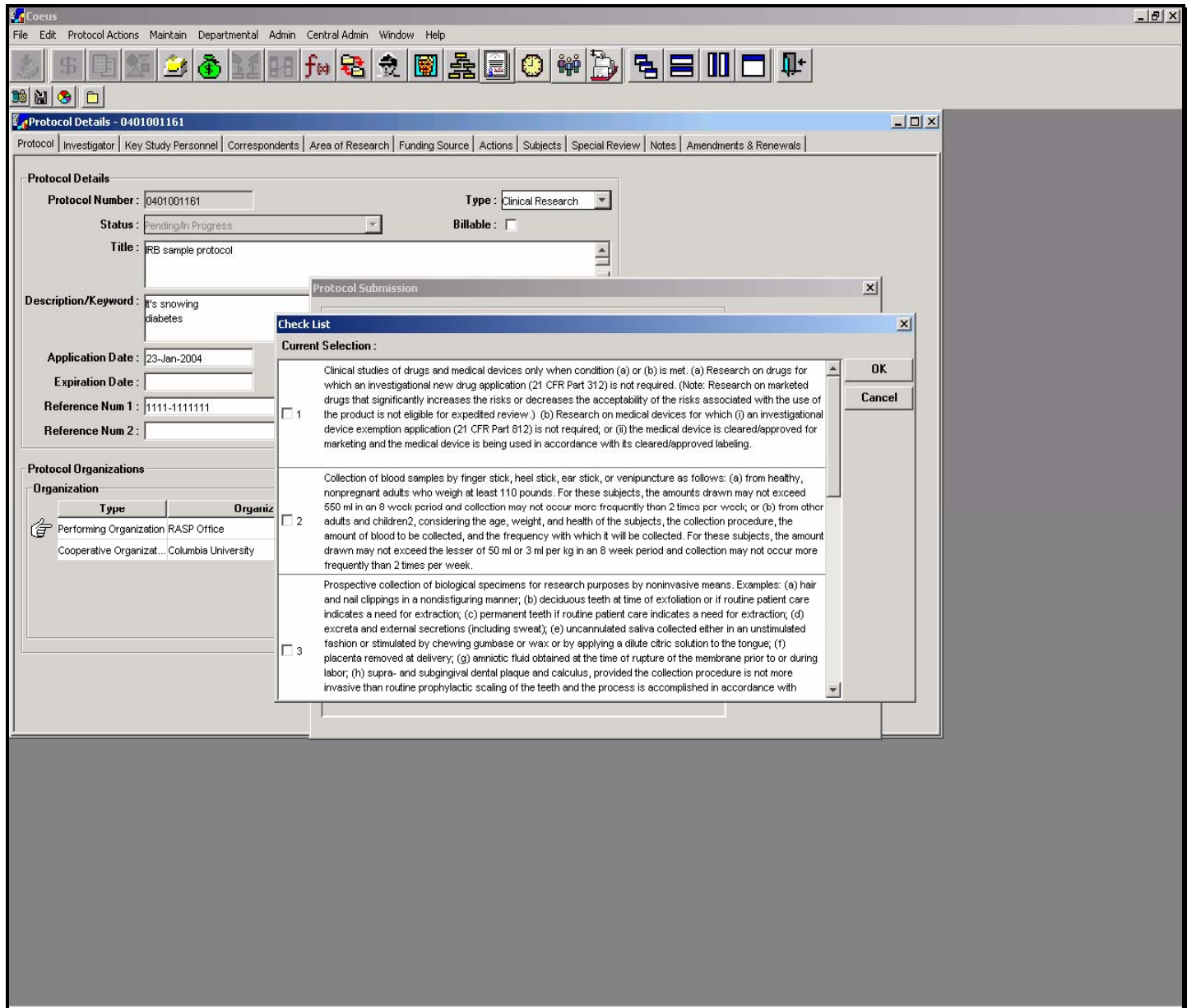
# How to Submit A Protocol For Review

3. Then go to the *Action* menu and select *Submit for Review*. This action will open the “Protocol Submission” window.



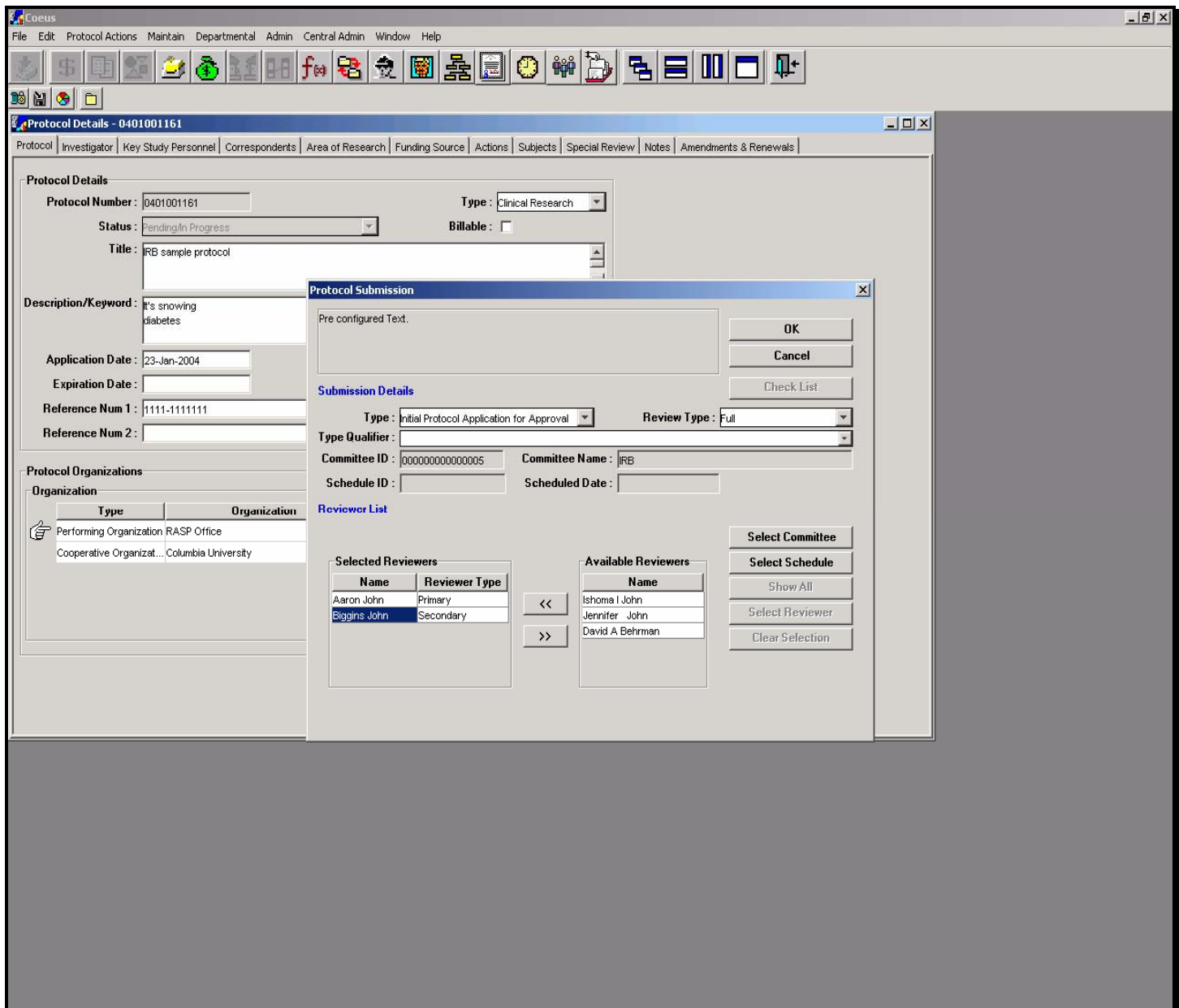
# How to Submit A Protocol For Review

4. In the “Protocol Submission” window begin to enter the type of submission that you are recording. For example, “Initial Protocol Review”, “Continuing Review” or an “Amendment”.
5. In the “Review Type” field select from either, *Full* meaning a “Full Board Review” or *Exempt, Expedited or Limited/Single Use* review types.
  - a. If you have selected an *Exempt* or *Expedited* review, the user must then click on the *Check List* button and choose a criteria type from the list. If the user does not select a criteria category from the list, Coeus will be triggered to make the user choose a criteria type or the process will not continue



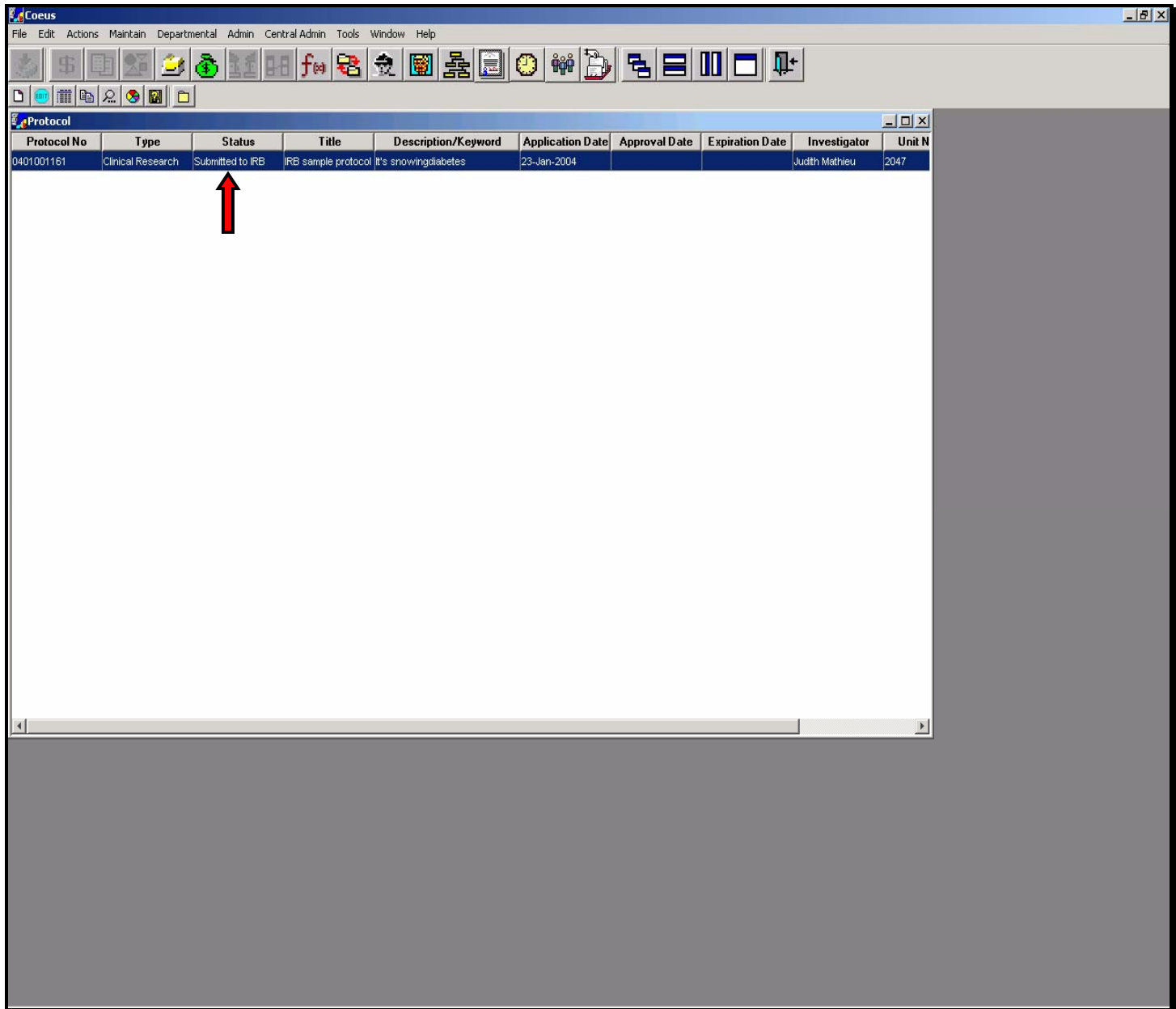
# How to Submit A Protocol For Review

6. Select a committee that will review the protocol.
7. Continue by hitting the *Select Schedule* button and choose a meeting date for the protocol to be reviewed.
8. Then click on the *Select Reviewer* button. You will see a list of names under the *Available Reviewers* section and an empty box under the *Selected Reviewers* area. Highlight/Select an *Available Reviewer* from the list then hit the “Left” arrow button to place that reviewer under the *Selected Reviewer* section.





# How to Submit A Protocol For Review

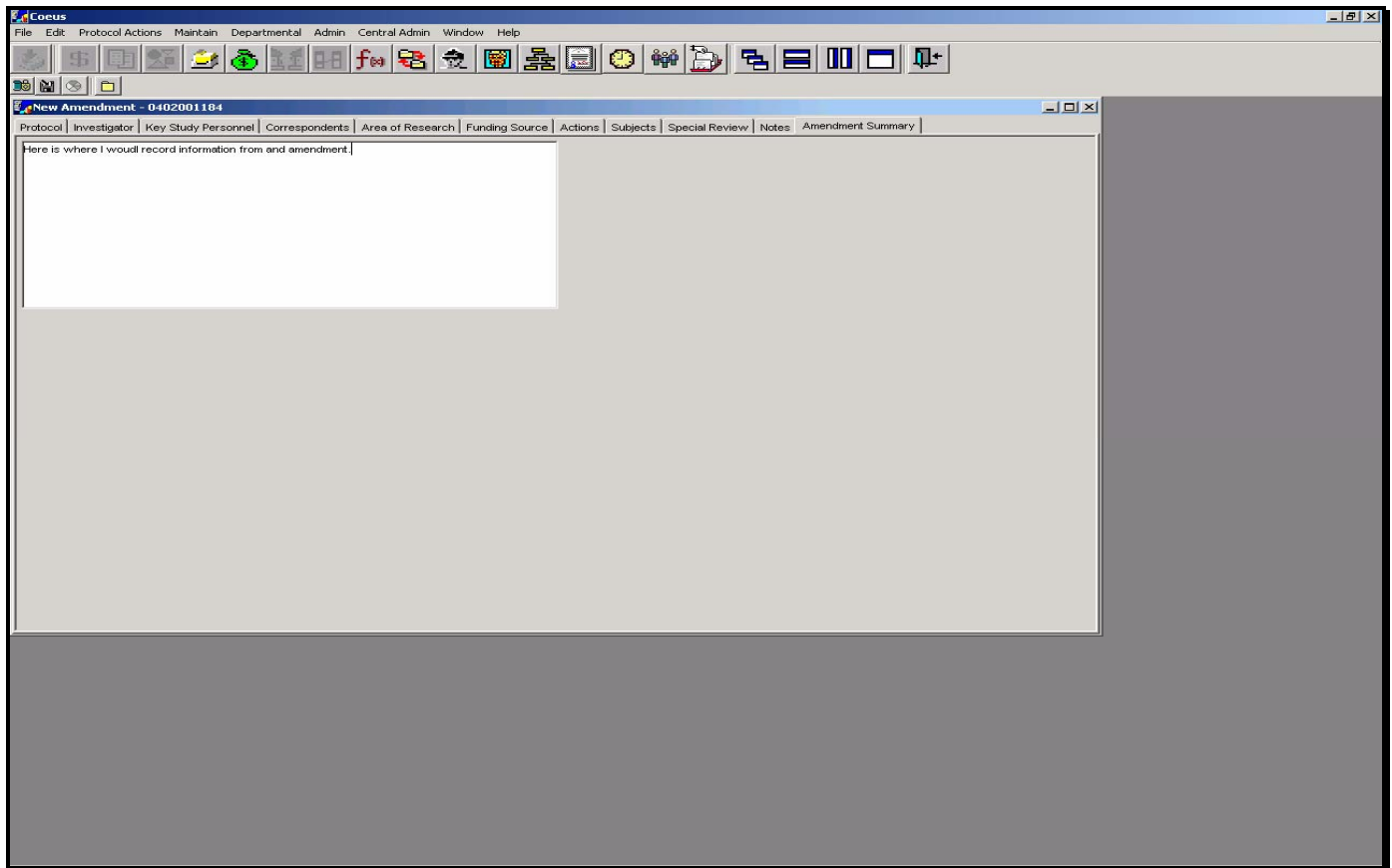
7. Once the reviewers have been placed in the Selected Reviewers side, click on the reviewer type field and assign the reviewer as either the Primary or Secondary reviewer from the drop down list.
8. When all of the submission details have been completed hit the *OK* button. Coeus will then ask you if you would like to submit the protocol for review, click on “Yes” and the status of the record will change from “Pending” to “Submitted to IRB”.




# How to Create An Amendment Or A Renewal

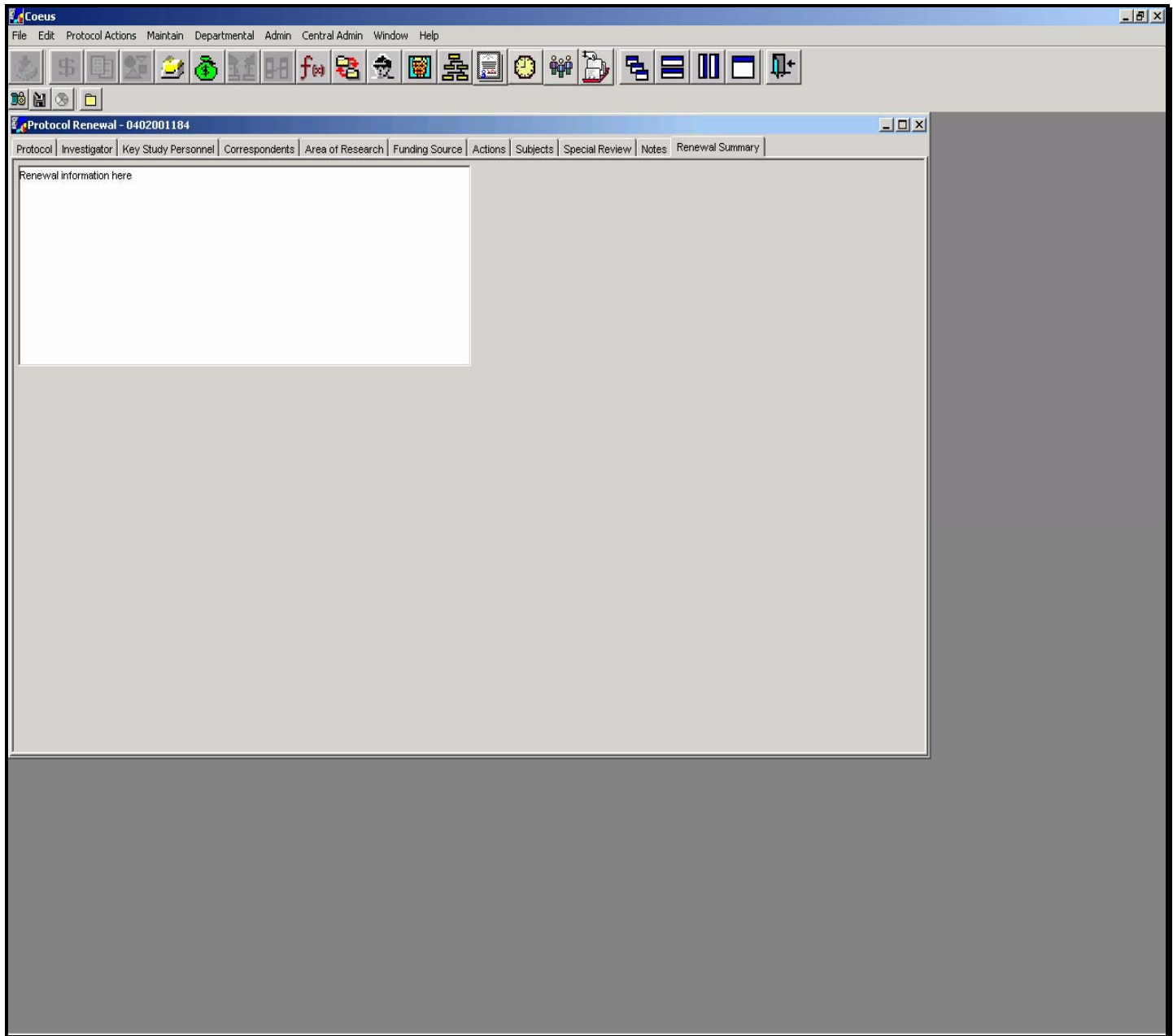
1. Open the Protocol Screen by hitting the Protocol Button  or by clicking on the Maintain menu and then selecting “Protocol”
2. When the screen opens, use the search window to locate the protocol that requires the Amendment or run a search by date range to enter renewals.
3. Once you have generated the protocol, or list of protocols you need, highlight a single record, then go to the *Edit* menu and select either “New Amendment” or “Protocol Renewal”
4. If you have selected to create an Amendment, the window for that particular protocol will open directly to the “Amendments Tab”, and you can begin type in the details of that amendment. It is extremely important to type in the sequential number of the amendment when entering it into Coeus, for example #1, or #5. Please note that Coeus allows users to approve amendments and renewals out of order, which is why sequencing is so important, more on this later. Then hit the

save button  when you have completed your entry.



# How to Create An Amendment Or A Renewal

5. On the other hand, if you have selected to create a Renewal, the window for that particular protocol will open directly to the “Renewal Tab”, and you can begin entering data for the renewal beginning with the sequential number of the renewal. Be sure to hit the save button  when you have completed your entry.



## **How to Create An Amendment Or A Renewal**

6. Selecting either of these sequences will now allow you to reenter that protocol for Review. This can be accomplished by going to the *Protocol Actions* menu, and selecting “Submit for Review”. (See How to Submit a Protocol for Review)
7. The “Protocol Submission” window will open and you can begin to select which submission type you’d like to make, Amendment or Annual Renewal, you can assign the committee and reviewers, along with all other submission details.
8. Please note that if you select an Expedited review you will be required to select an Expedited review type from the “Check List”.

# How to Bring Back A Letter

1. Begin by opening the Protocol Screen if it is not already open. You can do this by



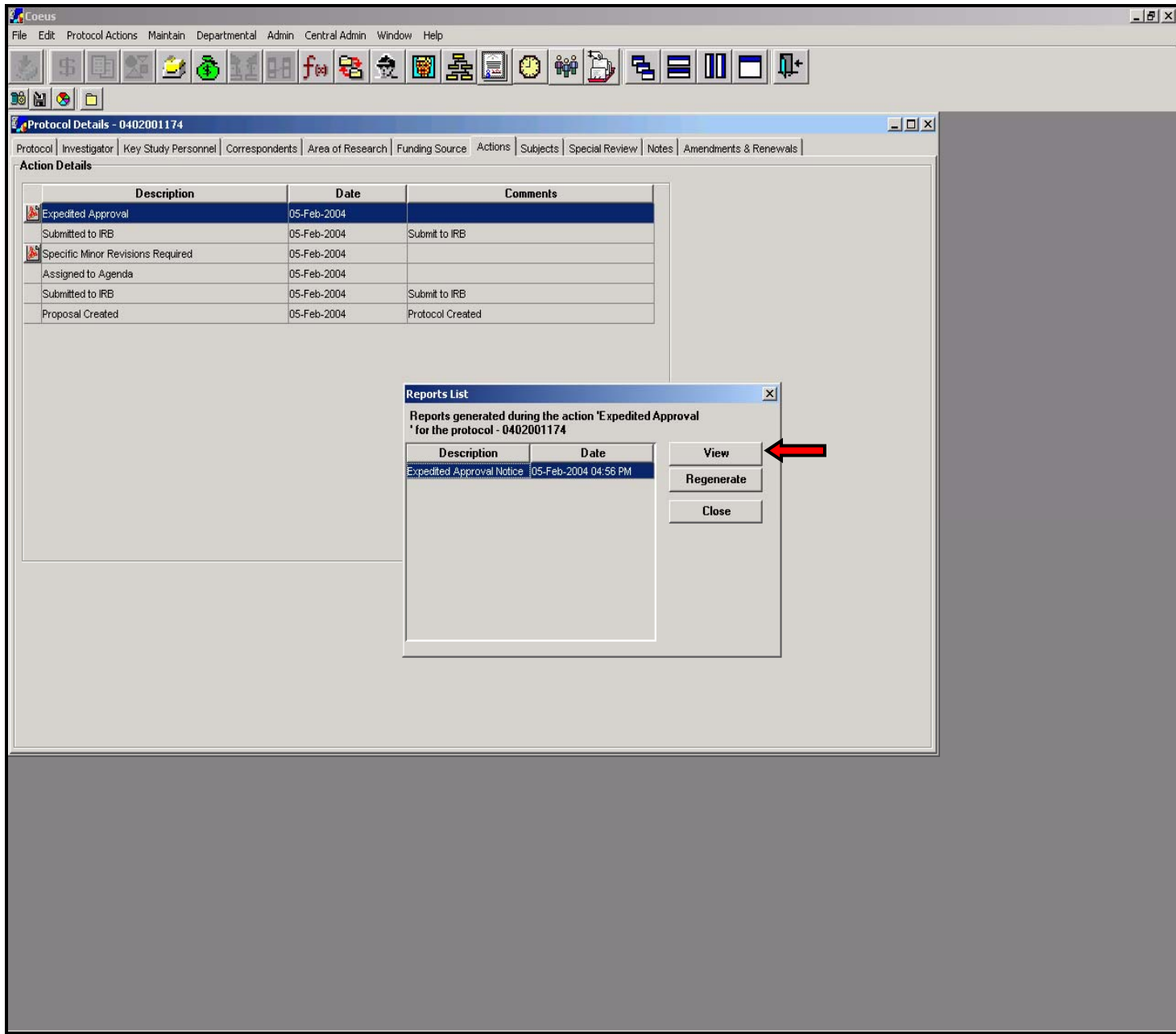
- hitting the *Protocol* button or by going to the Maintain menu and selecting Protocol.
2. In the Protocol Search window enter the protocol number whose letter you would like to regenerate.
  3. Once the search has listed the protocol you are looking for highlight your selection and click on the *OK* button.
  4. Double click on the protocol to open the screen.
  5. Go to the Actions tab on the screen, this will display a list of actions that have been made to that protocol. The most recent action will be listed first.

The screenshot shows the Coeus software interface. The title bar reads "Coeus" and the menu bar includes "File", "Edit", "Protocol Actions", "Maintain", "Departmental", "Admin", "Central Admin", "Window", and "Help". The toolbar contains various icons for file operations and navigation. The main window is titled "Protocol Details - 0402001174" and has several tabs: "Protocol", "Investigator", "Key Study Personnel", "Correspondents", "Area of Research", "Funding Source", "Actions", "Subjects", "Special Review", "Notes", and "Amendments & Renewals". The "Actions" tab is selected, displaying a table of actions. A red arrow points to the "Actions" tab.

Description	Date	Comments
Expedited Approval	05-Feb-2004	
Submitted to IRB	05-Feb-2004	Submit to IRB
Specific Minor Revisions Required	05-Feb-2004	
Assigned to Agenda	05-Feb-2004	
Submitted to IRB	05-Feb-2004	Submit to IRB
Proposal Created	05-Feb-2004	Protocol Created


# How to Bring Back A Letter

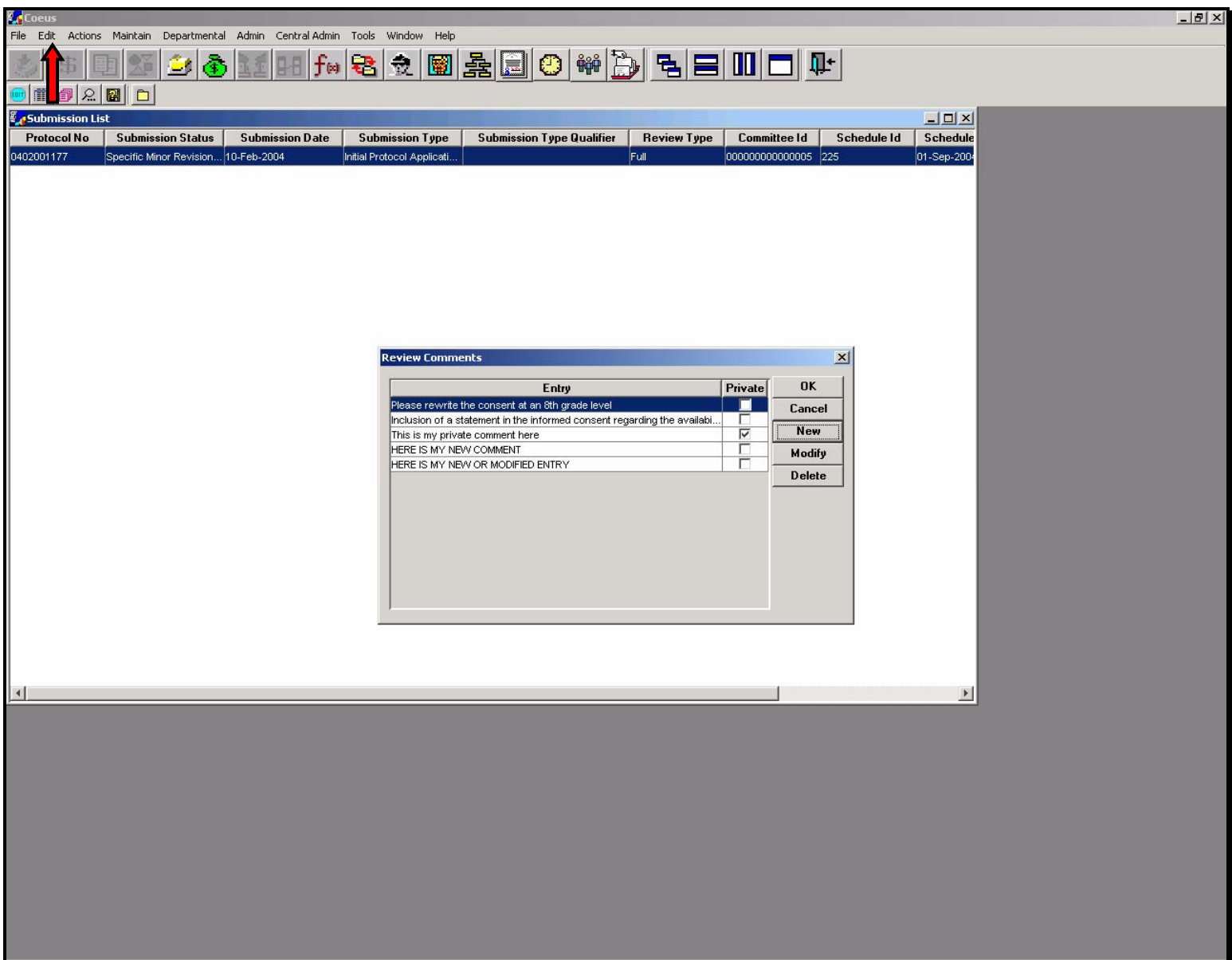
6. On the left hand side, you will see the icon for Adobe Acrobat. Click on the icon. Coeus will then notify you that it has generated the report or letter. Then click on the *View* button. In a separate window Coeus will launch the letter for you.



# How to Regenerate a Letter

**\*Why use this option?** The regeneration of a letter in Coeus is used in the event that the user has a modification(s) to make on the review comments, after the letter has been generated. This option allows the user to go back and add, remove, or modify any revision requests that have already been placed on a letter.

1. Begin by clicking on the *Protocol Submission* button  or by going to the Maintain menu and selecting Protocol Submissions.
2. When the screen opens type in the protocol number into the Protocol Submission search window.
3. Once Coeus has listed the protocol you need, highlight your option in the Submission List window.
4. Go to the Edit menu and click on the Review Comments selection. This will open the Review Comments window.



The screenshot displays the Coeus software interface. At the top, there is a menu bar with options: File, Edit, Actions, Maintain, Departmental, Admin, Central Admin, Tools, Window, and Help. Below the menu bar is a toolbar with various icons. A red arrow points to the 'Protocol Submission' icon in the toolbar. The main window is titled 'Submission List' and contains a table with the following data:

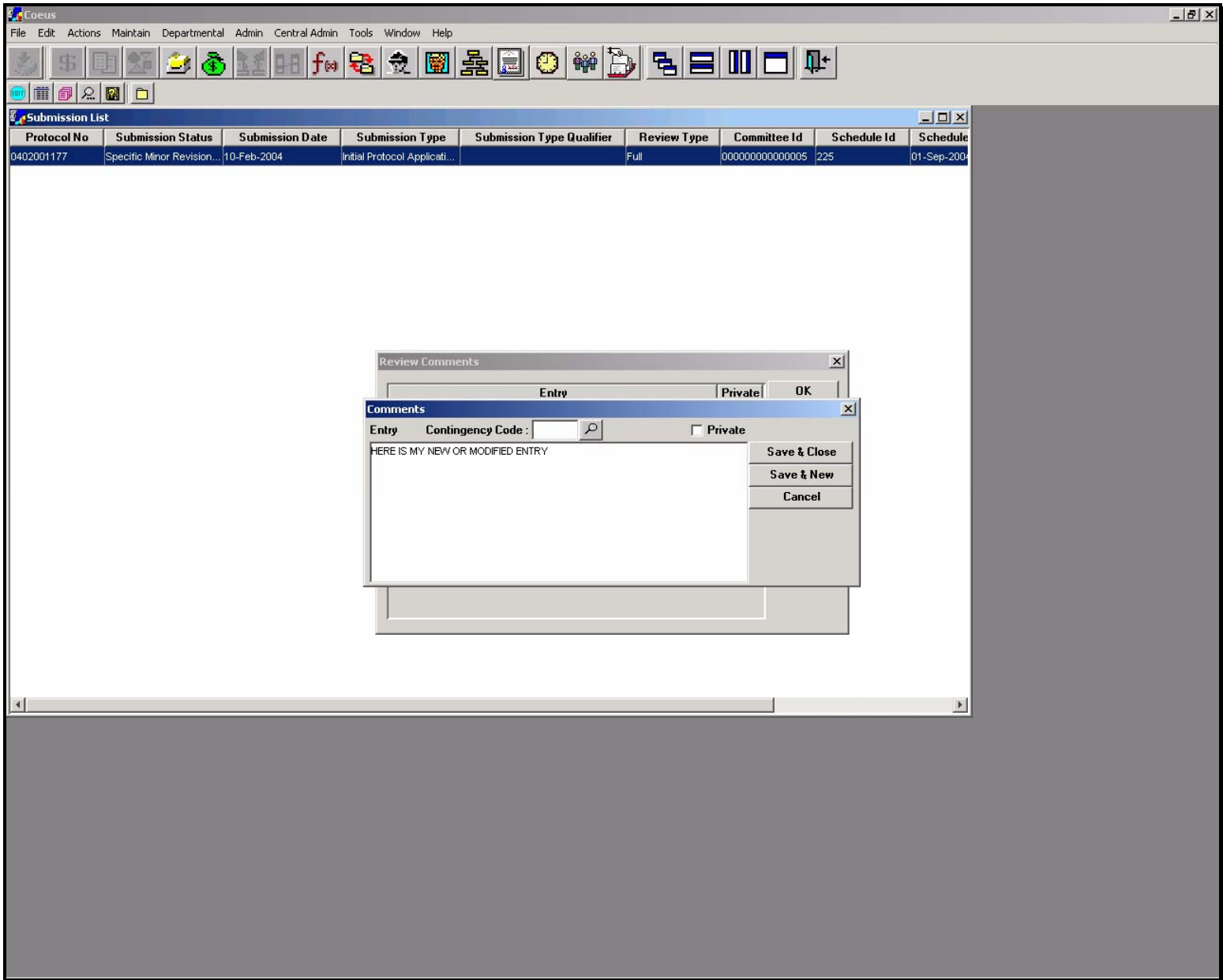
Protocol No	Submission Status	Submission Date	Submission Type	Submission Type Qualifier	Review Type	Committee Id	Schedule Id	Schedule
0402001177	Specific Minor Revision...	10-Feb-2004	Initial Protocol Applicati...		Full	000000000000005	225	01-Sep-2004

Overlaid on the Submission List window is a 'Review Comments' dialog box. It has a table with two columns: 'Entry' and 'Private'. The 'Private' column contains checkboxes. To the right of the table are buttons for 'OK', 'Cancel', 'New', 'Modify', and 'Delete'. The 'Entry' column contains the following text:


- Please rewrite the consent at an 8th grade level
- Inclusion of a statement in the informed consent regarding the availabi...
- This is my private comment here
- HERE IS MY NEW COMMENT
- HERE IS MY NEW OR MODIFIED ENTRY

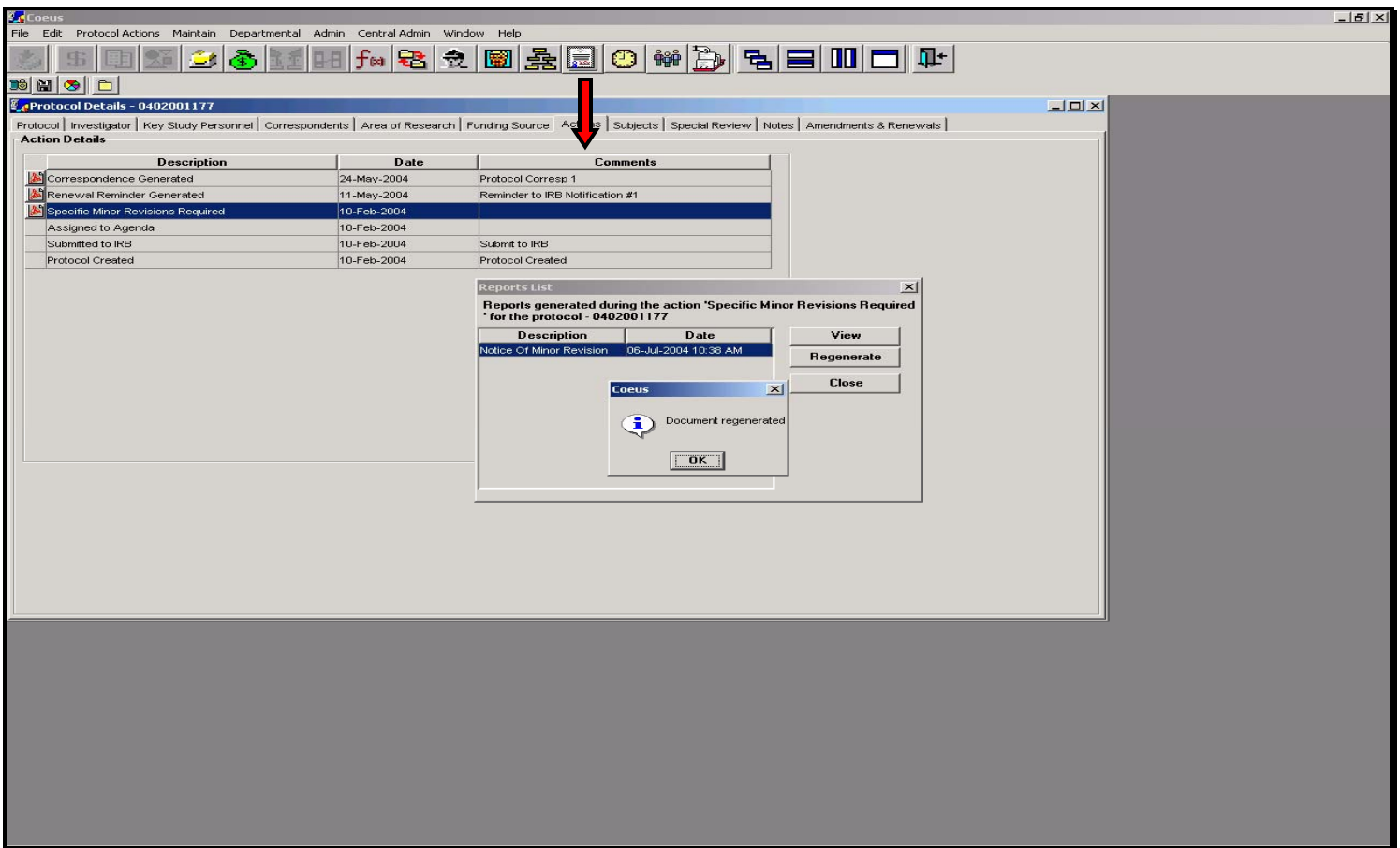
# How to Regenerate a Letter

5. To modify an entry, highlight the entry you would like to change and then click on the *Modify* button. This will open the Comments window to that particular revision request.
6. To add another entry, click on the *New* button and either select a revision from the contingency list, or you can free type your entry into the Entry field.



# How To Regenerate a Letter

7. Click on the *Save and Close* button in the Comments window when you have finished your modifications.
8. Go to the Protocol screen either by hitting on the *Protocol* button  or by going to the Maintain menu and selecting Protocol.
9. In the Protocol search window type in the protocol number again.
10. When the protocol you need is listed by Coeus, double click on that protocol and go to the Actions tab.
11. On the left hand side, you will see the Adobe Reader icon. Click on the icon.
12. Coeus will then notify you that the report, or letter, has been generated.
13. Click on the *Regenerate* button. When the document is ready, Coeus will let you know that the document has been regenerated. Click *OK*.



# How To Regenerate a Letter

14. After the letter has been regenerated click on the *View* button. The letter will open up in a separate window, and will reflect the changes made.

# Schedule Screen Description

## Schedule Tab:

Field Name	Field Description	Field Notes:
Committee ID	Unique Identifier for the committee	
Committee Name	Self Explanatory	
Schedule Date	Date of a particular IRB meeting	
Status	Identifies if protocols have been scheduled for a particular meeting date	
Place	Location of meeting	
Time	Time of meeting	
Agenda Generation		
Max Protocols	Identifies the maximum number of	
Deadline	Protocol deadline	
Agenda Generation	Identifies if an agenda has been created for a meeting date	
Start Time		
End Time		
Comments	Notes with regards to a particular committee	

## Protocols Submitted Tab:

Field Name	Field Description	Field Notes:
Protocol Number	Column-Self Explanatory	
Protocol Title	Column-Self Explanatory	
Submission Type	Column-Self Explanatory	
Sub. Type Qualifier	Column-Self Explanatory	
Sub. Review Type	Column-Self Explanatory	
Submission Status	Column-Self Explanatory	
Submission Date	Column-Self Explanatory	

# Schedule Screen Description

## Other Actions Tab:

Field Name	Field Description	Field Notes:
Type	Drop down list	Records the extra material that was covered during the IRB meeting
Description	Self Explanatory	Login any details describing extra material

## Attendance Tab:


Field Name	Field Description	Field Notes:
Name	IRB member name	
Guest Flag	Check Box	Check off for any members of the meeting that are guests
Alternate Flag	Check Box	
Alternate For	Text field	Enter the name of the IRB member that is being represented.
Comments	Self Explanatory	Enter any notes for a meeting member here
Absentees	Self Explanatory	Auto generated when a name of an IRB member is not selected as part of the attendees

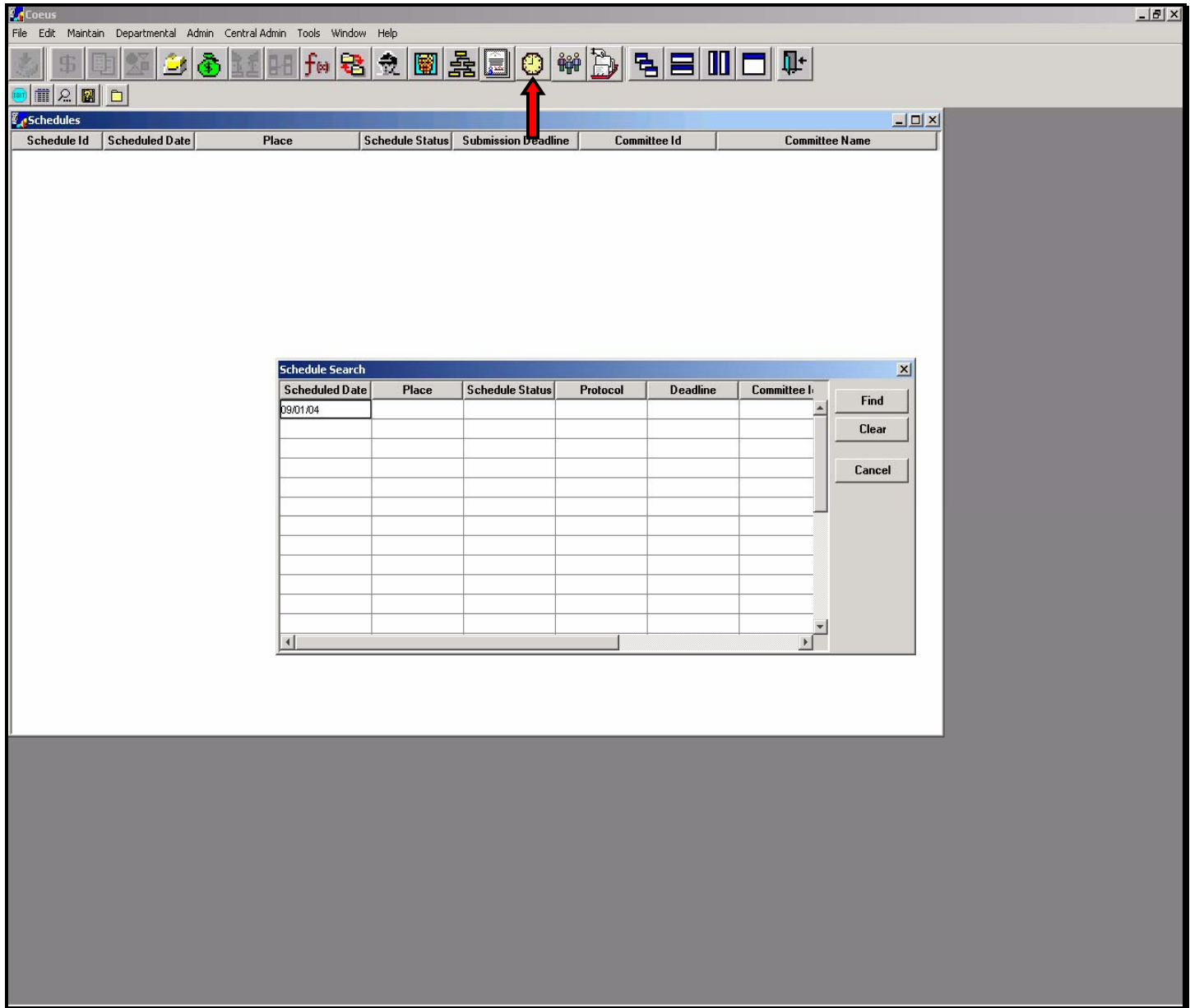
## Minutes Tab:

Field Name	Field Description	Field Notes:
Entry Type	Drop down list	
Entry	Text Field	
Private	Check Box	Use this to make a note that you would like in the minutes but not in the agenda

# Assigning A Protocol To An Agenda



- 1 Open the Schedule screen by hitting the Schedule button  or by selecting Schedule from the “Maintain” menu.
2. When the Schedule Search window opens, type in the date of the meeting you need.



The screenshot shows the Coeus Schedules application interface. The main window has a menu bar (File, Edit, Maintain, Departmental, Admin, Central Admin, Tools, Window, Help) and a toolbar with various icons. A red arrow points to the clock icon in the toolbar. Below the toolbar is a table with the following columns: Schedule Id, Scheduled Date, Place, Schedule Status, Submission Deadline, Committee Id, and Committee Name. The table is currently empty. A 'Schedule Search' dialog box is open in the foreground, containing a table with the following columns: Scheduled Date, Place, Schedule Status, Protocol, Deadline, and Committee Id. The 'Scheduled Date' column contains the value '09/01/04'. To the right of the table are three buttons: Find, Clear, and Cancel.

# Assigning A Protocol To An Agenda

3. When Coeus has generated the meeting date you are looking for, highlight that



4. Once the window for that meeting date has opened, click on the “Protocols Submitted” tab. Begin by highlighting the protocol at the top of the list. Then go into the *Actions* menu and choose “Assign to Agenda”.
5. When the Assign to Agenda Action window opens, type in any comments you would like to make and hit “OK”

The screenshot shows the Coeus software interface. The main window is titled "Schedule Details - 225" and has tabs for "Schedule", "Protocols Submitted", "Other Actions", "Attendance", and "Minutes". The "Protocols Submitted" tab is active, displaying a table with the following data:

Protocol No	Protocol Title	Submission Type	Sub. Type Qualifier	Sub. Review Type	Submission Status	Submission Date
0402001176	abc	Initial Protocol Application for Approval		Full	Approved	09-Feb-2004
0402001177	title here	Initial Protocol Application for Approval		Full	Specific Minor Revisio...	10-Feb-2004
0402001178	New Protocol - nov 13 - n...	Initial Protocol Application for Approval		Expedited	Approved	10-Feb-2004
0402001179	New Protocol - nov 13 - n...	Initial Protocol Application for Approval		Expedited	Approved	10-Feb-2004
0402001180	New Protocol - nov 13 - n...	Initial Protocol Application for Approval		Exempt	Exemption Granted	10-Feb-2004
0402001181	New Protocol - nov 13 - n...	Initial Protocol Application for Approval		Expedited	Approved	10-Feb-2004
0402001184	test - new protocol	Initial Protocol Application for Approval		Full	Approved	12-Feb-2004
0402001185	test - new protocol	Initial Protocol Application for Approval		Full	Approved	13-Feb-2004
0403001191	IRB sample protocol	Initial Protocol Application for Approval		Full	Submitted to Committee	09-Mar-2004

An "Assign to Agenda Action-0403001191" dialog box is open over the table. It contains the following text and controls:

Are you sure you want to assign this protocol to agenda ?

OK

Cancel

Review Comments

Comments :

All my comments for this protocol go here

# **Assigning A Protocol To An Agenda**

6. Once you have assigned all of the protocols to an agenda, go to the *Edit* menu and hit the “Generate Agenda” option. Coeus will then begin to launch Adobe and the agenda will open in a separate window.
7. Note that the agenda for each meeting date will always be available to view at a later date. You can view it again by selecting “View Agenda” from the *Edit* menu

# How to Generate Minutes

1. Begin by opening the Schedule screen. You can do this by either hitting the



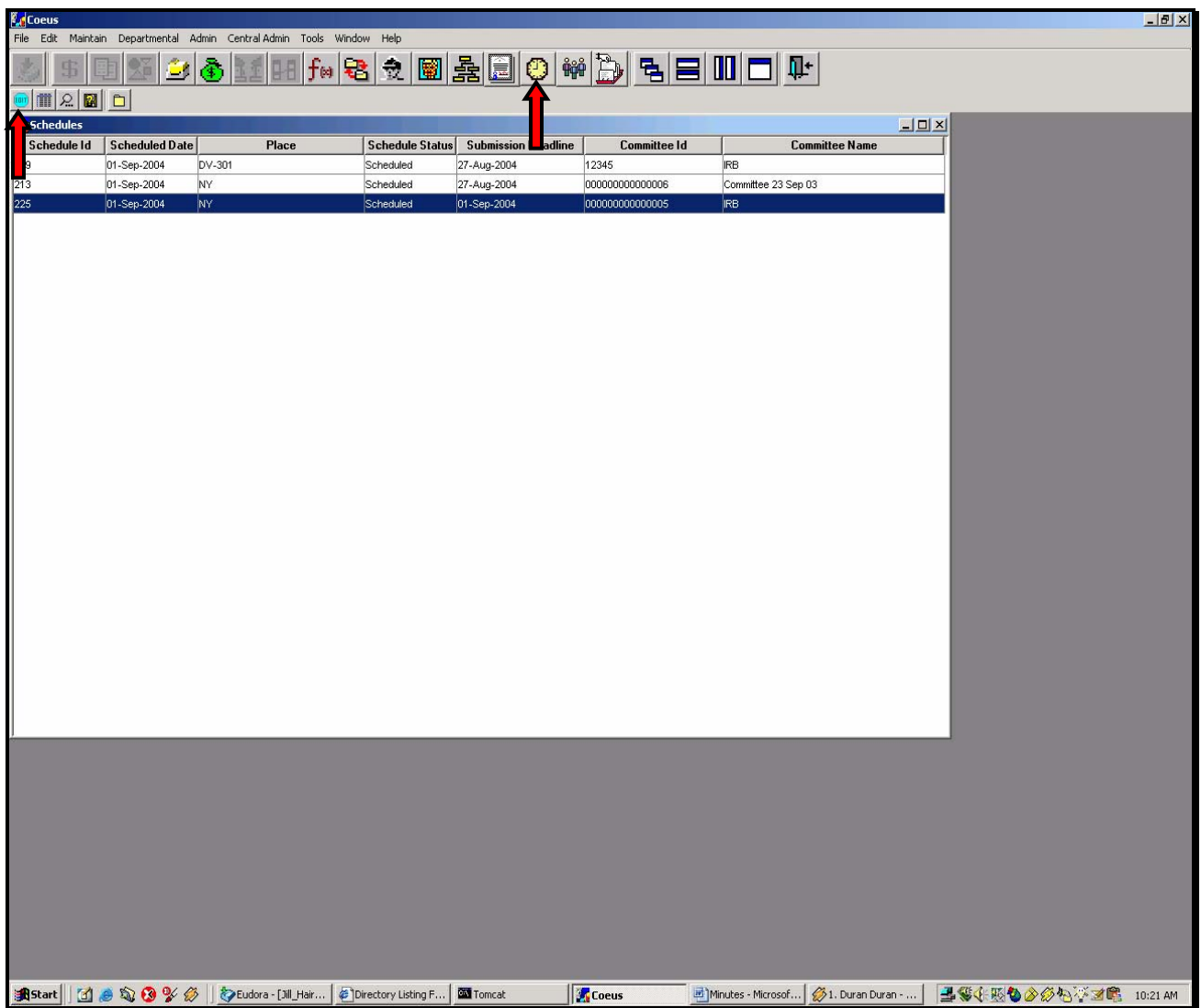
*Schedule* button or by going to the Edit menu and selecting the Schedule option.

2. In the search window type in the date of the meeting you are creating minutes for.
3. Once Coeus has generated the meeting date that you're looking for, highlight your



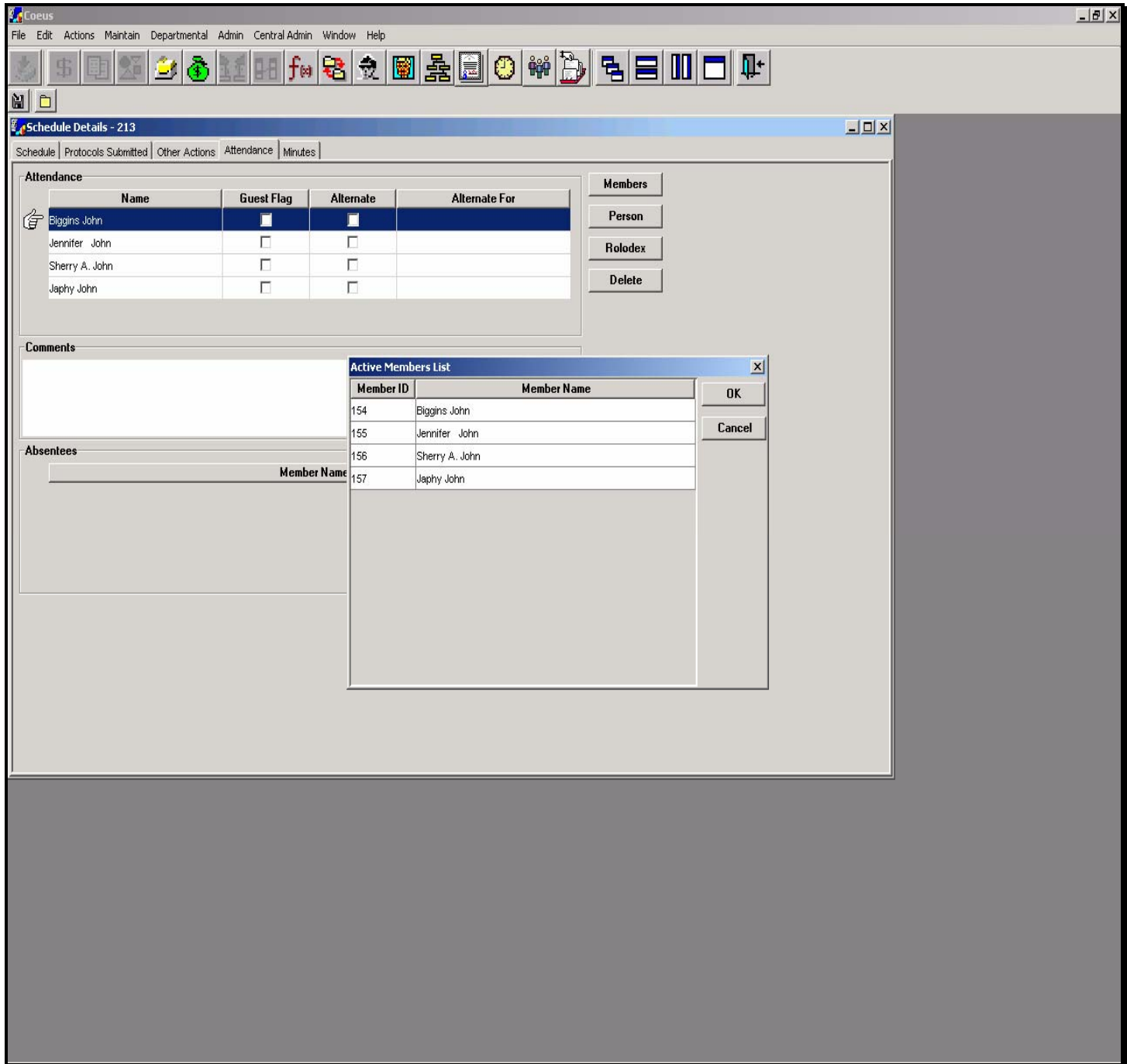
selection and hit the *Edit* button

4. Begin by going to the Attendance tab and hitting the *Members* button on the right hand side of the screen.



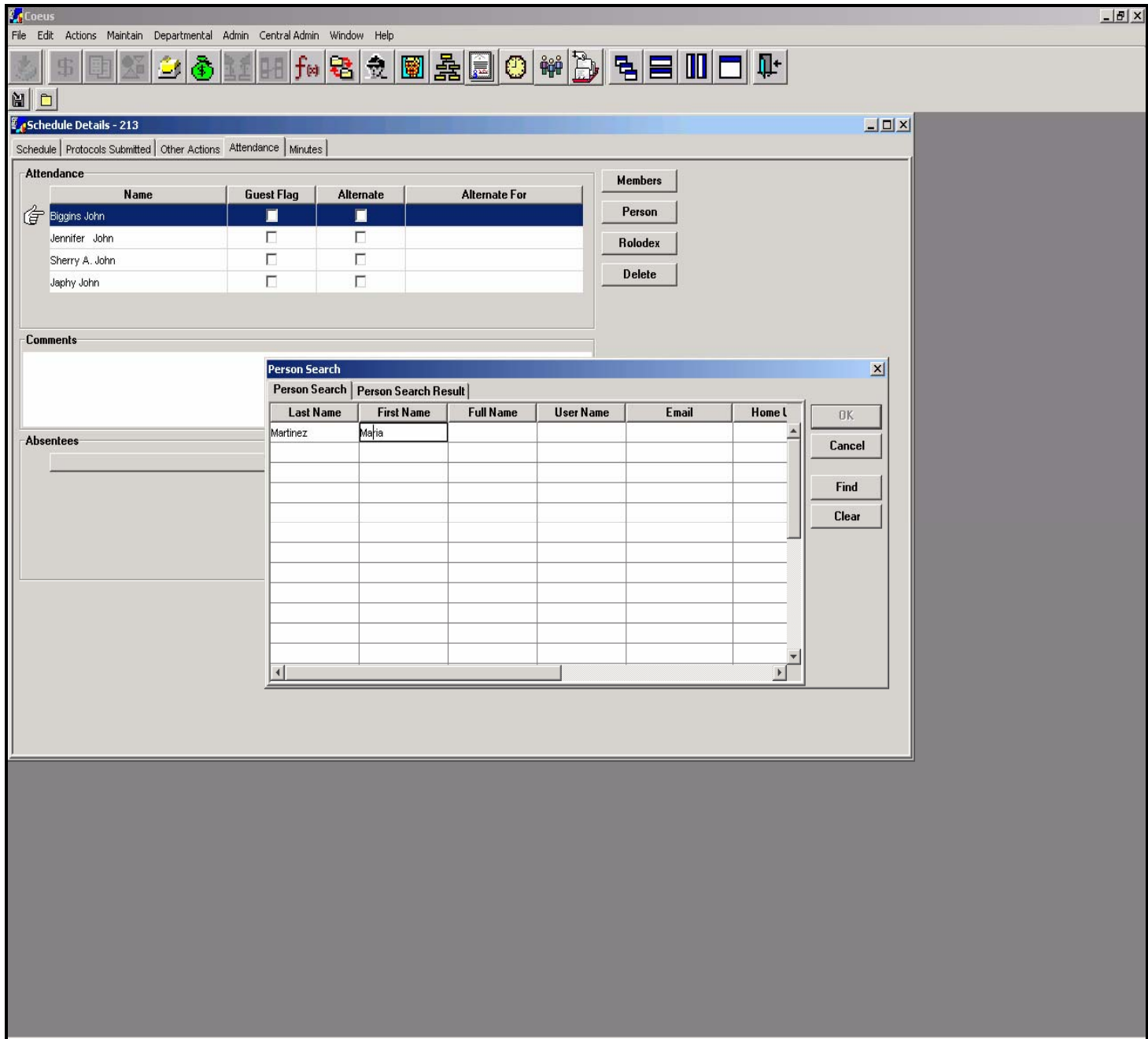
# How to Generate Minutes

5. This action will launch a screen which shows all of the members of that particular committee. Highlight the names for the members that attended from the list and click the *OK* button. Please note that by default, members whom are not selected are auto entered into the “Absentee” list.



# How to Generate Minutes

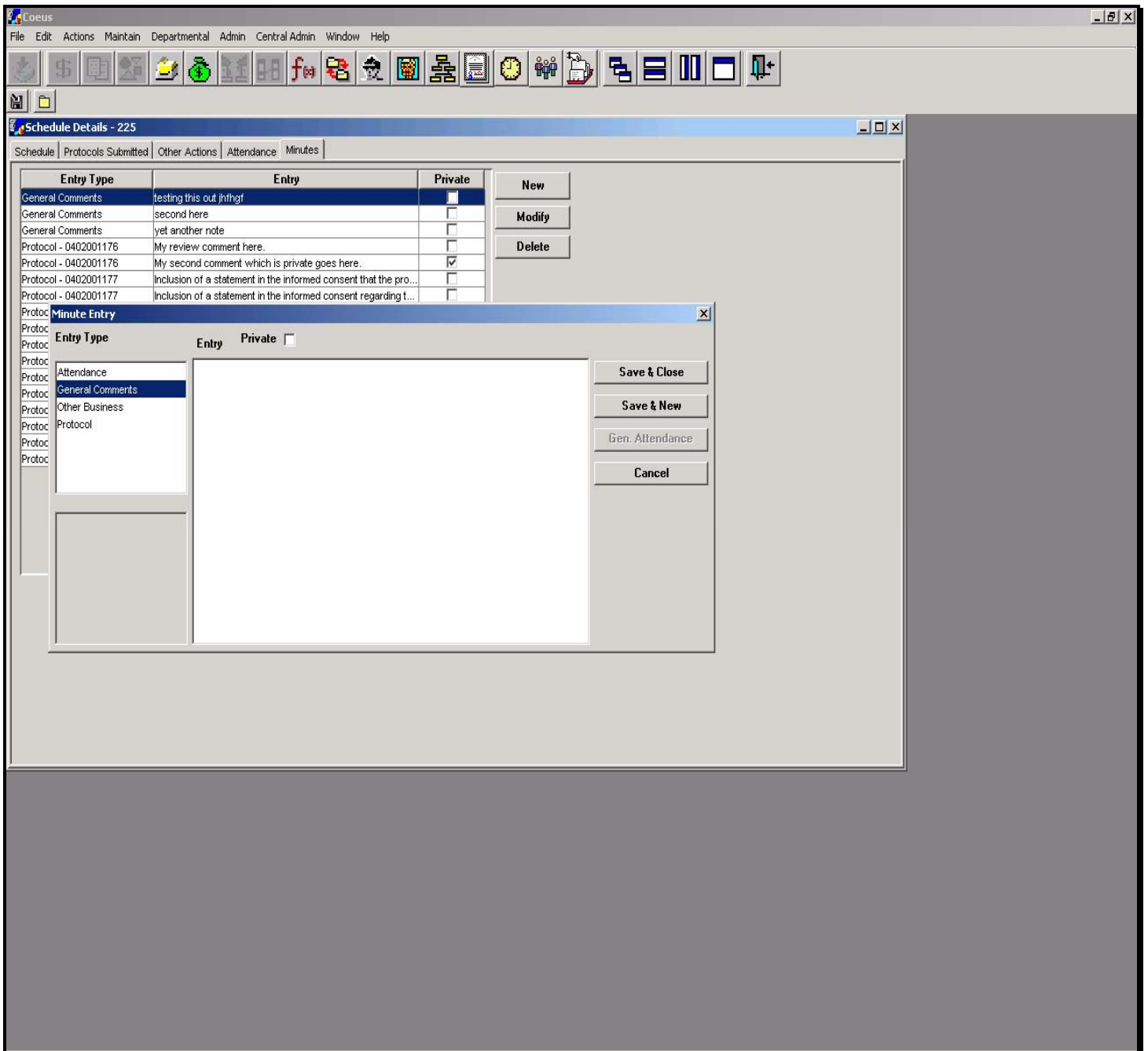
6. You can also list any other attendees that are not IRB committee members, but are WMC employees by hitting the *Person* button.
7. This action will launch the People search window. Type in the name of the WMC employee you would like to list. Once Coeus has generated the name you need highlight it and click the *OK* button. The “Guest” flag will be automatically placed for you.





# How to Generate Minutes

10. Next go to the Minutes tab, and hit the *New* button. This will launch the Minute Entry window which allows the user to record General Comments, make notes on Attendance, record Other Business, and any extra notes on Protocols.
  - a) Note that the primary notes for each protocol will be created when staff records the status of each protocol and the revisions required, if any.



# How to Generate Minutes

11. To begin to record some general comments, highlight the “General Comments” from the list located on the left hand side of the box. Then hit start typing in the blank box.
12. When you are done making the note and would like to make another entry hit the *Save & New* button. The Entry box will go blank and you can begin creating the next entry.
13. Once you are done with all of your entries, hit the *Save & Close* button.
14. To generate the minutes go to the Edit menu and select “Generate Minutes”. This will open the document in a separate window.
15. If changes need to be made to the Minutes, go back to the minutes tab, highlight the entry that needs to be altered and hit the *Modify* button. This will open the Minute Entry window directly to the comment you would like to modify.
16. The user can also delete an entry by highlighting the unwanted entry clicking on the *Delete* button.
17. Once all of the modifications have been made go back to the Edit menu and select Generate Minutes again, this will update the document.

# How to Approve Protocol

**\*Please note that any special reviews for a protocol must be approved first. Also, the attendance must be taken before a protocol can be approved.**

1. Begin by opening the Schedule screen. You can do this by hitting the *Schedule*



button or by going to the *Maintain* menu and selecting *Schedule*.

2. When the screen opens the search window will automatically come up with it. Type in the meeting date you are looking for.

3. When the meeting date you require is generated, highlight it and then hit the *Edit*



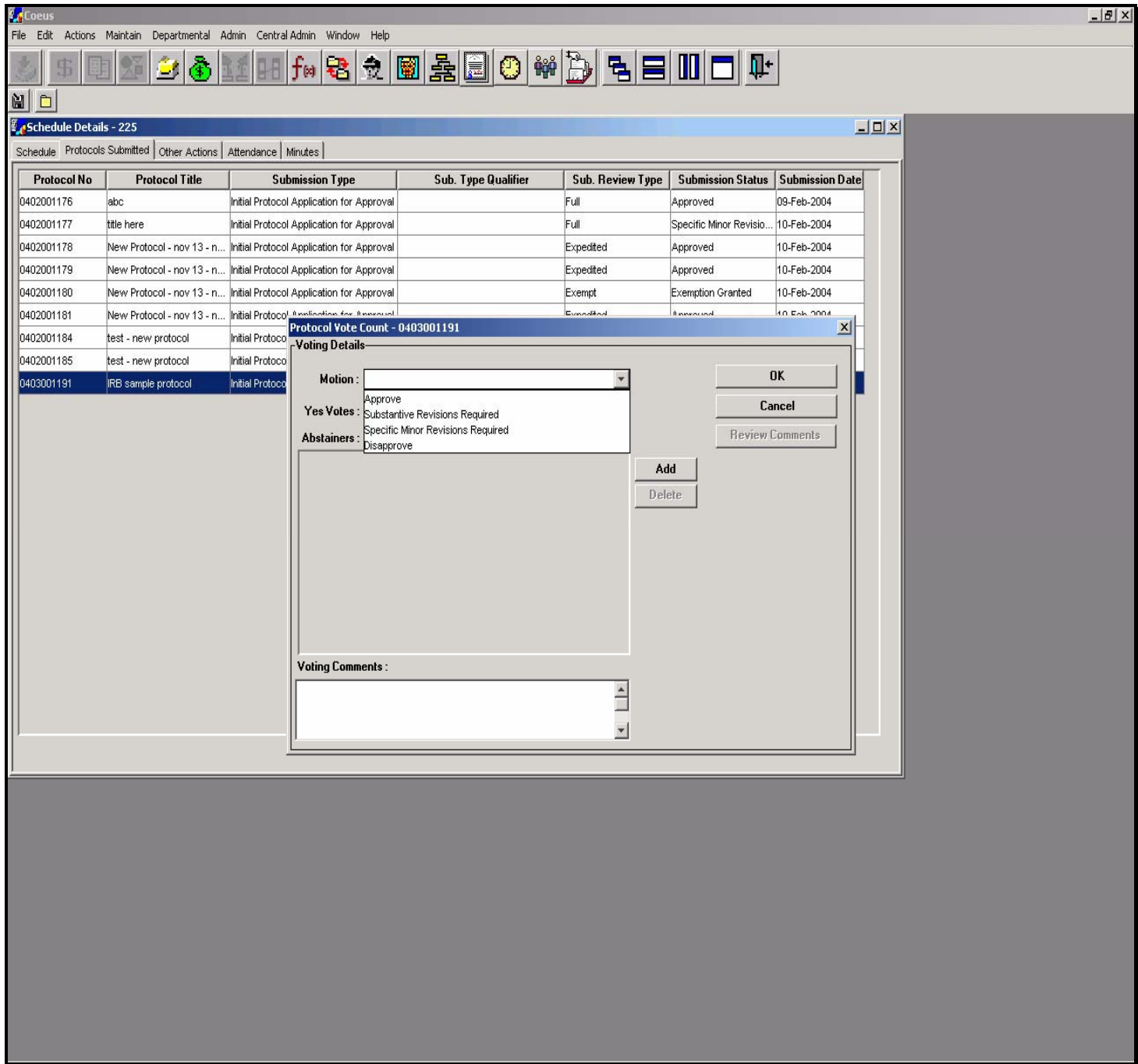
button. This will open the window for that particular meeting date.

The screenshot shows the Coeus application window with a menu bar (File, Edit, Maintain, Departmental, Admin, Central Admin, Tools, Window, Help) and a toolbar. A red arrow points to a clock icon in the toolbar. Below the toolbar is a window titled 'Schedules' containing a table with the following data:

Schedule Id	Scheduled Date	Place	Schedule Status	Submission Deadline	Committee Id	Committee Name
9	01-Sep-2004	DV-301	Scheduled	27-Aug-2004	12345	IRB
213	01-Sep-2004	NY	Scheduled	27-Aug-2004	000000000000006	Committee 23 Sep 03
225	01-Sep-2004	NY	Scheduled	01-Sep-2004	000000000000005	IRB

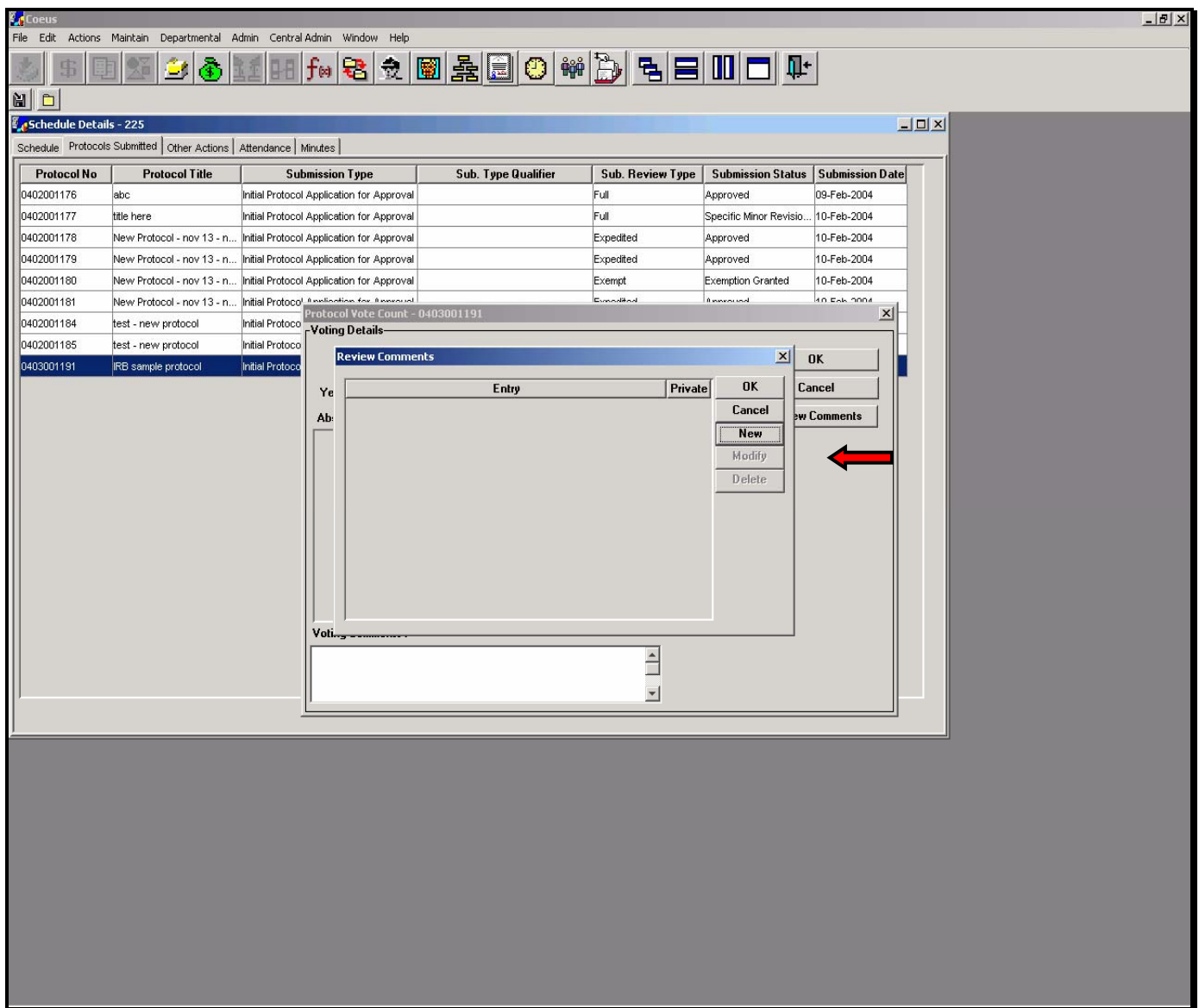
# How to Approve Protocol

4. In the *Schedule Details* window click on the *Protocols Submitted* tab.
5. Highlight the protocol you would like to approve. Then go to the *Actions* menu and select *Committee Actions*. This will open the *Protocol Vote Count* window.



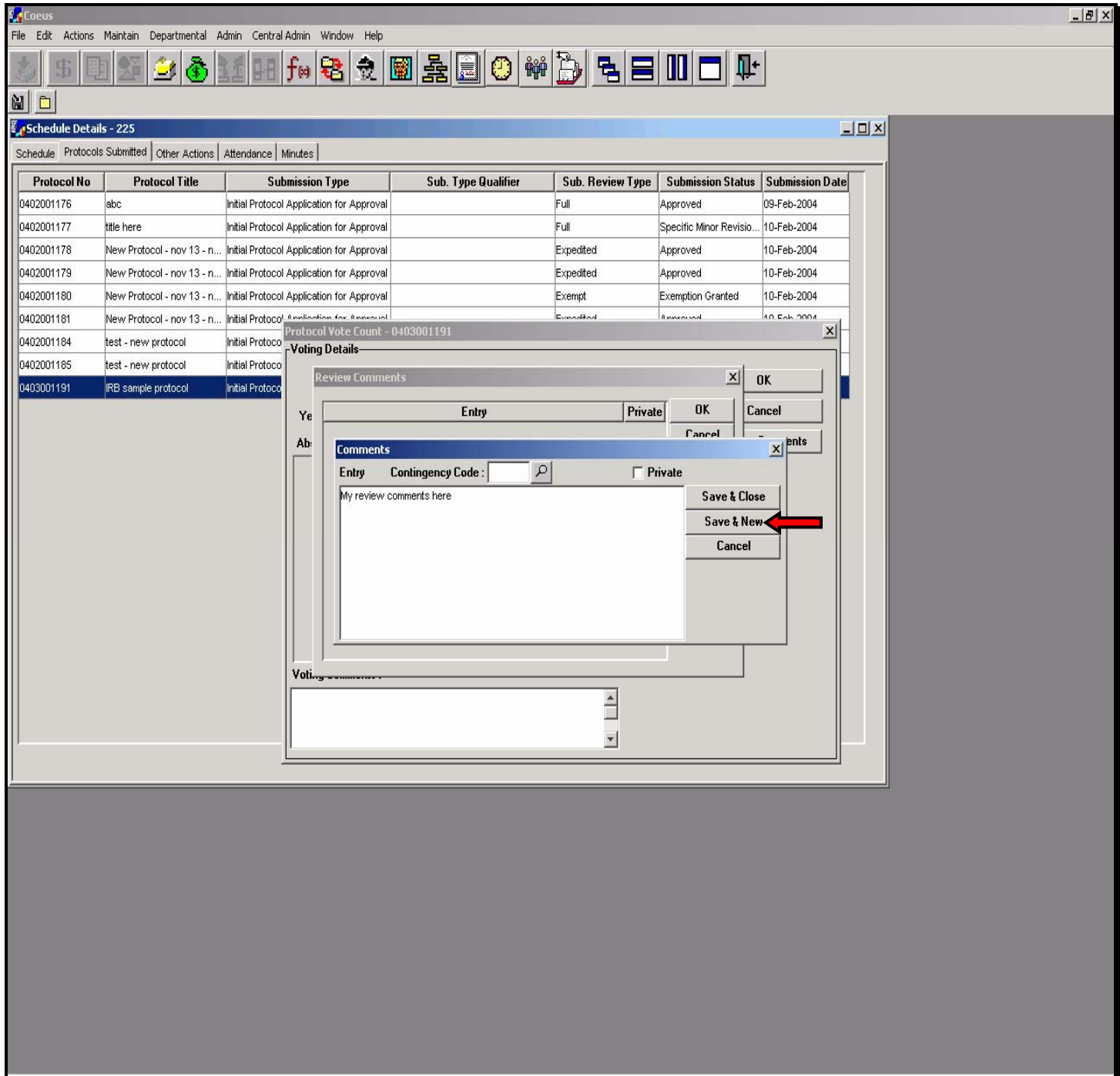
# How to Approve Protocol

6. In the *Motions* field select *Approval* from the drop down menu
7. Then enter in the number of “Yes” votes, “No” votes and “Abstained” votes.
8. If you have recorded any number of abstainers, click on the *Add* button to record those members of the meeting that abstained from the vote.
9. Click on the *Review Comments* button and add that particular information. This action will launch the “Review Comments” window. For each protocol the following three comments must be included: (Please be sure to click on the “Private Box”, for each of these comments so the note does not show up on the letter to the PI.)
  - A) Indication of any IRB members that have left the room during the vote of a particular protocol, if any.
  - B) Summary of the discussion of the protocol.
  - C) Revisions required and explanation for each revision.



# How to Approve Protocol

10. To add a review comment, click on the *New* button. This will launch the Comments window. In the empty box begin to type your comments.
11. If you have more than one comment, click on the *Save & New* button after each entry. This will save your previous entry and display an empty box for the next.



# How to Approve Protocol

12. Coeus comes equipped with a series of “canned” review comments that you can pull from the Contingency list. To view and select from the list hit the *Search*



button. Then highlight the item you would like to use and click the *OK* button.

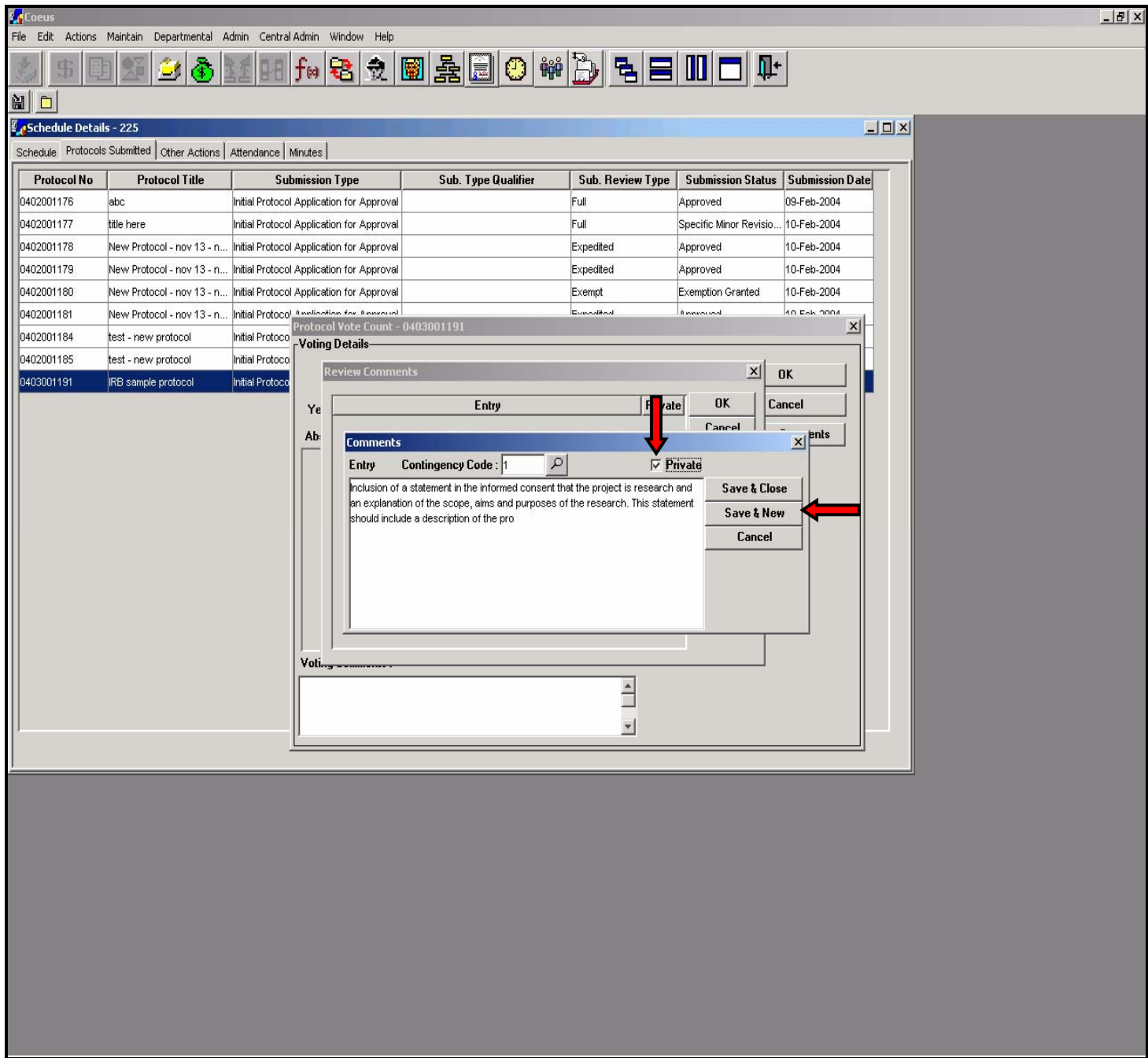
The screenshot shows the Coeus software interface. The main window is titled "Schedule Details - 225" and contains a table of protocols. A "Contingency LookUp" dialog box is open, displaying a list of contingency codes and their descriptions. A red arrow points to the search icon in the "Comments" dialog box, which is also open.

Protocol No	Protocol Title	Submission Type	Sub. Type Qualifier	Sub. Review Type	Submission Status	Submission Date
0402001176	abc	Initial Protocol Application for Approval		Full	Approved	09-Feb-2004
0402001177	title here	Initial Protocol Application for Approval		Full	Specific Minor Revisio...	10-Feb-2004
0402001178	New Protocol - nov 13 - n...	Initial Protocol Application for Approval		Expedited	Approved	10-Feb-2004
0402001179	New Protocol - nov 13 - n...	Initial Protocol Application for Approval		Expedited	Approved	10-Feb-2004
0402001180	New Protocol - nov 13 - n...	Initial Protocol Application for Approval		Exempt	Exemption Granted	10-Feb-2004
0402001181	New Protocol - nov 13 - n...	Initial Protocol Application for Approval		Expedited	Approved	10-Feb-2004
0402001184	test - new protocol	Initial Protocol Application for Approval		Full	Approved	10-Feb-2004
0402001185	test - new protocol	Initial Protocol Application for Approval		Full	Approved	10-Feb-2004
0403001191	IRB sample protocol	Initial Protocol Application for Approval		Full	Approved	10-Feb-2004

Code	Description
1	Inclusion of a statement in the informed consent that the project is research and an explanation of the scope, aims and purposes of the research. This statement should include a description of the pro
2	Inclusion of a statement in the informed consent regarding the expected amount of time for the subject's participation
3	Inclusion of a statement in the informed consent regarding the availability of compensation and/or medical treatment if injury occurs.
4	Inclusion of a statement in the informed consent describing the extent to which confidentiality of records indrtifying the subject will be maintained or if subjects will be anonymous.
5	Inclusion of a statement in the informed consent that participation is voluntary and that nonparticipation will not result in penalty of loss of benefits to which the subject is otherwise entitled. If

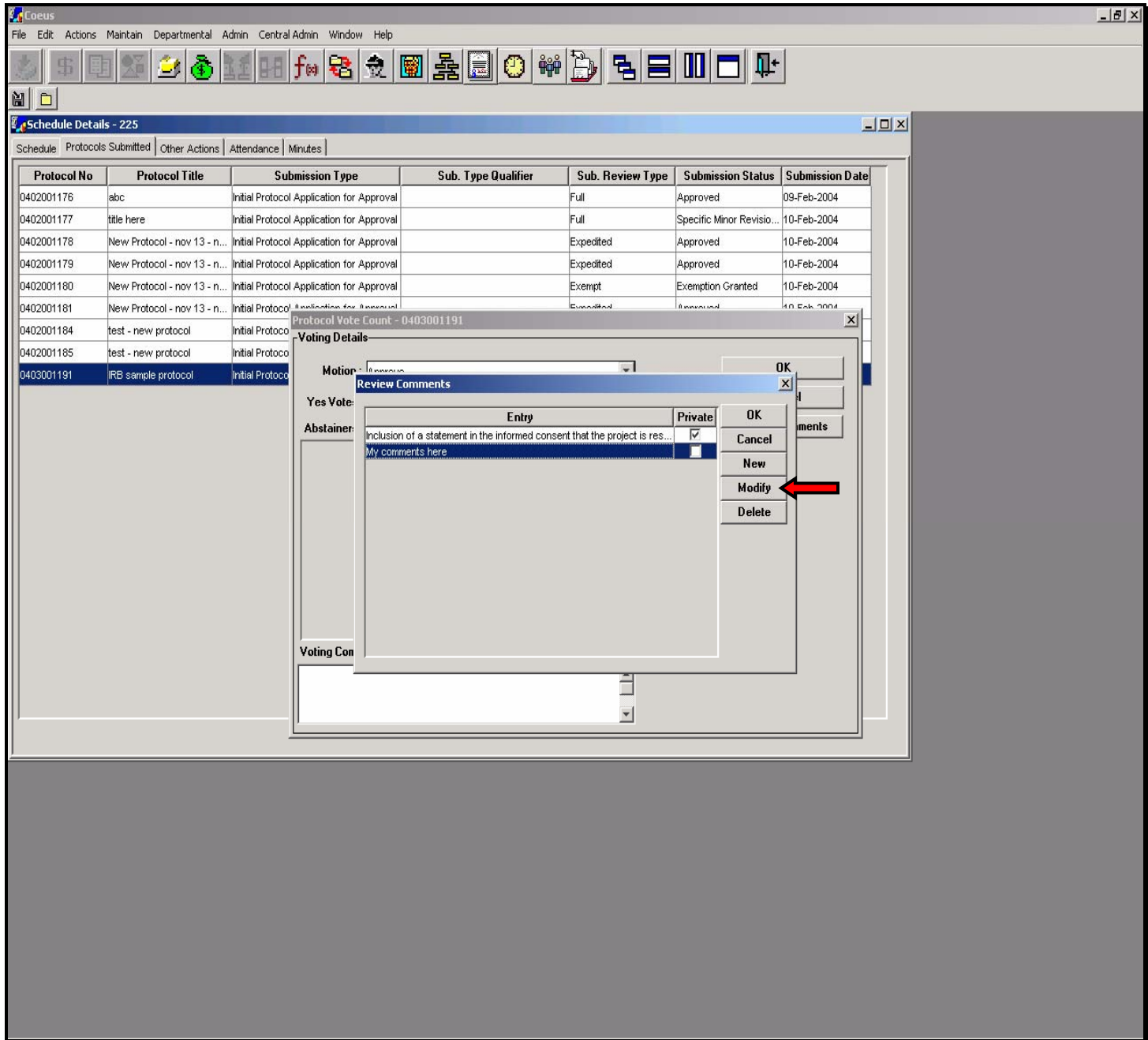
# How to Approve Protocol

13. When you have finished entering all of the comments click on the *Save & Close* button
14. In the event that there is a comment that you would like to be shown in the minutes, but not in the approval letter, be sure to click on the *Private* box, **before** you save your entry.



# How to Approve Protocol

15. The final result will look like a shopping list of review comments.
16. If you notice that you will need to make a change to any of the comments simply highlight the comment that needs correction and click on the modify button
17. Once you have completed all of the review comments click the *OK* button.



# How to Approve for Expedited to Exempt



1. Begin by hitting the *Protocol Submissions* button or by going to the Maintain menu and selecting Protocol Submissions.
2. When the search window opens type in the protocol number that needs an Expedited or Exempt approval.
3. For *Expedited* approval, highlight the record then go to the Protocol Actions menu and select Expedited Approval.
4. For *Exempt* Approval highlight the record, go to the Protocol Actions menu and select Grant Exemption.
5. This will launch either the Expedited Approval or Grant Exemption windows.

The screenshot displays the Coeus software interface. At the top, there is a menu bar with options: File, Edit, Actions, Maintain, Departmental, Admin, Central Admin, Tools, Window, Help. Below the menu bar is a toolbar with various icons. The main window shows a 'Submission List' table with the following data:

Protocol No	Submission Status	Submission Date	Submission Type	Submission Type Qualifier	Review Type	Committee Id	Schedule Id	Schedule
0405001214	In Agenda	14-May-2004	Initial Protocol Applicati...		Expedited	000000000000005	227	01-Nov-2004

An 'Expedited Approval Action-0405001214' dialog box is open in the foreground. It contains the following text and fields:

Are you sure you want to perform Expedited Approval on this protocol ?

Approval Date : 11/01/2004

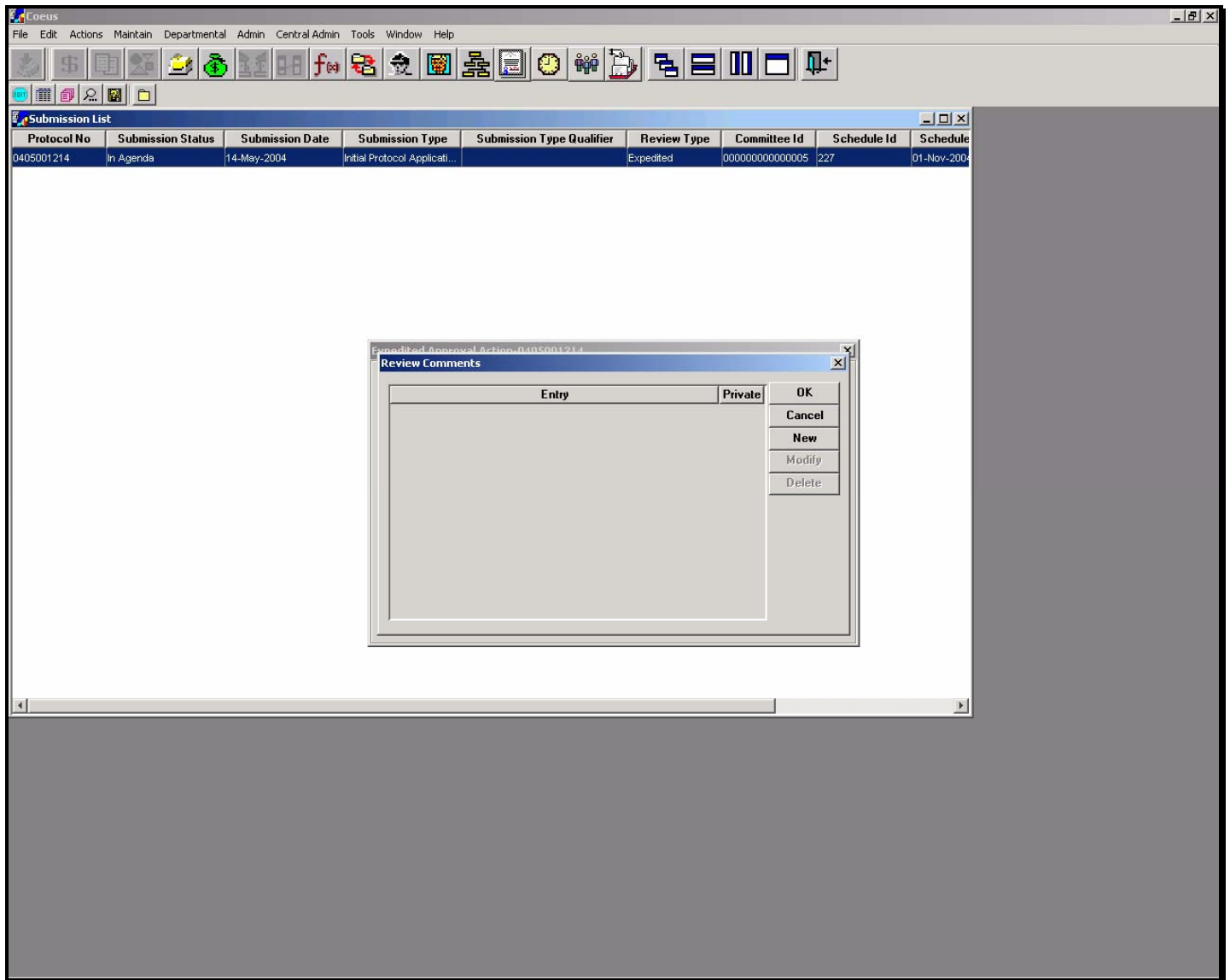
Expiration Date : 31-Oct-2005

Comments :

Buttons: OK, Cancel, Review Comments

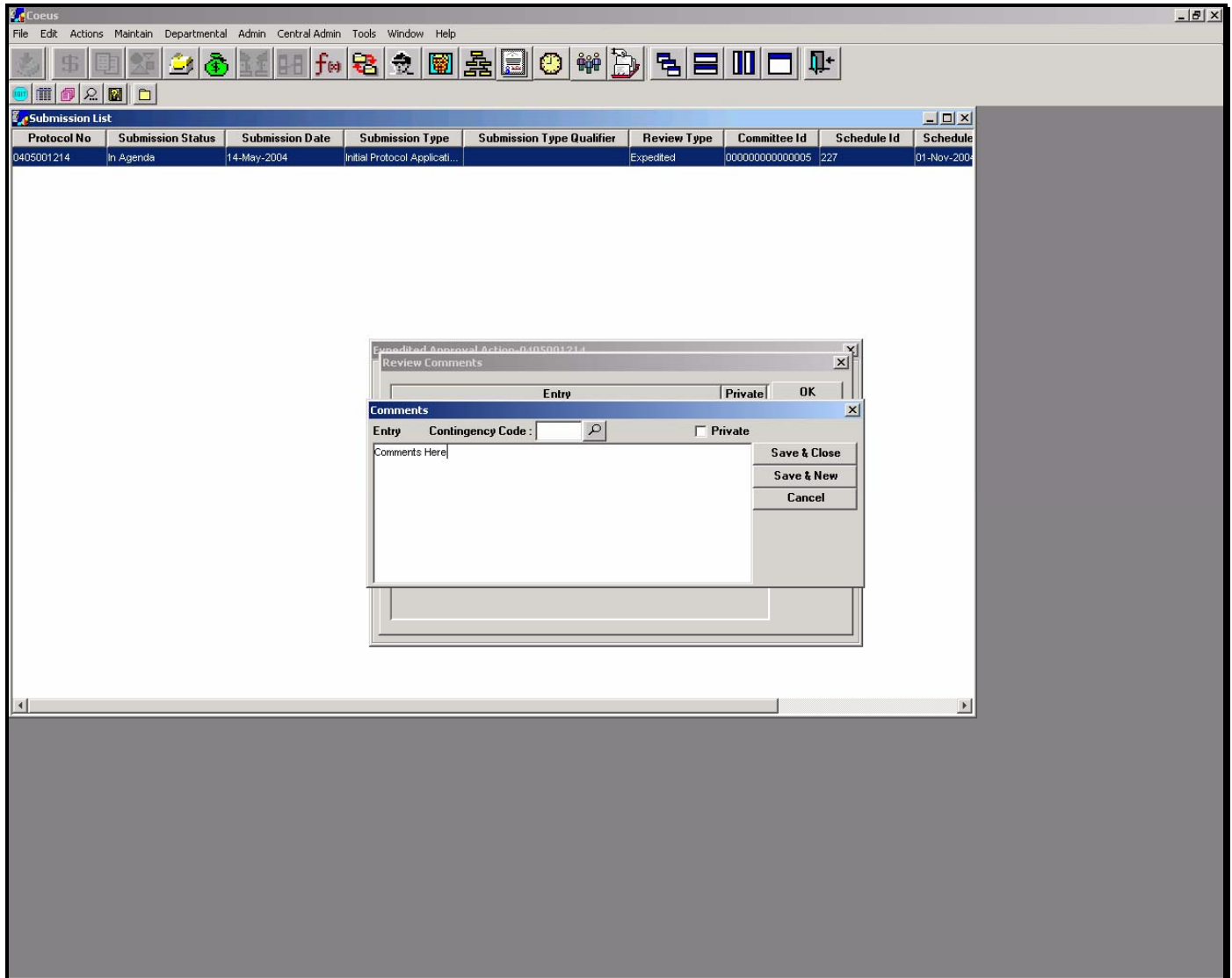
# How to Approve for Expedited to Exempt

6. If you have any review comments to add to the record click on the *Review Comments* button. This will launch the, Review Comments window.



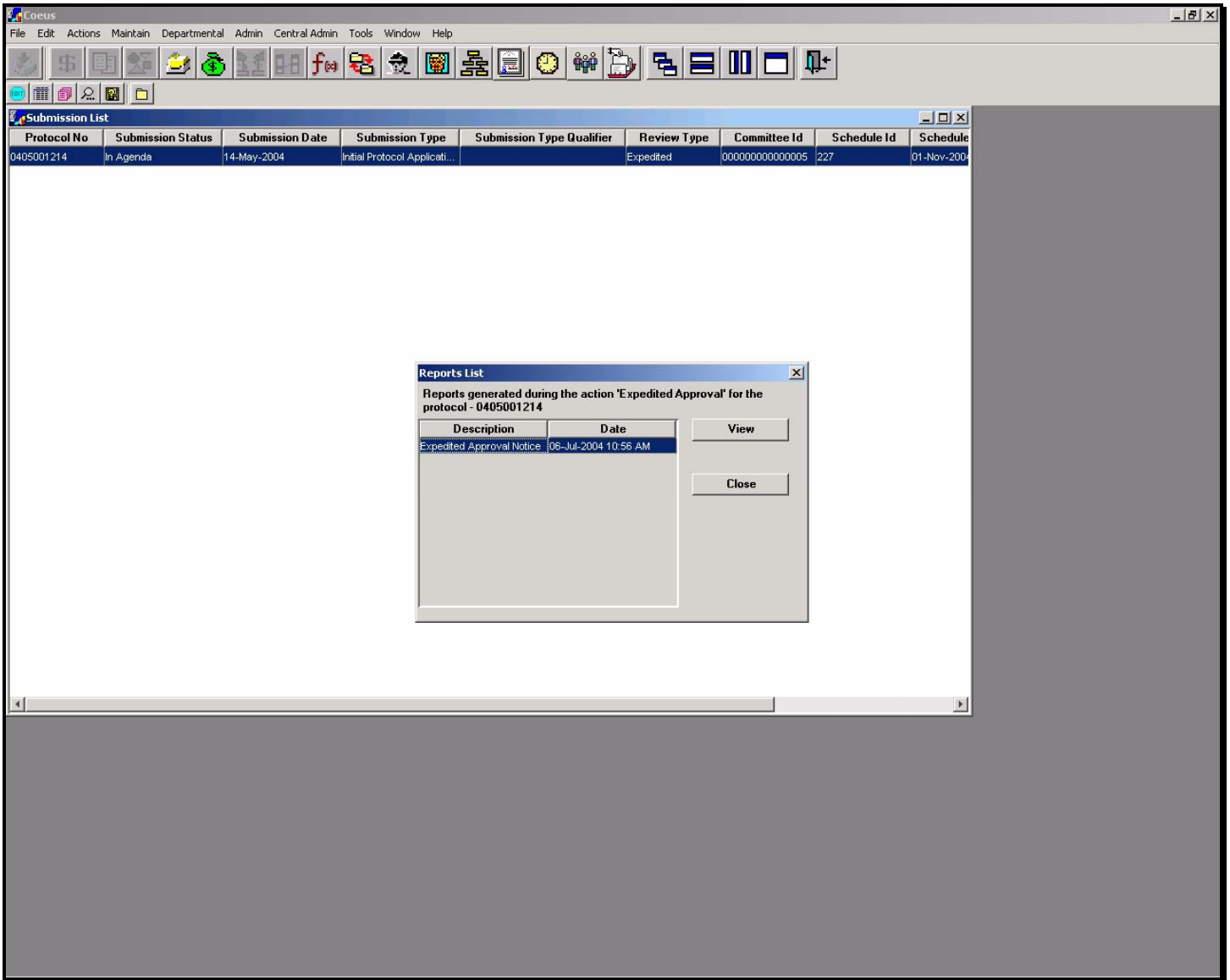
7. Next click on the *New* button to enter the review comments, this will launch the Comments window.

# How to Approve for Expedited to Exempt



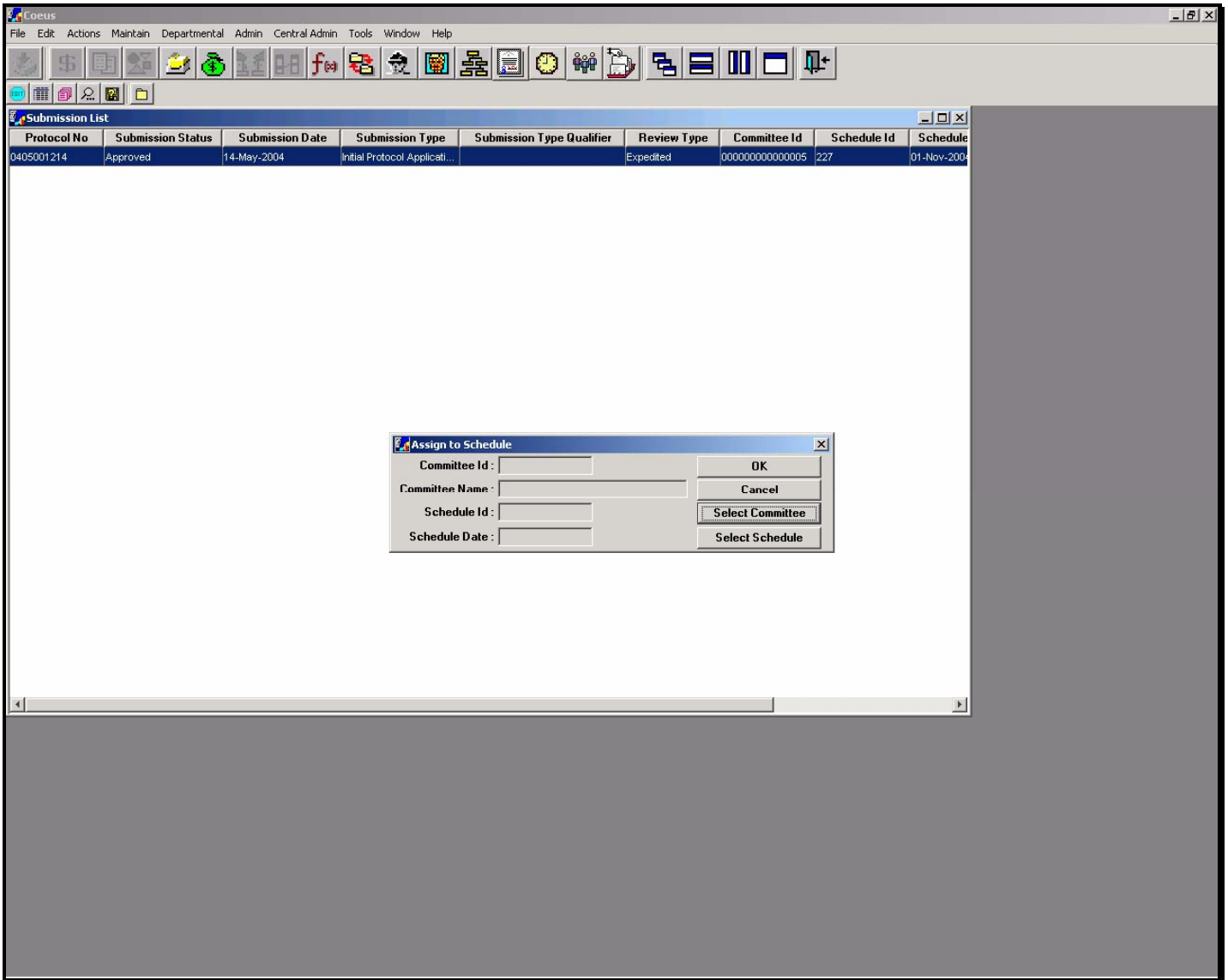
8. Enter the review comments, and when done click on the *Save & Close* button. Please note that for each Expedited protocol the following must be included: (Please be sure to click on the “Private Box”, for any comments that should not show up on the letter to the PI.)
  - a. Revisions required and an explanation for each revision.
9. Then click *OK* on the Review Comments window and click *OK* again on the Expedited Approval or the Grant Exemption window.
10. This will then launch the Report List window which will show the Expedited or Exempt Approval letter that was created. Click on the View button to launch the letter.

# How to Approve for Expedited to Exempt



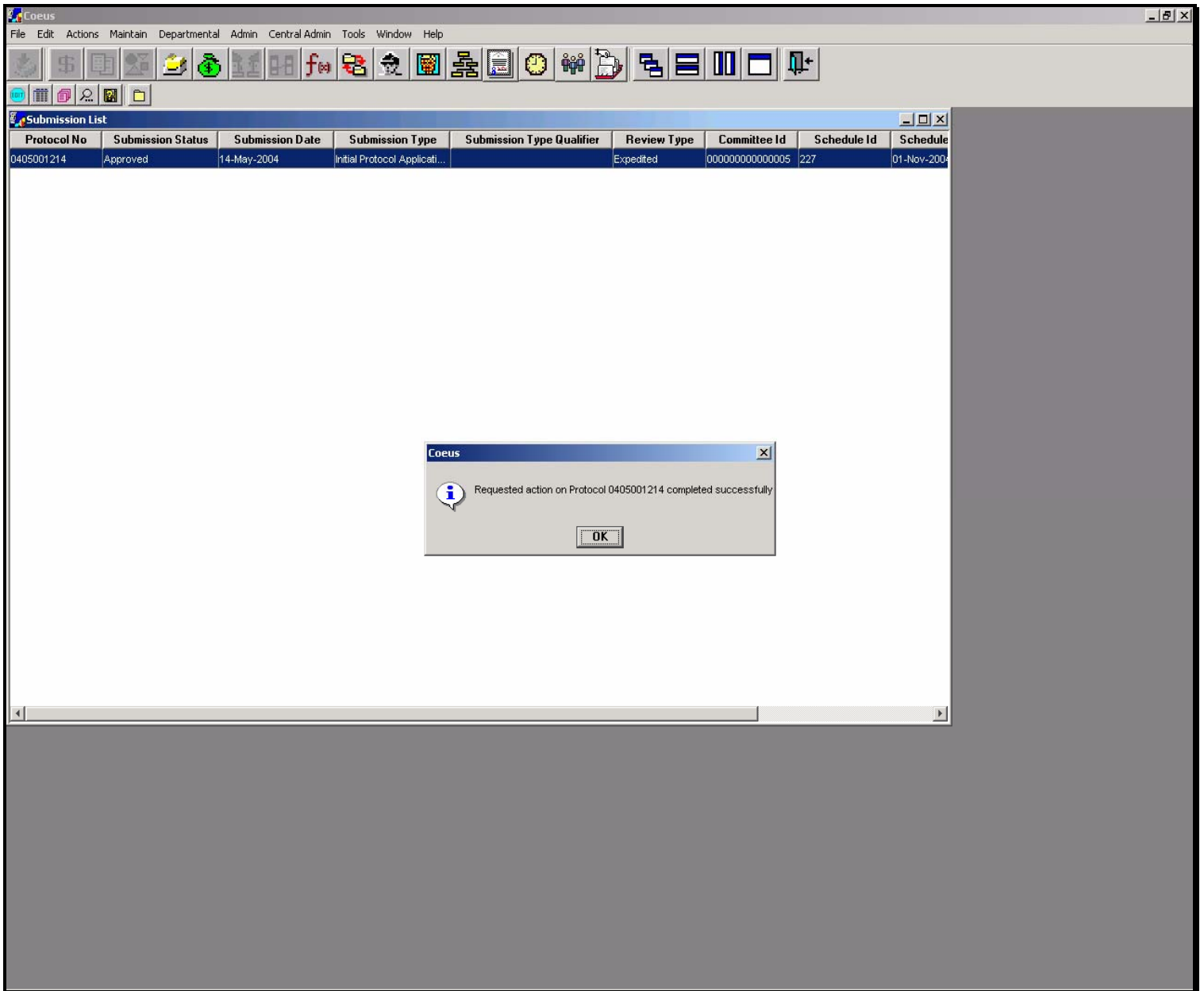
11. Coeus will load the letter in a separate window.
12. The final step is to then go to the Actions menu and select Notify Committee.  
This action is done in order to place the Expedited approval on an agenda for the IRB committee to be notified.

# How to Approve for Expedited to Exempt



13. Click on the *Select Committee* button to choose the corresponding committee.
14. Then Click the *Select Schedule* button to place on the next following meeting date for the Committee you have selected, in order for the protocol to show on the minutes.( Please note that even if the protocol has been assigned to a schedule and committee Coeus will ask you to make that selection again. This is to ensure that the protocol is placed on an agenda for the next following, and correct, meeting.)
15. When done click the OK button. Coeus will notify you that the requested action has been successfully completed.

# How to Approve for Expedited to Exempt





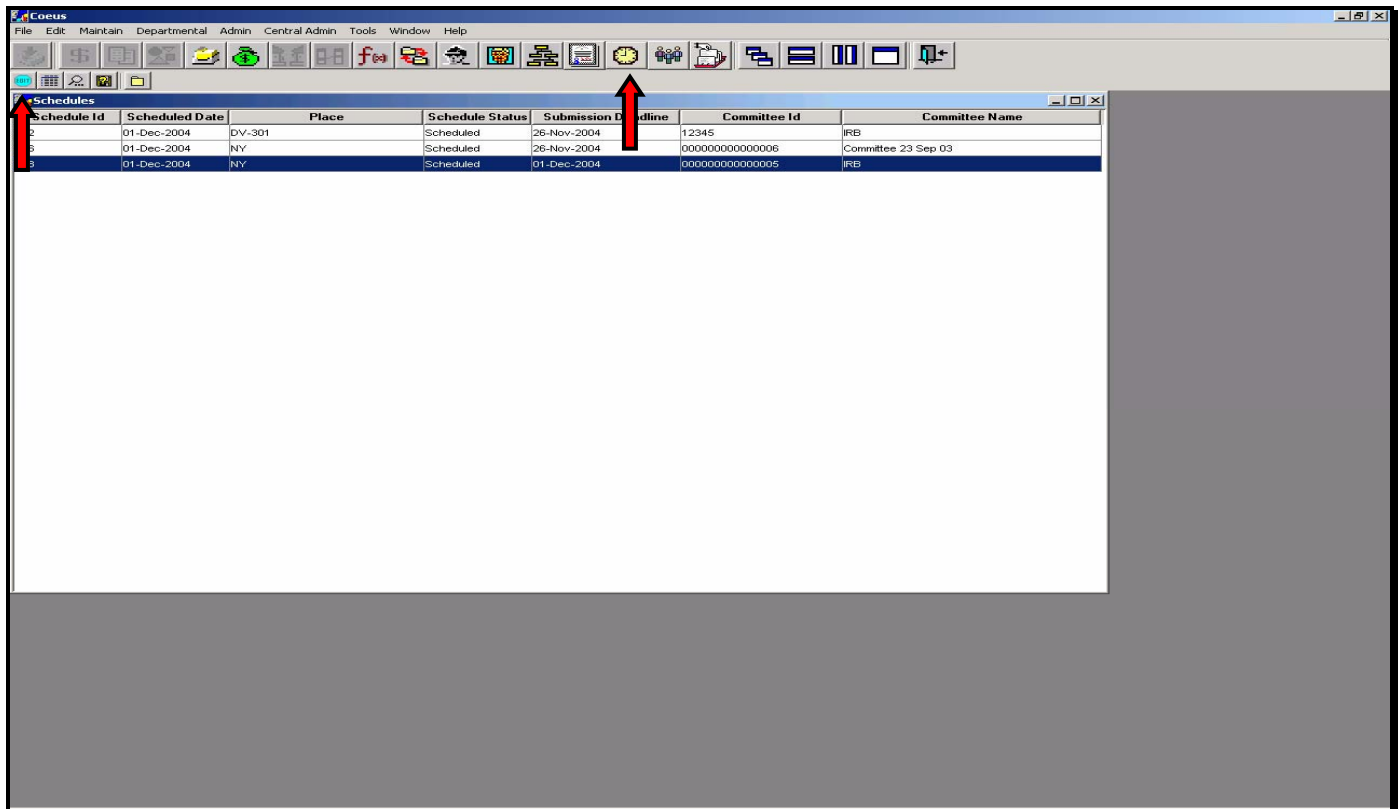
# How to Approve an Amendment or a Renewal

## Sequencing:

It was mentioned earlier on in this manual that Coeus will allow users to approve both amendments and renewals out of order. Let's consider the following scenario. Say there is a protocol that has an amendment pending, and that the same protocol is up for renewal after the amendment has been created. There is a possibility that the renewal will be reviewed and approved before the amendment is. In Coeus, if the user were to approve the renewal before the amendment Coeus will block the user out of any previous actions that have been created. In this case the user would be blocked out of approving the amendment. Similarly, if a protocol has two amendments and the second one is approved before the first, users will be blocked out of modifying any information for the first amendment.

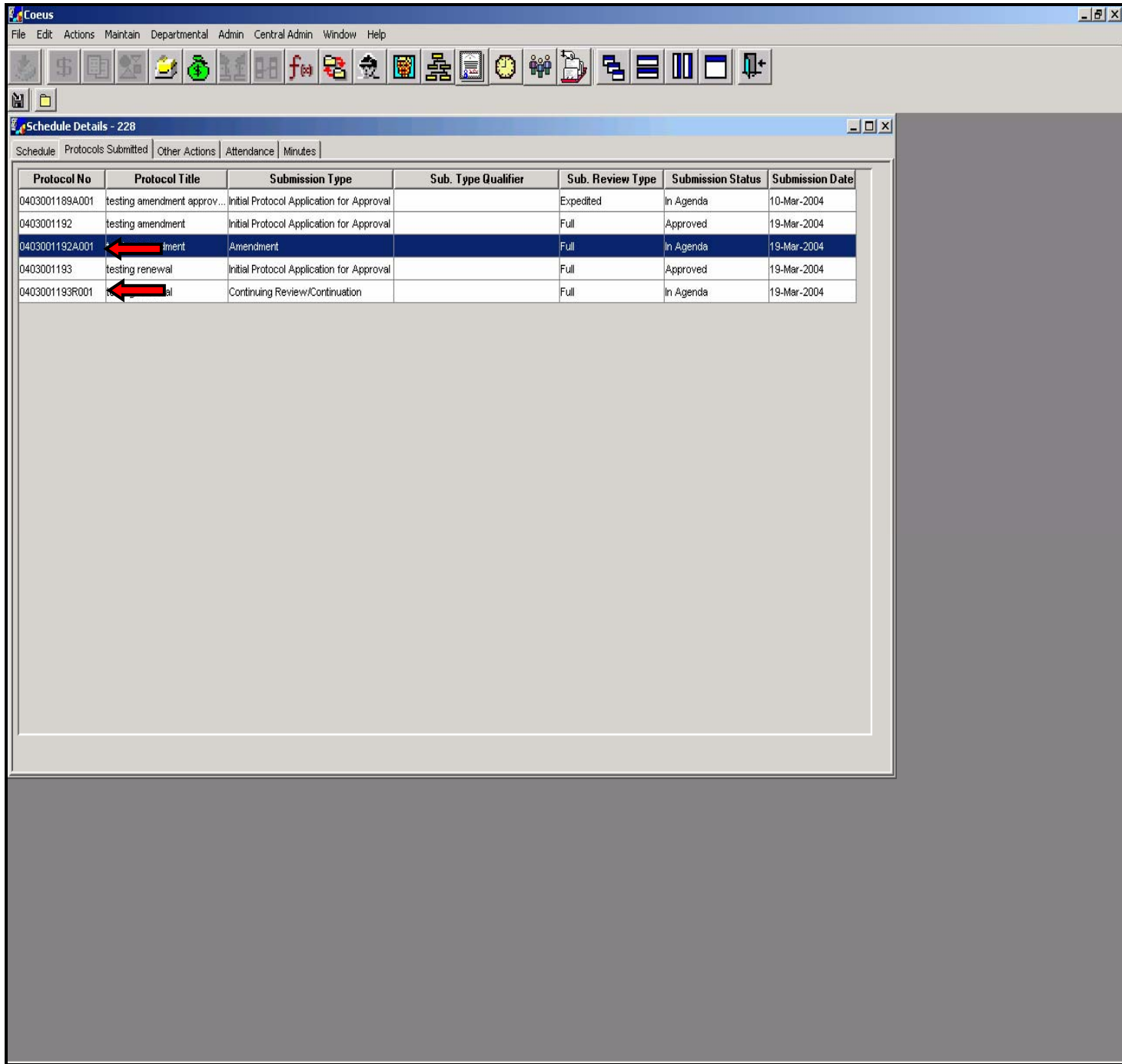
It is this order-based functionality that makes the approval sequencing crucial. Part of the process of approving amendments and renewals is making sure that they are approved in the correct order.

1. Begin by going to the schedule screen. You can do this by hitting the *Schedule* button  and using the search window to locate the meeting date the amendment or renewal was reviewed.
2. Once Coeus has generated the committee and meeting date that you need highlight it and click on the *Edit* button .



# How to Approve an Amendment or a Renewal

- When the record opens go to the protocol submitted tab. You will see a listing of all items that have been submitted for review on that particular date. Please note that all amendments are listed with the protocol number followed by either the letter "A" or "R" and the sequential number followed by it



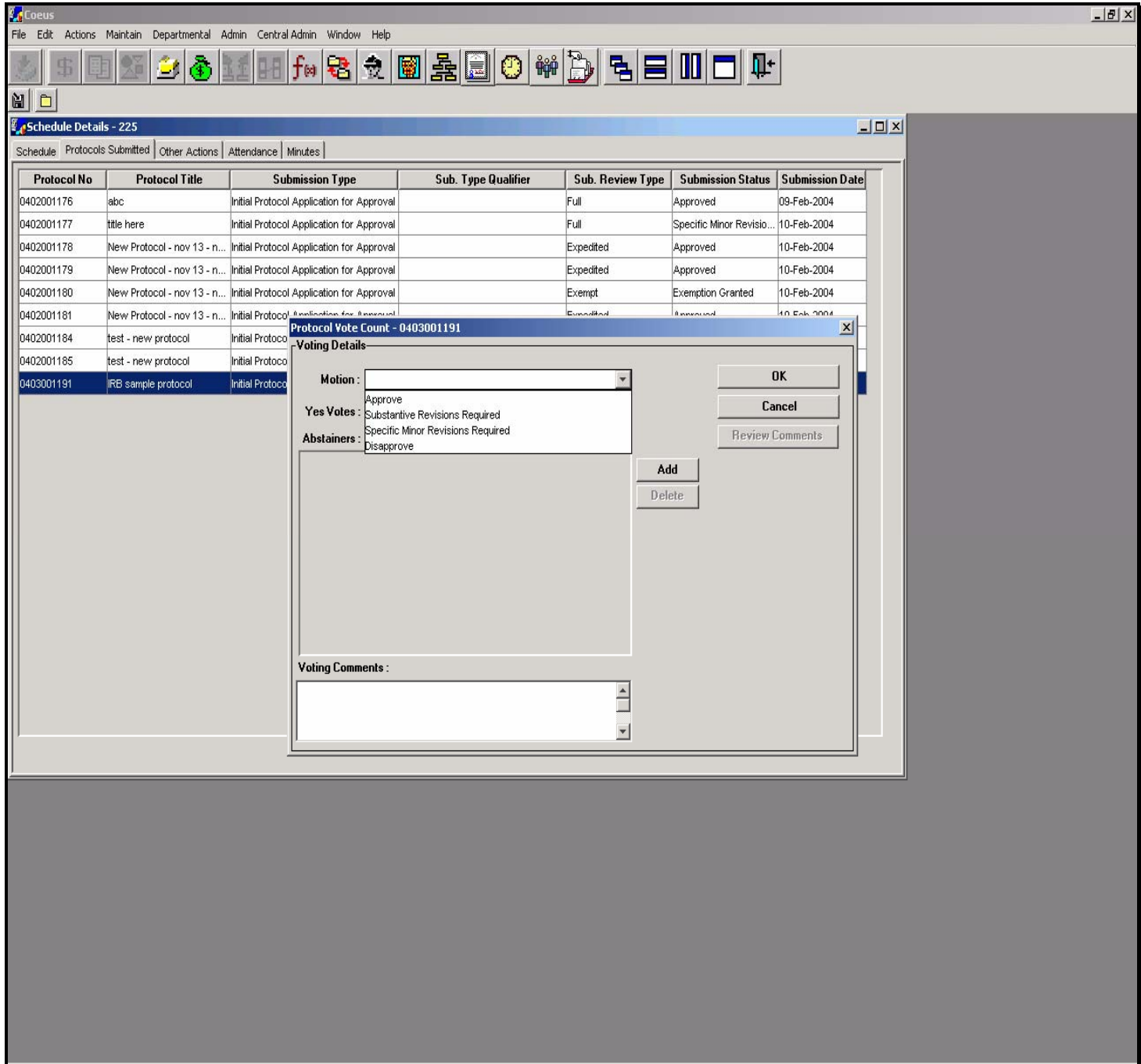
The screenshot shows the Coeus software interface. The main window is titled "Schedule Details - 228" and has tabs for "Schedule", "Protocols Submitted", "Other Actions", "Attendance", and "Minutes". The "Protocols Submitted" tab is active, displaying a table with the following data:

Protocol No	Protocol Title	Submission Type	Sub. Type Qualifier	Sub. Review Type	Submission Status	Submission Date
0403001189A001	testing amendment approv...	Initial Protocol Application for Approval		Expedited	In Agenda	10-Mar-2004
0403001192	testing amendment	Initial Protocol Application for Approval		Full	Approved	19-Mar-2004
0403001192A001	testing amendment	Amendment		Full	In Agenda	19-Mar-2004
0403001193	testing renewal	Initial Protocol Application for Approval		Full	Approved	19-Mar-2004
0403001193R001	testing renewal	Continuing Review/Continuation		Full	In Agenda	19-Mar-2004

Red arrows point to the "A" in "0403001192A001" and the "R" in "0403001193R001" in the Protocol No column.

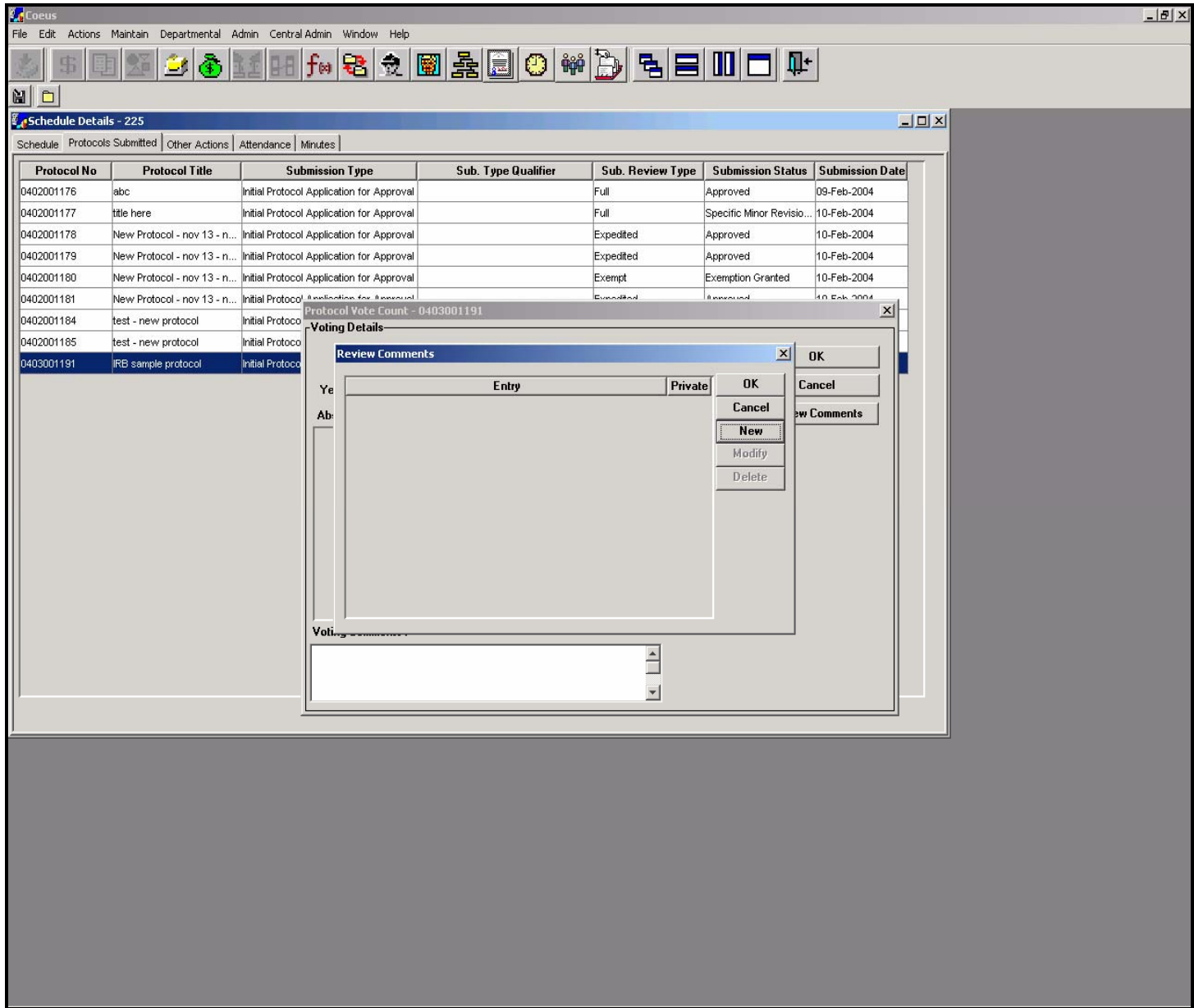
# How to Approve an Amendment or a Renewal

4. Highlight the protocol you would like to approve. Then go to the *Actions* menu and select *Committee Actions*. This will open the *Protocol Vote Count* window.



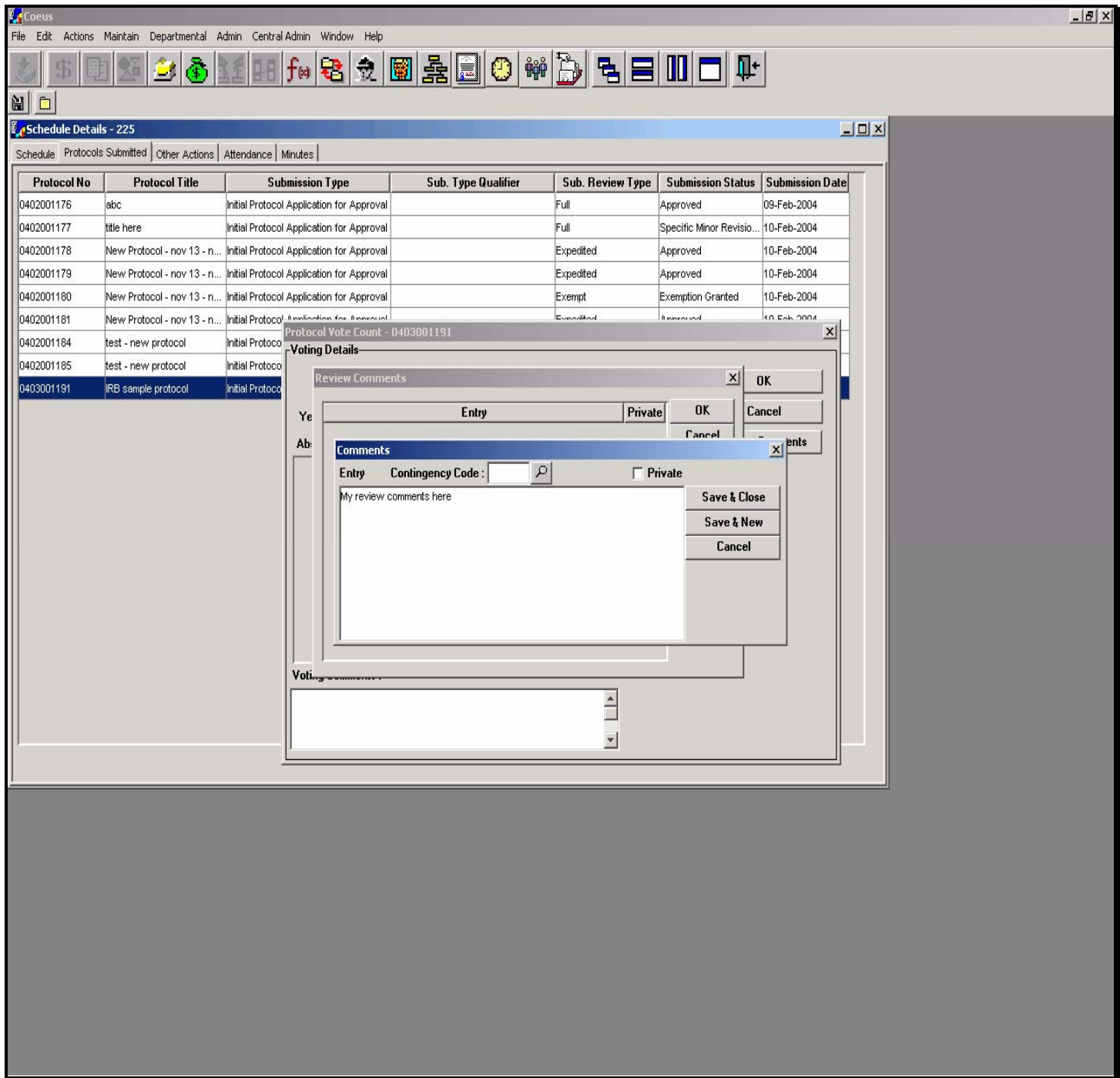
# How to Approve an Amendment or a Renewal

5. In the *Motions* field select *Approval* from the drop down menu.
6. Then enter in the number of “Yes” votes, “No” votes and “Abstained” votes.
7. If you have recorded any number of abstainers, click on the *Add* button to record those members of the meeting that abstained from the vote.
8. Click on the *Review Comments* button and add that particular information. This action will launch the “Review Comments” window.




# How to Approve an Amendment or a Renewal

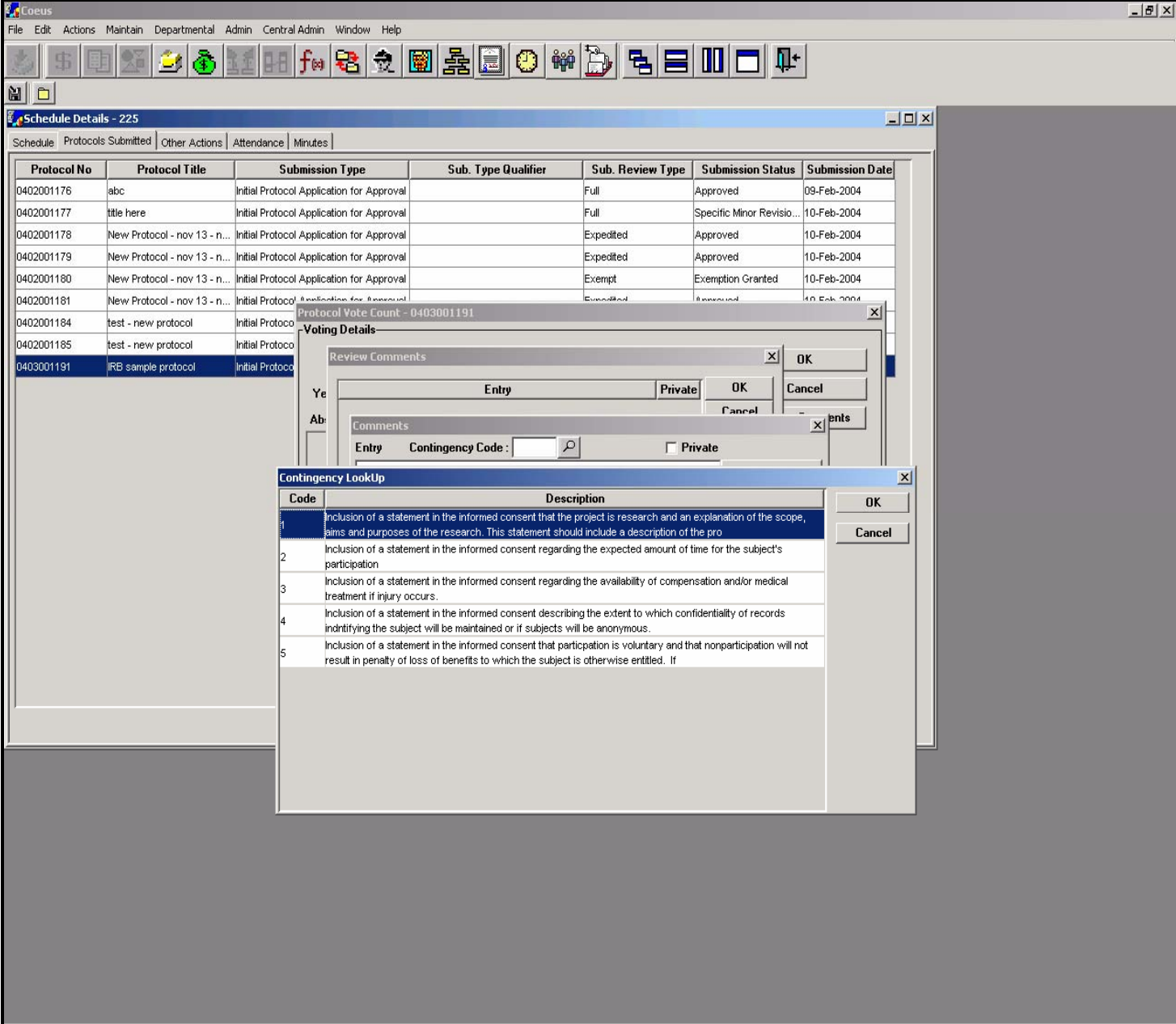
- To add a review comment, click on the *New* button. This will launch the Comments window. In the empty box begin to type your comments.
- If you have more than one comment, click on the *Save & New* button after each entry. This will save your previous entry and display an empty box for the next.



# How to Approve an Amendment or a Renewal

11. Coeus comes equipped with a series of “canned” review comments that you can pull from the Contingency list. To view and select from the list hit the

 *Search* button. Then highlight the item you would like to use and click the *OK* button.



The screenshot displays the Coeus software interface. The main window is titled "Schedule Details - 225" and contains a table with the following data:

Protocol No	Protocol Title	Submission Type	Sub. Type Qualifier	Sub. Review Type	Submission Status	Submission Date
0402001176	abc	Initial Protocol Application for Approval		Full	Approved	09-Feb-2004
0402001177	title here	Initial Protocol Application for Approval		Full	Specific Minor Revisio...	10-Feb-2004
0402001178	New Protocol - nov 13 - n...	Initial Protocol Application for Approval		Expedited	Approved	10-Feb-2004
0402001179	New Protocol - nov 13 - n...	Initial Protocol Application for Approval		Expedited	Approved	10-Feb-2004
0402001180	New Protocol - nov 13 - n...	Initial Protocol Application for Approval		Exempt	Exemption Granted	10-Feb-2004
0402001181	New Protocol - nov 13 - n...	Initial Protocol Application for Approval		Exempt	Approved	10-Feb-2004
0402001184	test - new protocol	Initial Protocol Application for Approval		Full	Approved	10-Feb-2004
0402001185	test - new protocol	Initial Protocol Application for Approval		Full	Approved	10-Feb-2004
0403001191	IRB sample protocol	Initial Protocol Application for Approval		Full	Approved	10-Feb-2004

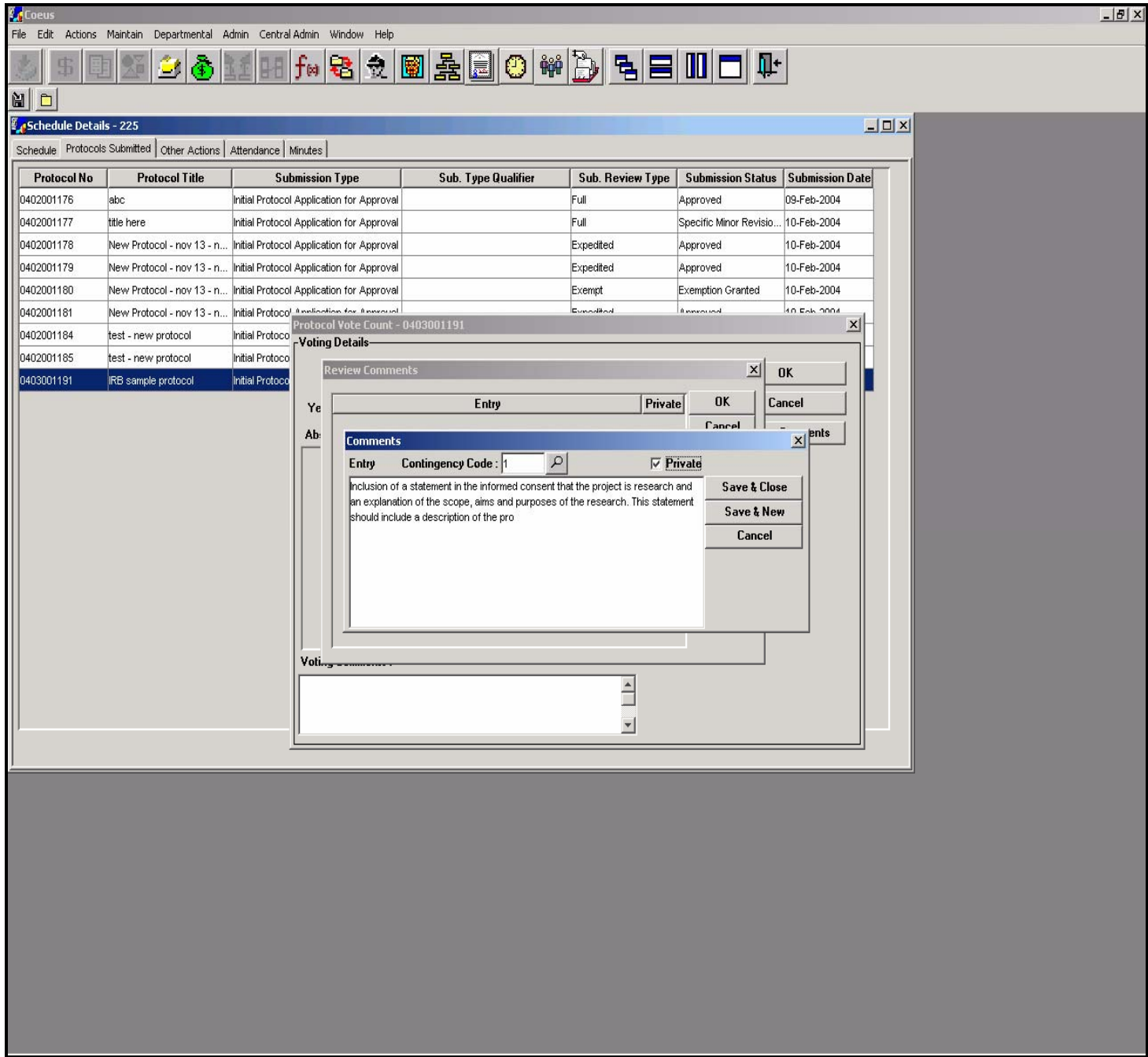
Overlaid on the table are several dialog boxes:

- Protocol Vote Count - 0403001191**: A dialog box with a "Review Comments" section and "OK" and "Cancel" buttons.
- Voting Details**: A dialog box with "Entry" and "Private" buttons, and "OK" and "Cancel" buttons.
- Comments**: A dialog box with an "Entry" field, a "Contingency Code" field with a search icon, and a "Private" checkbox. It has "OK" and "Cancel" buttons.
- Contingency LookUp**: A dialog box with a table of contingency codes and descriptions, and "OK" and "Cancel" buttons.

Code	Description
1	Inclusion of a statement in the informed consent that the project is research and an explanation of the scope, aims and purposes of the research. This statement should include a description of the project.
2	Inclusion of a statement in the informed consent regarding the expected amount of time for the subject's participation.
3	Inclusion of a statement in the informed consent regarding the availability of compensation and/or medical treatment if injury occurs.
4	Inclusion of a statement in the informed consent describing the extent to which confidentiality of records identifying the subject will be maintained or if subjects will be anonymous.
5	Inclusion of a statement in the informed consent that participation is voluntary and that nonparticipation will not result in penalty or loss of benefits to which the subject is otherwise entitled. If

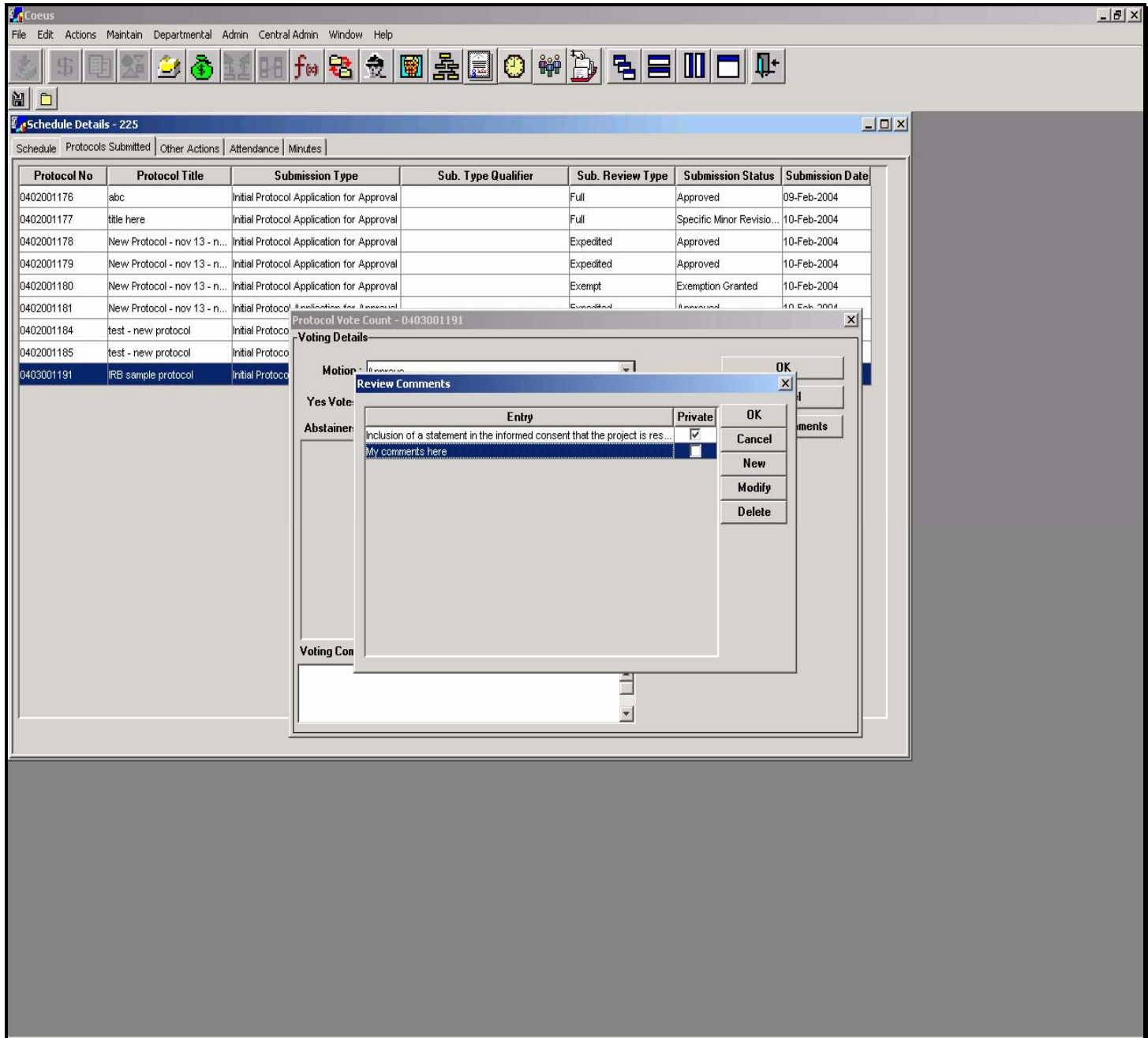
# How to Approve an Amendment or a Renewal

- When you have finished entering all of the comments click on the *Save & Close* button
- In the event that there is a comment that you would like to be shown in the minutes, but not in the approval letter, be sure to click on the *Private* box, **before** you save your entry.



# How to Approve an Amendment or a Renewal

14. The final result will look like a shopping list of review comments.
15. you notice that you will need to made a change to any of the comments simply highlight the comment that needs correction and click on the modify button
16. Once you have completed all the review comments click the *OK* button.



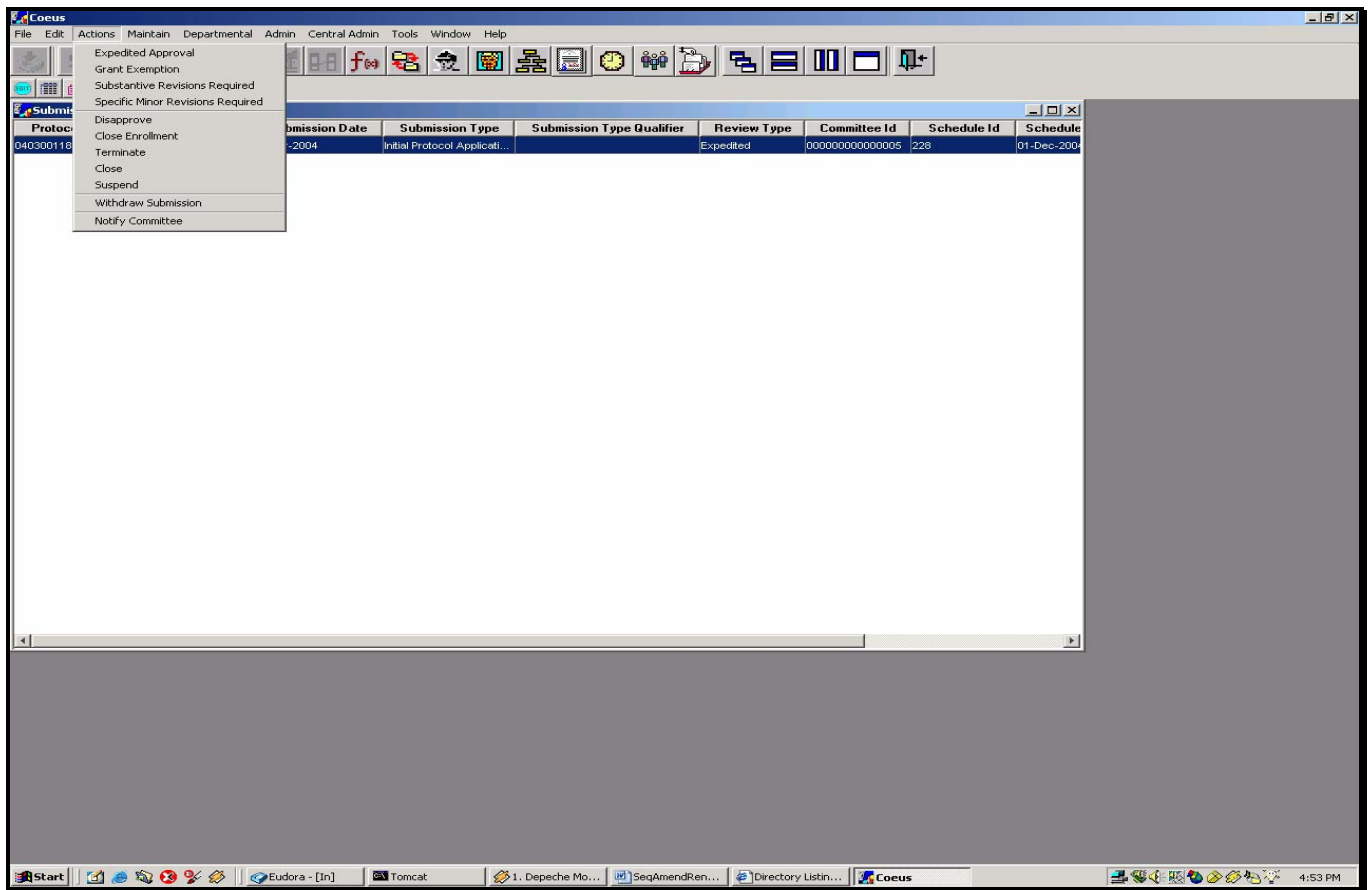
# How To Approve an Expedited/Exempt Amendment or a Renewal

\*\*It is important to note that Coeus allows for the entry of many amendments and renewals. It also allows the user to approve them out of order. For example if a protocol has 2 amendments and amendment #2 was approved before amendment #1, Coeus will allow the user to approve amendment #2 before amendment #1 has been approved. This however, can cause to be a problem as the second amendment would over ride the first; thereby blocking out the user to create any actions on the first amendment. The same will occur when there is as an amendment and a renewal that occur around the same time, and may be approved out of order.

It is that function, that makes the sequencing of approvals for both amendments and renewals very important.



1. Begin by opening the submission list screen and using the search feature to locate the protocol whose amendment or renewal requires approval.
2. When approving via Expedited or Exempt review, go to the Actions menu and select either, Grant Exemption or Expedited Approval”.



3. The remaining steps are the same as those for approving a first time protocol. (See How to Approve a Protocol.)

# How to Record for Revisions Major or Minor

**\*Please note that the attendance for the IRB meeting must be taken before any Revision requests get recorded**

1. Begin by opening the Schedule screen. This can be done by either hitting the



*Schedule* button or by going to the maintain menu and selecting Schedule.

2. In the Search window type in the date of the meeting your protocol was reviewed.
3. Once Coeus has generated the meeting date you are looking for, highlight it and



click on the *Edit* button

Schedule Id	Scheduled Date	Place	Schedule Status	Submission Deadline	Committee Id	Committee Name
	01-Sep-2004	DV-301	Scheduled	27-Aug-2004	12345	IRB
213	01-Sep-2004	NY	Scheduled	27-Aug-2004	0000000000000006	Committee 23 Sep 03
225	01-Sep-2004	NY	Scheduled	01-Sep-2004	0000000000000005	IRB

# How to Record for Revisions Major or Minor

4. Go to the Protocol Submitted tab and select the protocol you would like to modify.

The screenshot displays the Coeus software interface. The main window is titled 'Schedule Details - 225' and has several tabs: 'Schedule', 'Protocols Submitted', 'Other Actions', 'Attendance', and 'Minutes'. The 'Protocols Submitted' tab is active, showing a table with the following data:

Protocol No	Protocol Title	Submission Type	Sub. Type Qualifier	Sub. Review Type	Submission Status	Submission Date
0402001176	abc	Initial Protocol Application for Approval		Full	Approved	09-Feb-2004
0402001177	title here	Initial Protocol Application for Approval		Full	Specific Minor Revisio...	10-Feb-2004
0402001178	New Protocol - nov 13 - n...	Initial Protocol Application for Approval		Expedited	Approved	10-Feb-2004
0402001179	New Protocol - nov 13 - n...	Initial Protocol Application for Approval		Expedited	Approved	10-Feb-2004
0402001180	New Protocol - nov 13 - n...	Initial Protocol Application for Approval		Exempt	Exemption Granted	10-Feb-2004
0402001181	New Protocol - nov 13 - n...	Initial Protocol Application for Approval		Expedited	Approved	10-Feb-2004
0402001184	test - new protocol	Initial Protocol Application for Approval		Full	Approved	12-Feb-2004
0402001185	test - new protocol	Initial Protocol Application for Approval		Full	Approved	13-Feb-2004
0403001191	IRB sample protocol	Initial Protocol Application for Approval		Full	In Agenda	09-Mar-2004

# How to Record for Revisions Major or Minor

5. Go to the Action menu and select Committee Actions. This will launch the Protocol Vote Count window.

The screenshot displays the Coeus software interface. The main window is titled "Schedule Details - 225" and contains a table of protocol submissions. A modal window titled "Protocol Vote Count - 0403001191" is open over the table, showing voting details for the selected protocol.

Protocol No	Protocol Title	Submission Type	Sub. Type Qualifier	Sub. Review Type	Submission Status	Submission Date
0402001176	abc	Initial Protocol Application for Approval		Full	Approved	09-Feb-2004
0402001177	title here	Initial Protocol Application for Approval		Full	Specific Minor Revisio...	10-Feb-2004
0402001178	New Protocol - nov 13 - n...	Initial Protocol Application for Approval		Expedited	Approved	10-Feb-2004
0402001179	New Protocol - nov 13 - n...	Initial Protocol Application for Approval		Expedited	Approved	10-Feb-2004
0402001180	New Protocol - nov 13 - n...	Initial Protocol Application for Approval		Exempt	Exemption Granted	10-Feb-2004
0402001181	New Protocol - nov 13 - n...	Initial Protocol Application for Approval		Expedited	Approved	10-Feb-2004
0402001184	test - new protocol	Initial Protocol Application for Approval				
0402001185	test - new protocol	Initial Protocol Application for Approval				
0403001191	IRB sample protocol	Initial Protocol Application for Approval				

**Protocol Vote Count - 0403001191**

**Voting Details**

Motion :

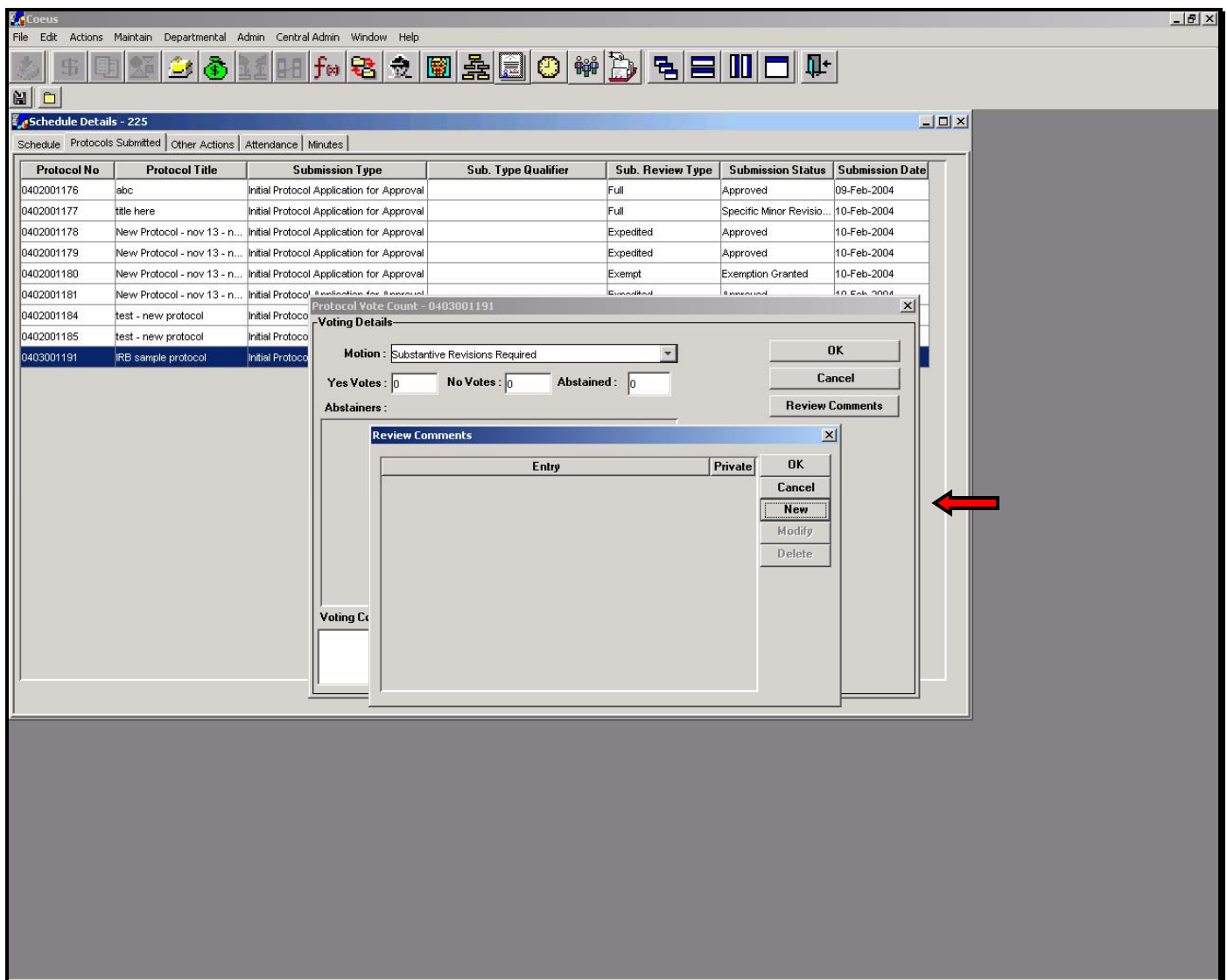
Yes Votes : Substantive Revisions Required

Abstainers : Specific Minor Revisions Required  
Disapprove

Voting Comments :

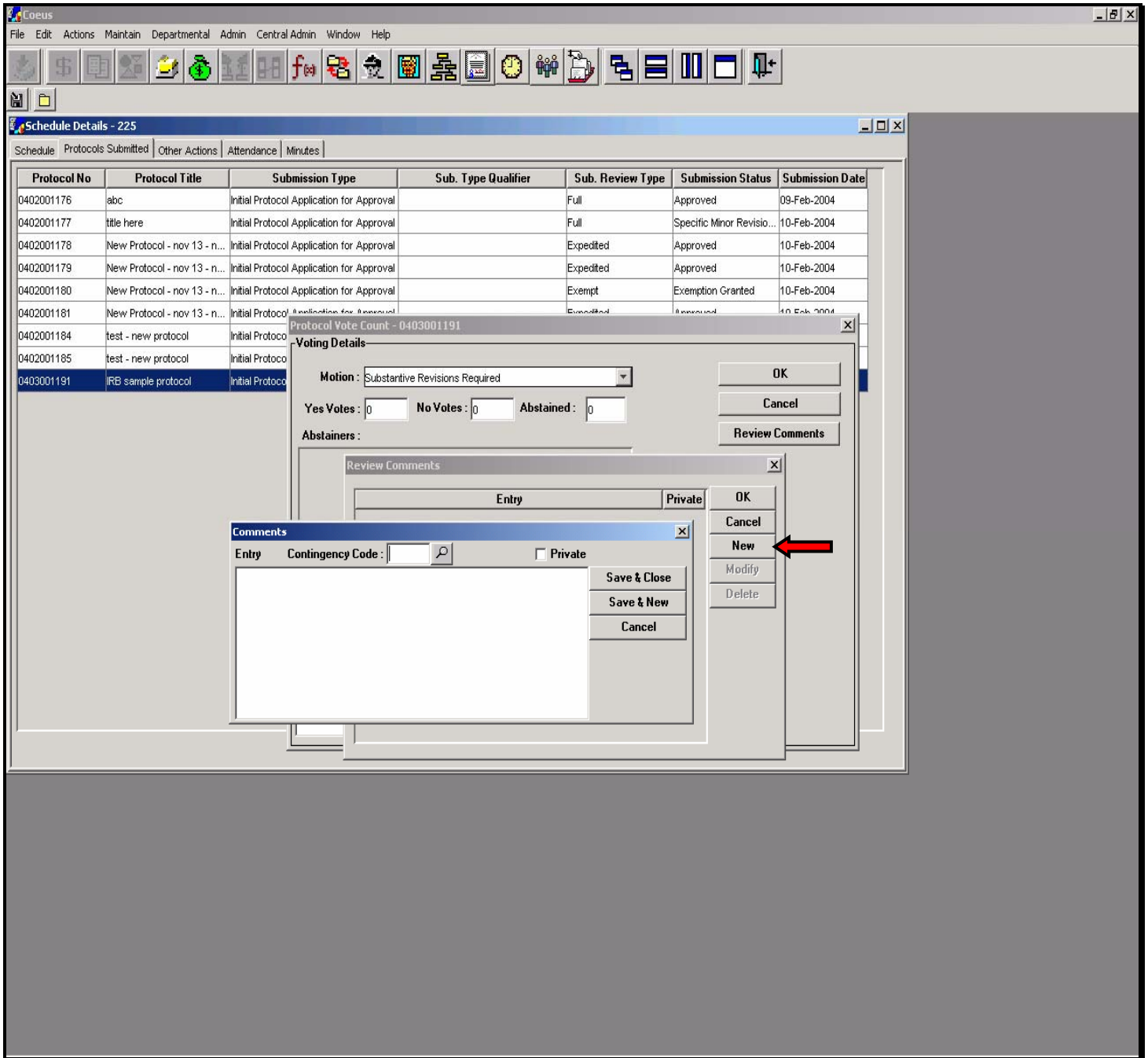
# How to Record for Revisions Major or Minor

6. For the drop down menu in the Motion field, select either Substantive Revisions Required or Specific Minor Revision Required.
7. Enter the vote count into their perspective fields.
8. If you have entered any abstained counts, click on the *Add* button to enter which IRB members have abstained from the vote.
9. Click on the *Review Comments* button; the Review Comments window will open. For each protocol the following three criteria must be included: (Please be sure to click on the “Private Box”, for the first two comments so they are not listed on the letter to the PI. Also, note that for Expedited reviews only the third comment is required)
  - a. Indication of any IRB members that have left the room during the review of that particular protocol, if any.
  - b. Summary of the discussion of the protocol.
  - c. Revisions required and explanation for each revision.




# How to Record for Revisions Major or Minor

10. Then click on the *New* button to begin entering the first review comment. This will open the Comments window.



# How to Record for Revisions Major or Minor



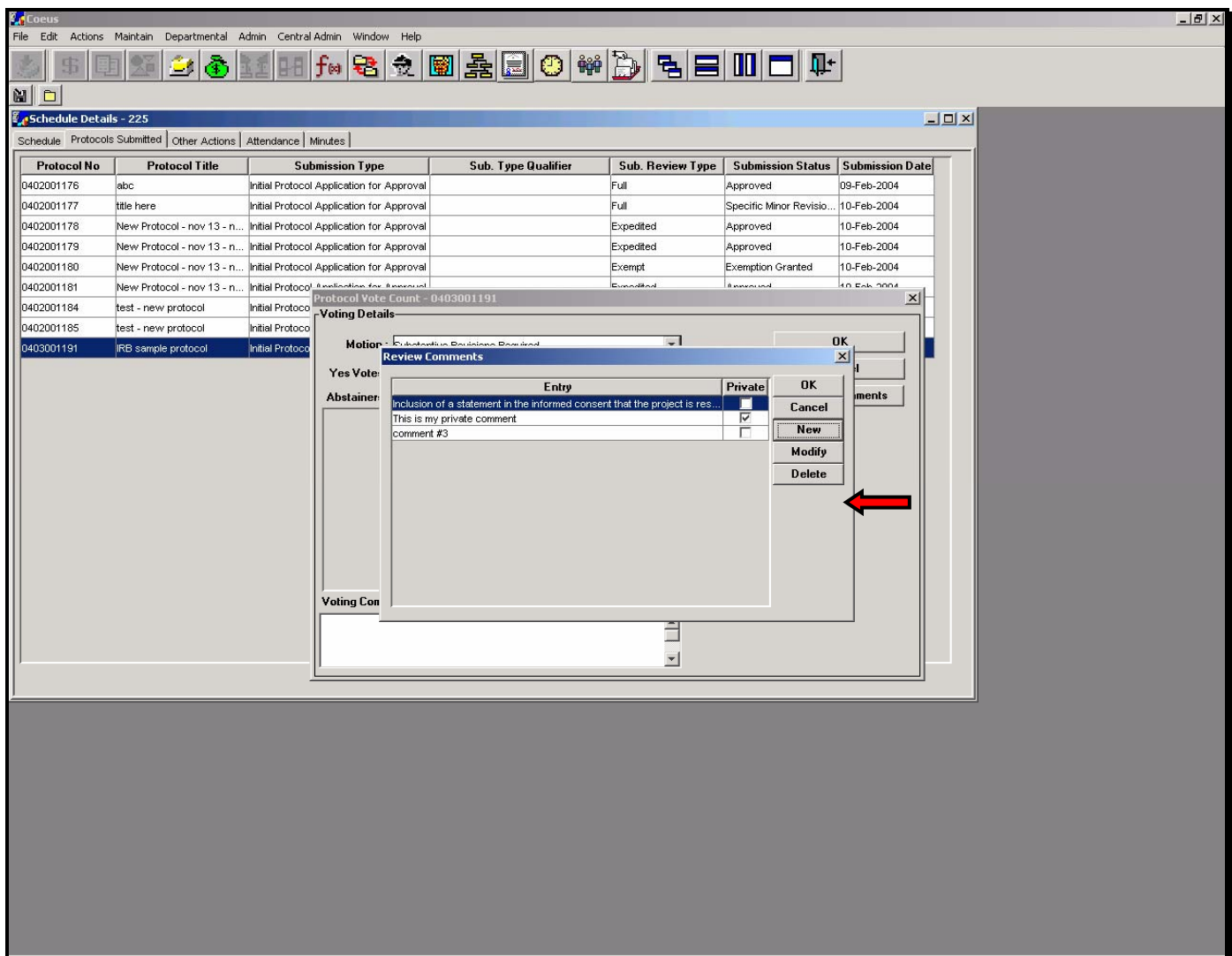
11. By the Contingency Code field, click on the search button  to select a “canned” revision request from the list.

The screenshot shows the Coeus software interface. The main window is titled "Schedule Details - 225" and contains a table with columns: Protocol No, Protocol Title, Submission Type, Sub. Type Qualifier, Sub. Review Type, Submission Status, and Submission Date. A "Comments" dialog box is open over the table, with a red arrow pointing to the search button in the "Contingency Code" field. A "Contingency LookUp" dialog box is also open, displaying a list of contingency codes and their descriptions. The "Contingency LookUp" dialog box has the following data:

Code	Description
1	Inclusion of a statement in the informed consent that the project is research and an explanation of the scope, aims and purposes of the research. This statement should include a description of the pro
2	Inclusion of a statement in the informed consent regarding the expected amount of time for the subject's participation
3	Inclusion of a statement in the informed consent regarding the availability of compensation and/or medical treatment if injury occurs.
4	Inclusion of a statement in the informed consent describing the extent to which confidentiality of records identifying the subject will be maintained or if subjects will be anonymous.
5	Inclusion of a statement in the informed consent that participation is voluntary and that nonparticipation will not result in penalty of loss of benefits to which the subject is otherwise entitled. If

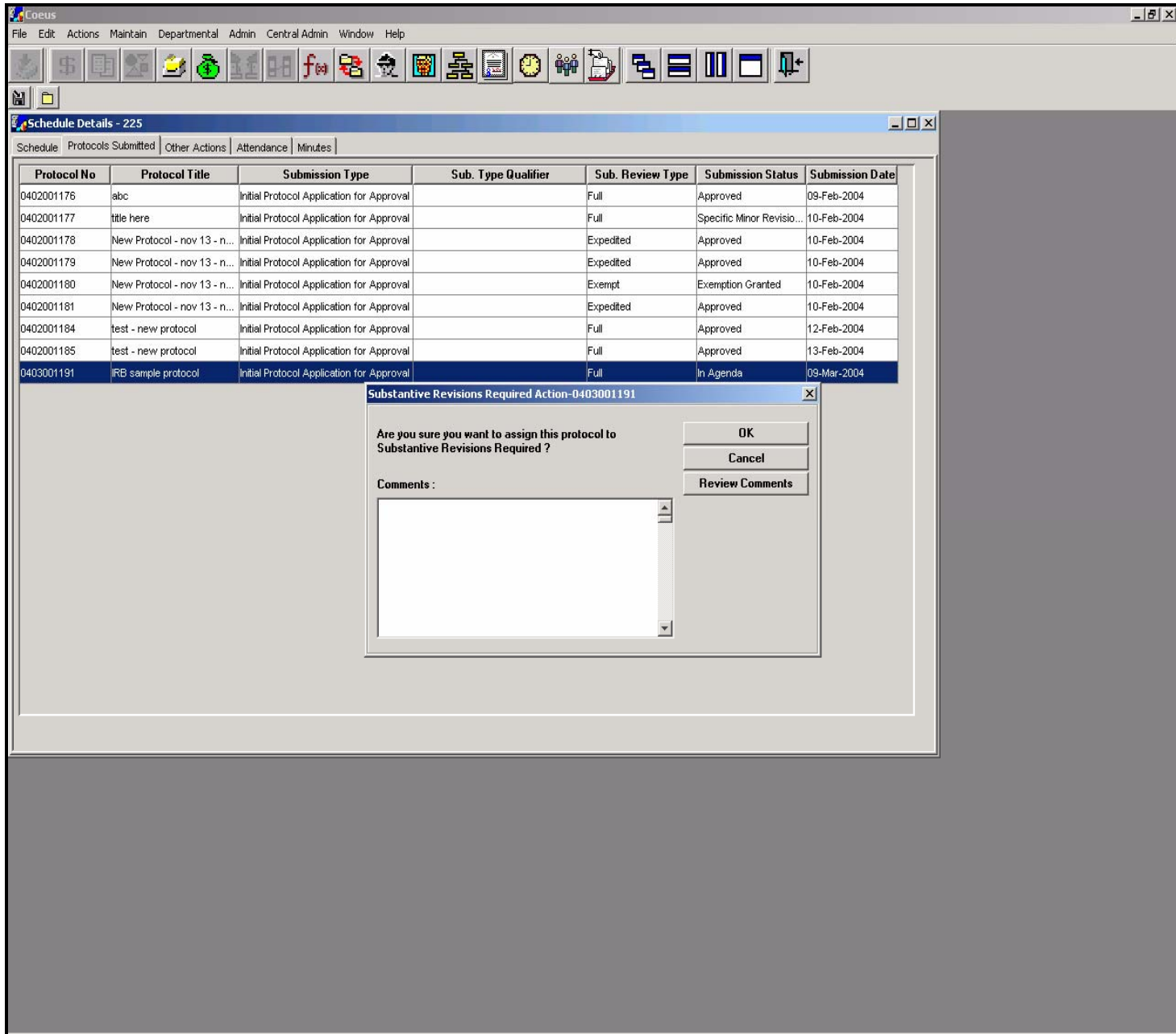
# How to Record for Revisions Major or Minor

12. Highlight your selection and click on the *OK* button. This will automatically place the text into the Comments window for you.
13. If your entry is not listed, click on the Cancel button and “free type” the revision right into the Entry window.
14. In the event that you have a comment that should be listed on the minutes, but not in the letter to the PI, be sure to click on the *Private* box **before** you save your entry.
15. To add more revisions click on the *Save & New* button. This will save the initial entry and display an empty comments window for the next.
16. Once you have entered your last revision request, click on the *Save and Close* button. You will then see all of your entries in the Review Comments Window.
17. To make changes to a comment, highlight the comment and click on the *Modify* button. This will open the comments window directly to that particular entry changes can be made from there.



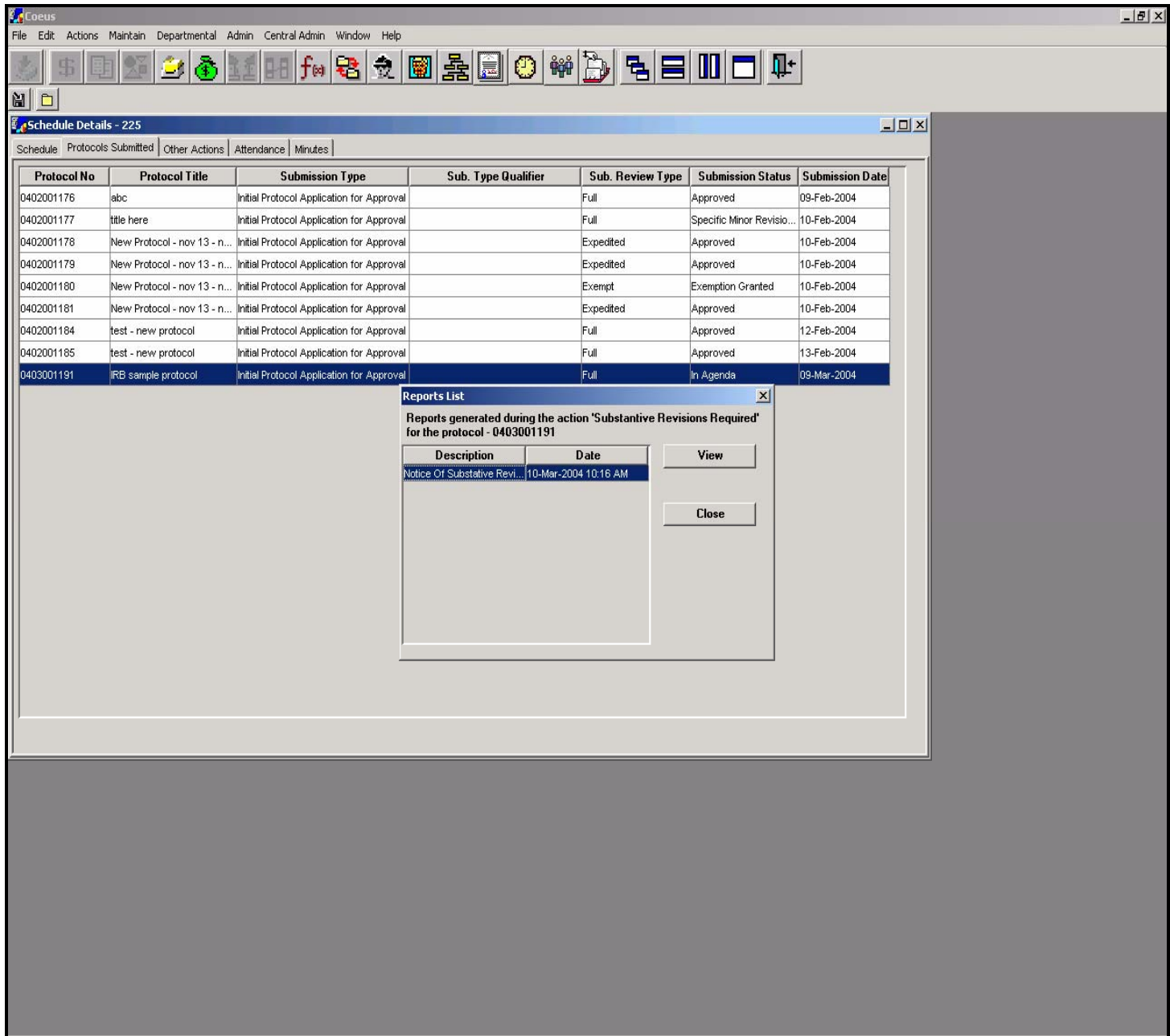
# How to Record for Revisions Major or Minor

18. Once you are fully finished entering all of the revision requests, click on the *OK* button on the Review Comments window, and then click *OK* on the Vote Count window. Coeus will then launch the following window to verify that this is the status you would like to assign to that protocol:



# How to Record for Revisions Major or Minor

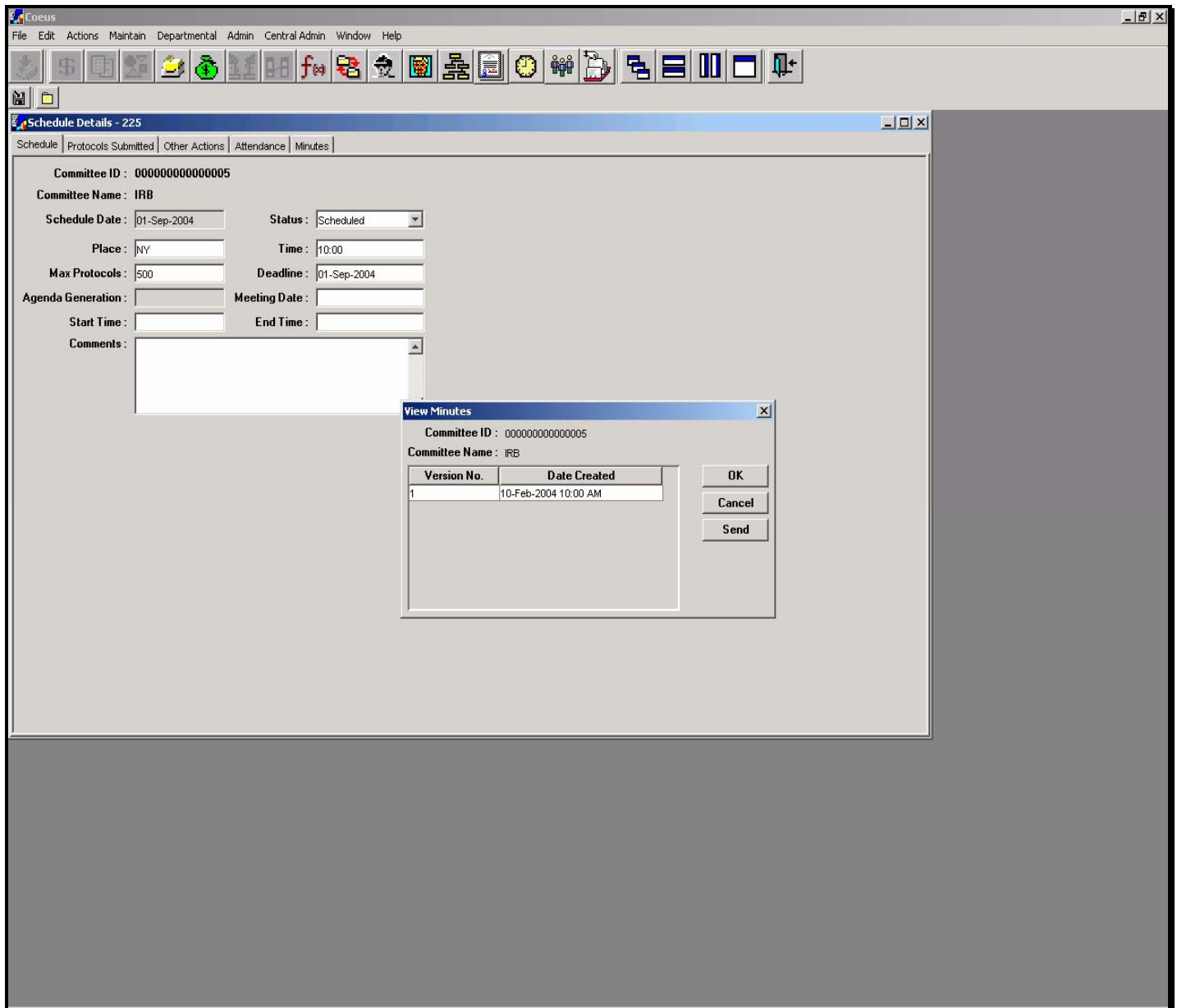
19. This window will provide you with another chance to add or modify the Review Comments. You can do this by clicking on the *Review Comments* button. Also, in the comments box enter any note that you would like to make for that particular protocol. When done, click on the *OK* button.
20. Coeus will then notify you that the “report” has been generated. Report in this case means that the letter has been generated. Click on the view button and Coeus will then, in a separate window, launch Adobe Reader where you can view and print the letter.



# How to Bring Back Minutes



1. From in the Schedule screen, click on the *Search* button and in the Schedule Date column type in the date of the meeting whose minutes you need.
2. Once Coeus has brought up that meeting date double click on it.
3. When the window opens, go to the Edit menu and select View minutes.
4. Coeus will open the View Minutes window. Notice that there are two columns, one entitled “Version No.” and the other “Date Created”. The Version No. list the number of time the Minutes document has been modified and regenerated. Coeus will list the most recent version on at the bottom of the list.
5. Highlight the version desired and click on the *OK* button.
6. Coeus will launch the Minutes in a separate window.



# Rolodex Screen Details

## Rolodex Window:

Field Name	Field Description	Field Notes:
Rolodex ID	Unique identifier	Auto generated
Last Update	Date stamp	Auto generated
Update User	Lists user that last modified record	Auto generated
Last Name	Self Explanatory	
First Name	Self Explanatory	
Middle Name	Self Explanatory	
Suffix	Self Explanatory	
Prefix	Self Explanatory	
Title	Self Explanatory	
Sponsor	Self Explanatory	
Organization	Name of the organization this contact works for	
Address	Self Explanatory	
City	Self Explanatory	
County	Self Explanatory	
Postal Code	Self Explanatory	
Country	Self Explanatory	
Email	Self Explanatory	
Phone	Self Explanatory	
Fax	Self Explanatory	
Comments	Self Explanatory	

# How to Add a Record to the Rolodex

1. Open the *Rolodex* screen. You can do this either by hitting the rolodex button



or by going to the *Maintain* menu and selecting *Rolodex*

2. Cancel out of the search window, when the screen opens.



3. Hit the *Add* button and begin to enter the contact information for the person you are adding into the rolodex.

The screenshot shows the 'Add New Rolodex' dialog box within the Coeus application. The dialog has the following fields and values:

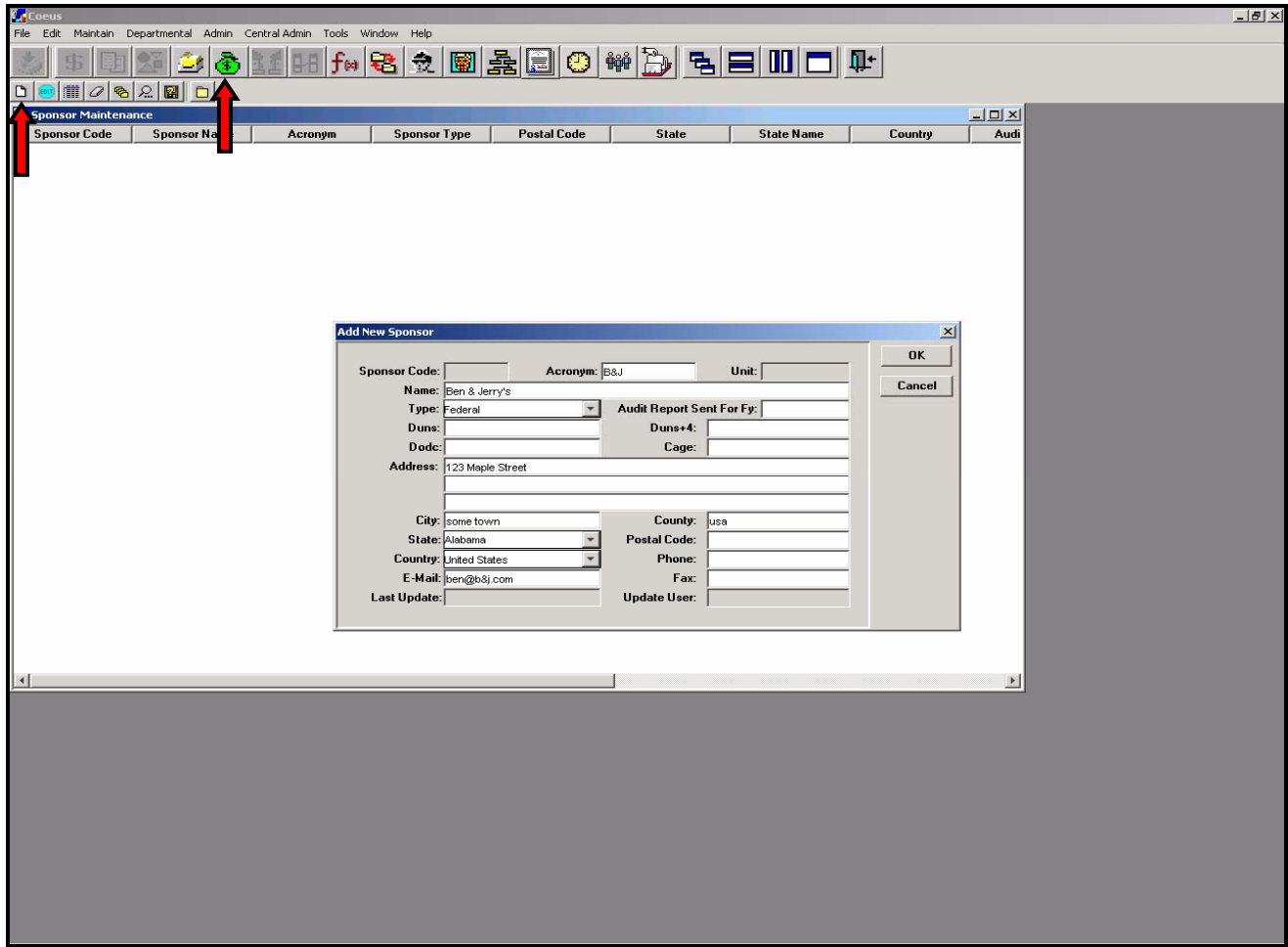
Field	Value
Rolodex Id	
Last Update	
Update User	
Last	Vador
First	Darth
Middle	A
Suffix	
Prefix	
Title	Lord
Sponsor	
Organization	The Empire
Address	Death Star
City	Galaxy Far Far Away
County	Universe
State	
Postal Code	
Country	United States
Phone	
Fax	
E Mail	jordvador@deathstar.com
Comments	Never under estimate the power of the dark side!



# Sponsor Screen Details

## Sponsor Window:

Field Name	Field Description	Field Notes:
Sponsor Code	Unique identifier for a particular sponsor	User creates the number
Acronym	Self Explanatory	
Name	Sponsor name	
Type	Drop down	
Audit Report for Fiscal Yr	Lists year of last audit report	
Duns	Self Explanatory	
Duns+4		
Dodc		
Cage		
Address	Self Explanatory	
City	Self Explanatory	
County	Self Explanatory	
State	Self Explanatory	
Postal Code	Self Explanatory	
Country	Self Explanatory	
Phone	Self Explanatory	
Email	Self Explanatory	
Fax	Self Explanatory	
Last Update	Date Stamp for that last modification	
Last User	List User who last modified the record	

# Creating A Sponsor



1. Begin by clicking on the *Maintain Sponsor* button or  by going to the Edit menu and selecting Sponsor.
2. Cancel out of the search window when it pops open
3. Click on the *Add* button  or go to the Edit menu and select Add
4. When the window opens begin by entering a "Sponsor Code". The Sponsor Code is a six character unique identifier.
5. Then Enter the Acronym for the name of the sponsor
6. Enter the name of the sponsor
7. From the Type field select the type of institution the sponsor is from the drop down list
8. Enter the DUNS information if known. As this is not a required field the user can skip directly to the Address field.
9. Complete the remaining contact information fields for the Sponsor.

# Organization Screen Details

## Name & Address Tab:

Organization ID	Unique Identifier: Must be 6 digits	Coeus auto-generates the number for the user
Organization Name <b>(Required)</b>	Self Explanatory	
Contact Address <b>(Required)</b>	Self Explanatory	Created in the Roldex and auto generated in Organization screen
Address <b>(Required)</b>	Self Explanatory	
Cable Address		Fill-in if known
Telex Number		Fill-in if known
County		Fill-in if known
Congressional Number		Fill-in if known

## Organization – 2 Tab:

Field Name	Field Description	Field Notes:
Incorporated In		Fill-in if known
Incorporated Date		Fill-in if known
Number of Employees		Fill-in if known
IRS Exemption number		Fill-in if known
Federal Employer		Fill-in if known
Mass Tax Exemption Number		Fill-in if known
Agency		Fill-in if known
Com Gov. Entity Code		Fill-in if known
Vendor		Fill-in if known
Mass Employee Claim		Fill-in if known
Duns		Fill-in if known
Duns +4		Fill-in if known
Dodac		Fill-in if known
Cage		Fill-in if known

# Organization Screen Details

## Organization – 3 Tab:

Human Sub Assurance		Fill-in if known
Animal Welfare Assurance		Fill-in if known
Science Misconduct Comp Date		Fill-in if known
PHS Account		Fill-in if known
NSA Institutional Code		Fill-in if known
Indirect Cost Rate Agreement		Fill-in if known
Cognizant Auditor		Fill-in if known
ONR Resident Rep		Fill-in if known

## Type

Type	A number that is created by Coeus to list organization type	Auto-generated by Coeus
Description	Summary of the kind of organization being listed	For example, Non-Profit or Federal.

## Question

Not used.		Disabled function that WMC IRB office deos not use

## Audit

Fiscal Year	Self Explanatory	Fill-in if known
Audit Accepted	Drop down list of various audit statuses	Fill-in if known
Comment	Free text field where users can make notes on an audit	Fill-in if known

# Organization Screen Details

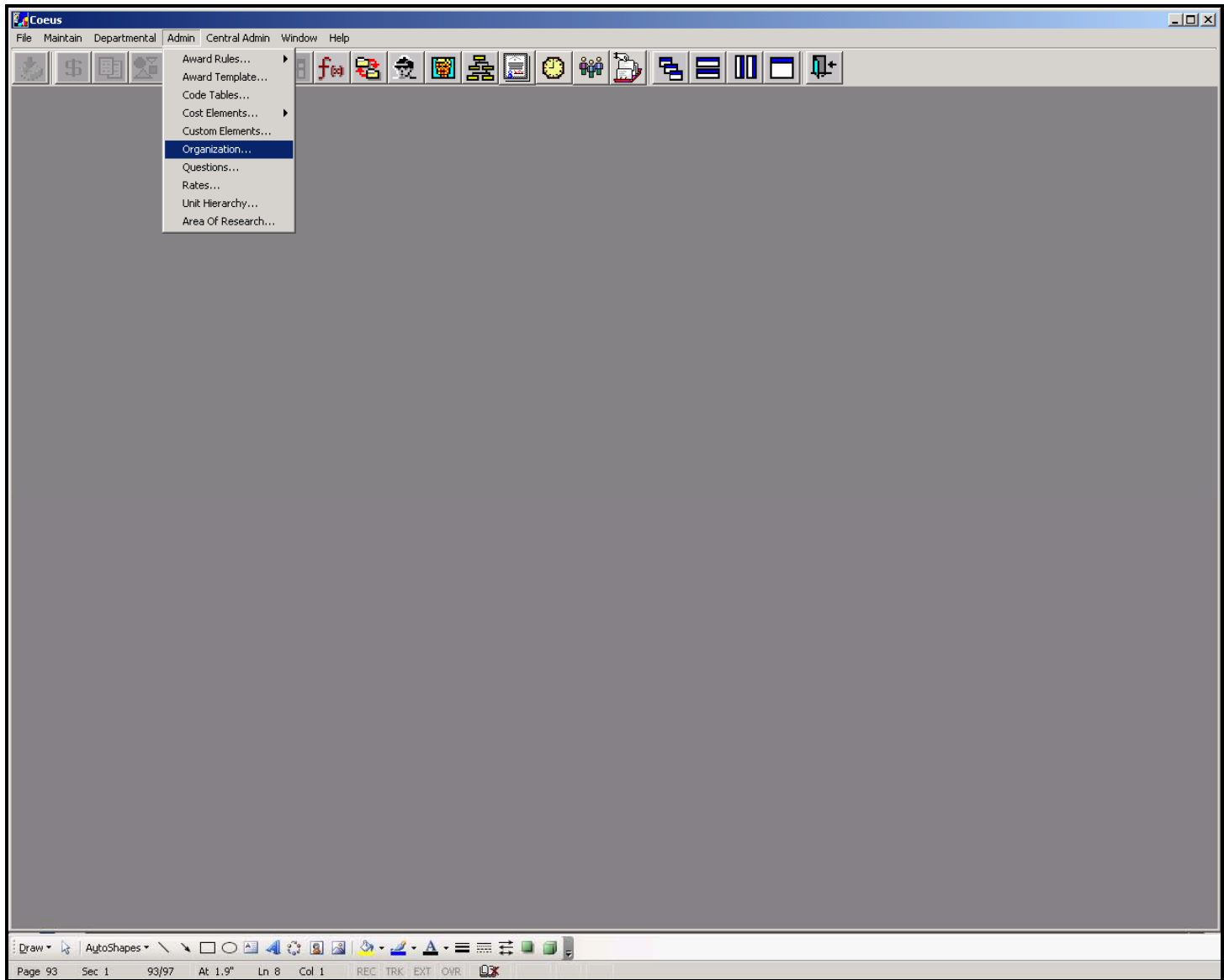
## IDC

Rate	Self Explanatory	Fill-in if known
Type	Drop down list of the various kinds of IDC rates	Fill-in if known
Start Date	Self Explanatory	Fill-in if known
End Date	Self Explanatory	Fill-in if known
Requested Date	Self Explanatory	Fill-in if known
Comments	Free text field where users can create notes for the IDC rate	Fill-in if needed

# Adding a New Organization to a Protocol

\* Please note that in order to create a new organization the contact information for that organization must be entered in the Rolodex

1. Begin by going to the *Amin* menu and then selecting Organization from the list.



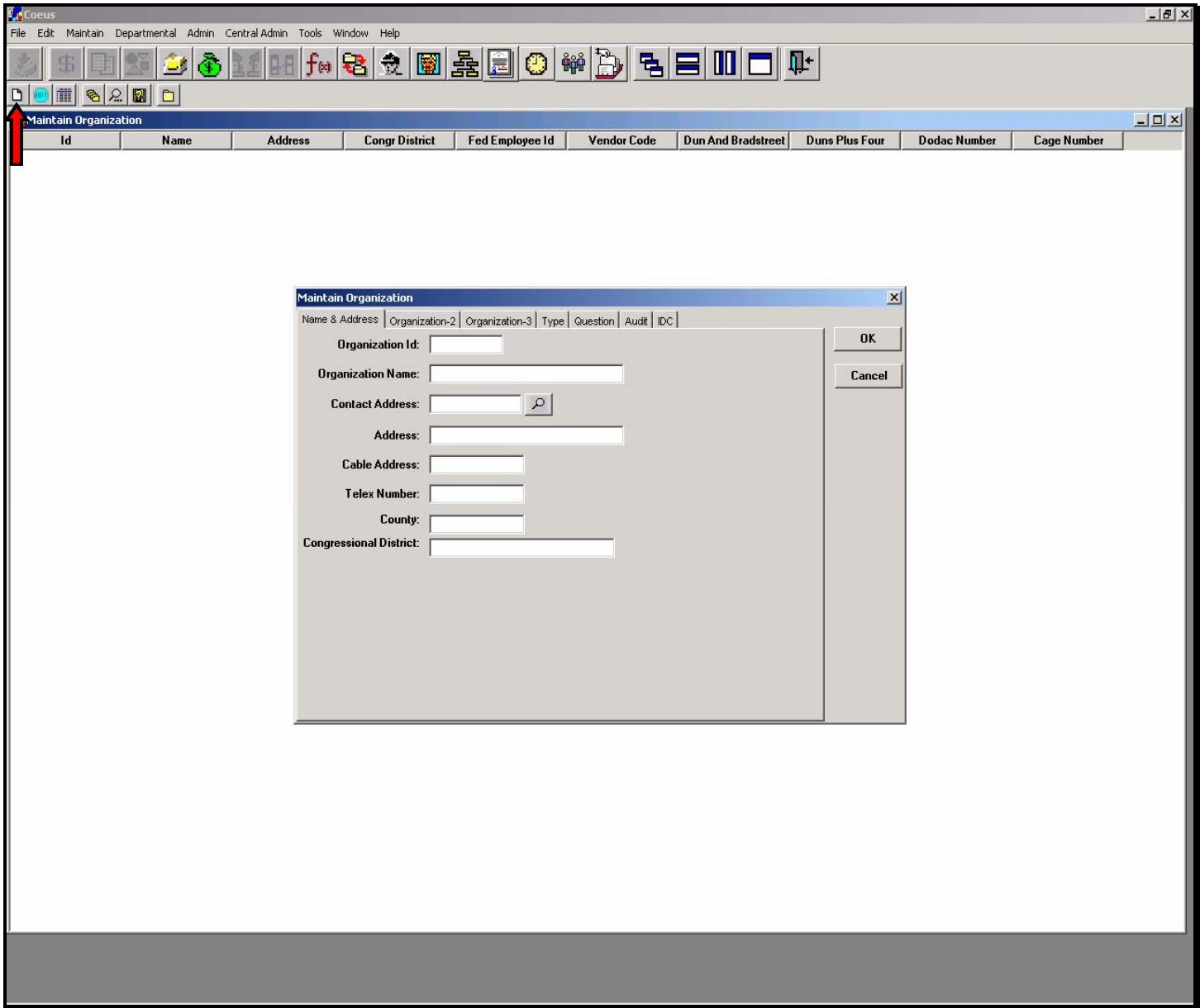
# Adding a New Organization to a Protocol

2. This action will launch the Organization window. Hit cancel in the search




window and then click on the *Add* button.

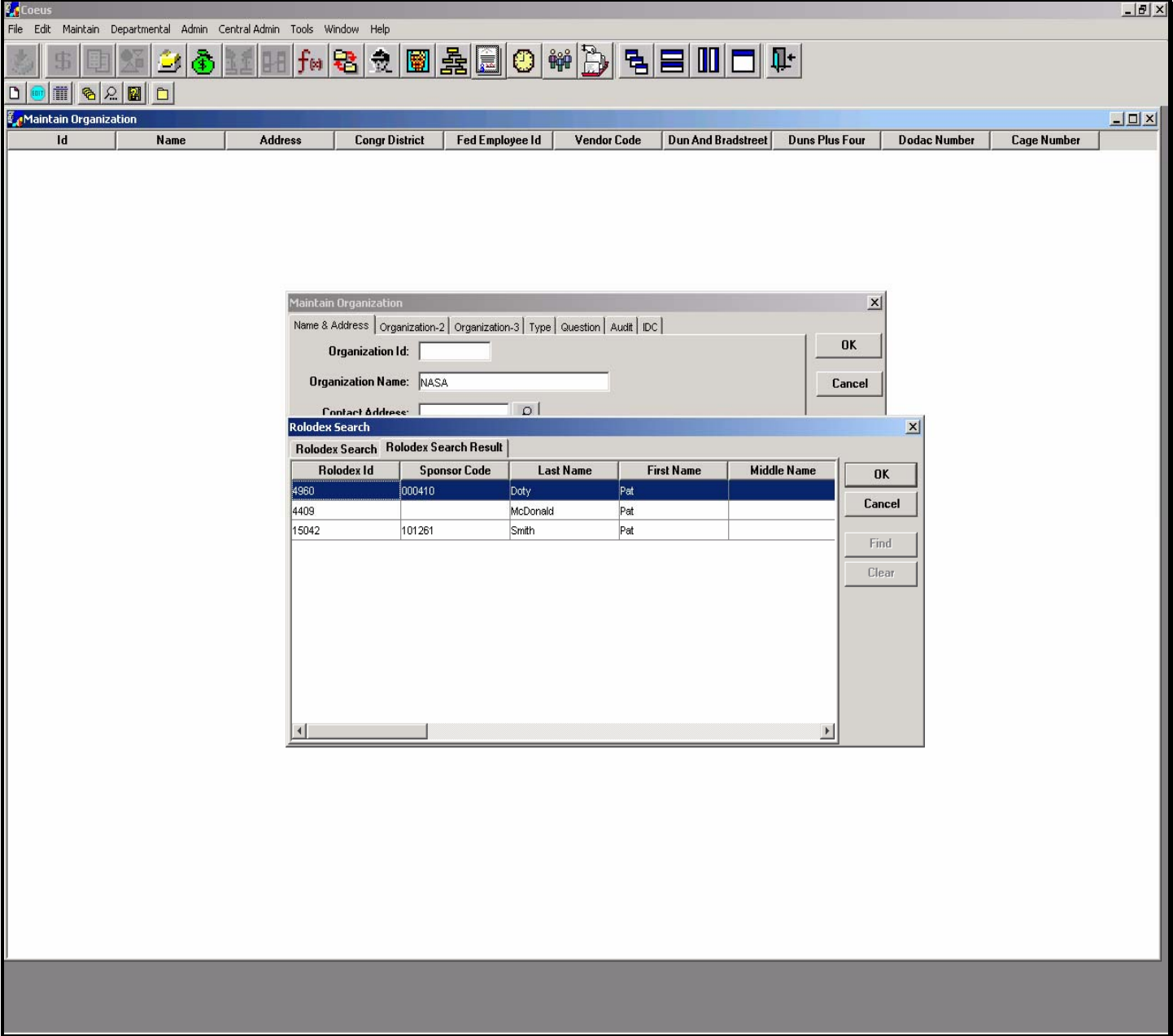
3. Begin by entering the name of the organization.



# Adding a New Organization to a Protocol

4. To retrieve the information for the contact person at this organization click on the

Search button .



The screenshot displays the Coeus software interface. The main window is titled 'Maintain Organization' and features a menu bar (File, Edit, Maintain, Departmental, Admin, Central Admin, Tools, Window, Help) and a toolbar with various icons. Below the toolbar is a table with columns: Id, Name, Address, Congr District, Fed Employee Id, Vendor Code, Dun And Bradstreet, Duns Plus Four, Dodac Number, and Cage Number. The table is currently empty.

Overlaid on the main window are two dialog boxes:

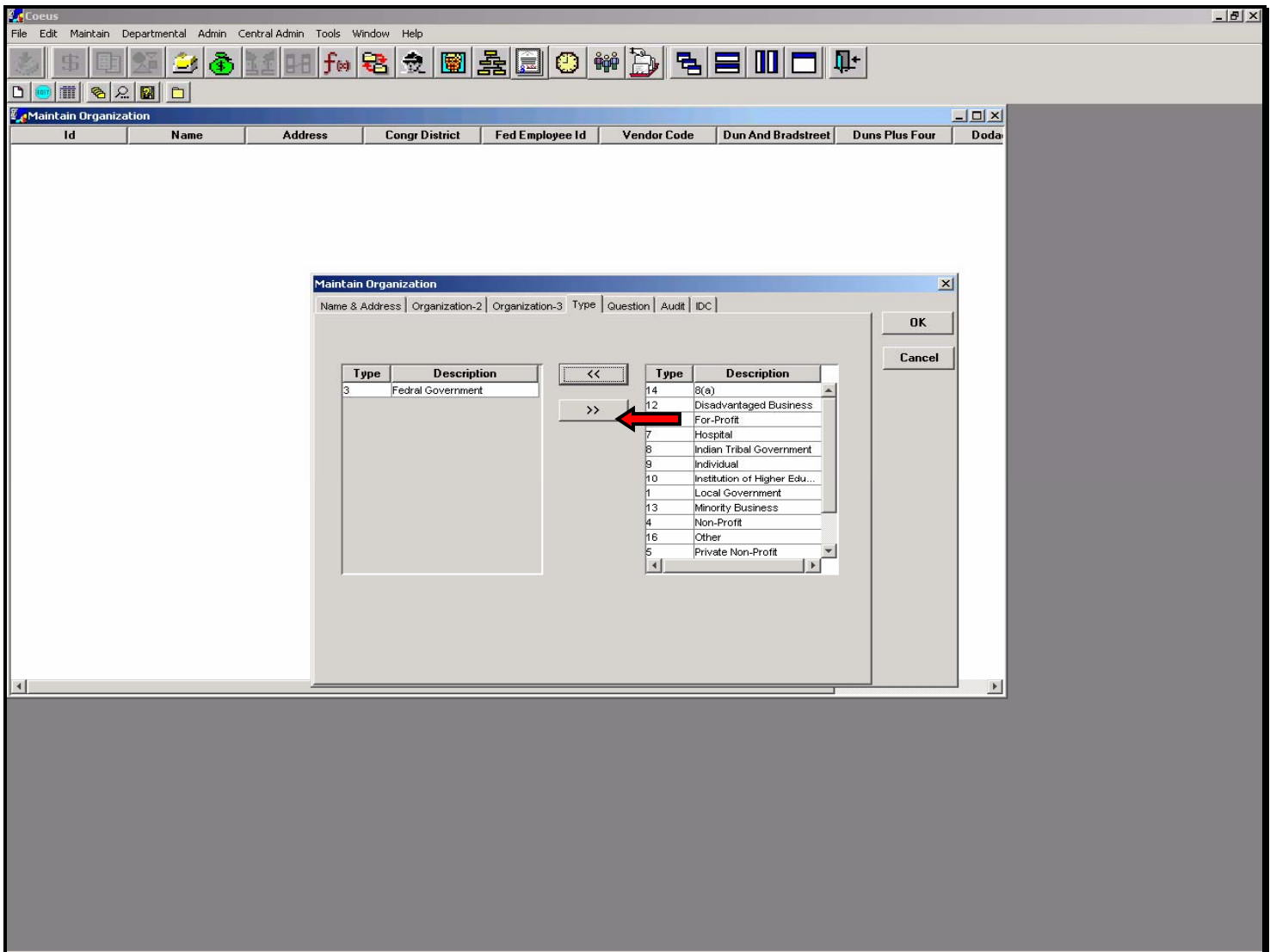
- Maintain Organization (Dialog):** This dialog has tabs for 'Name & Address', 'Organization-2', 'Organization-3', 'Type', 'Question', 'Audit', and 'IDC'. The 'Name & Address' tab is active. It contains input fields for 'Organization Id', 'Organization Name' (with 'NASA' entered), and 'Contact Address'. There are 'OK' and 'Cancel' buttons.
- Rolodex Search (Dialog):** This dialog has tabs for 'Rolodex Search' and 'Rolodex Search Result'. The 'Rolodex Search Result' tab is active, displaying a table with the following data:

Rolodex Id	Sponsor Code	Last Name	First Name	Middle Name
4960	000410	Doty	Pat	
4409		McDonald	Pat	
15042	101261	Smith	Pat	

There are 'OK', 'Cancel', 'Find', and 'Clear' buttons on the right side of the dialog.

# Adding a New Organization to a Protocol

5. Coeus will ask you for the address in this window twice. This is because, on occasion, the contact person at the organization has a different address than the main address of the organization.
6. The remainder of the fields should only be completed if the information is know.
7. Then go to the Type tab, and from the right hand side of the window highlight the type of organization you need.
8. Then click on the left arrow button and Coeus will plug your selection on the left hand side of the screen.



9. It is not mandatory to complete the remainder of the tabs. However, if the information is know please enter it. It is always best to enter as much information as possible.

# Creating Reminder Letters

\* It is important that all IRB Notifications and renewal entries have been entered into the system before batch jobs are run. Otherwise, the job will encompass those records that require updates, unnecessarily. Reminder letters are default to generate on a period of 60 days. In the case of Renewal reminders, the letters will generate 60 days prior to the expiration date. With regards to revision reminders, the letters are generated 60 days from the last review date.



1. Begin by hitting the *Committee* button or by clicking on the Maintain menu and selecting Committee. This will launch the Committee Screen

2. Highlight the Committee that you would like to start with first.



3. Click on the *Edit* button, this will open the Committee Details window.

4. Go to the Edit Menu and select Batch Correspondence.

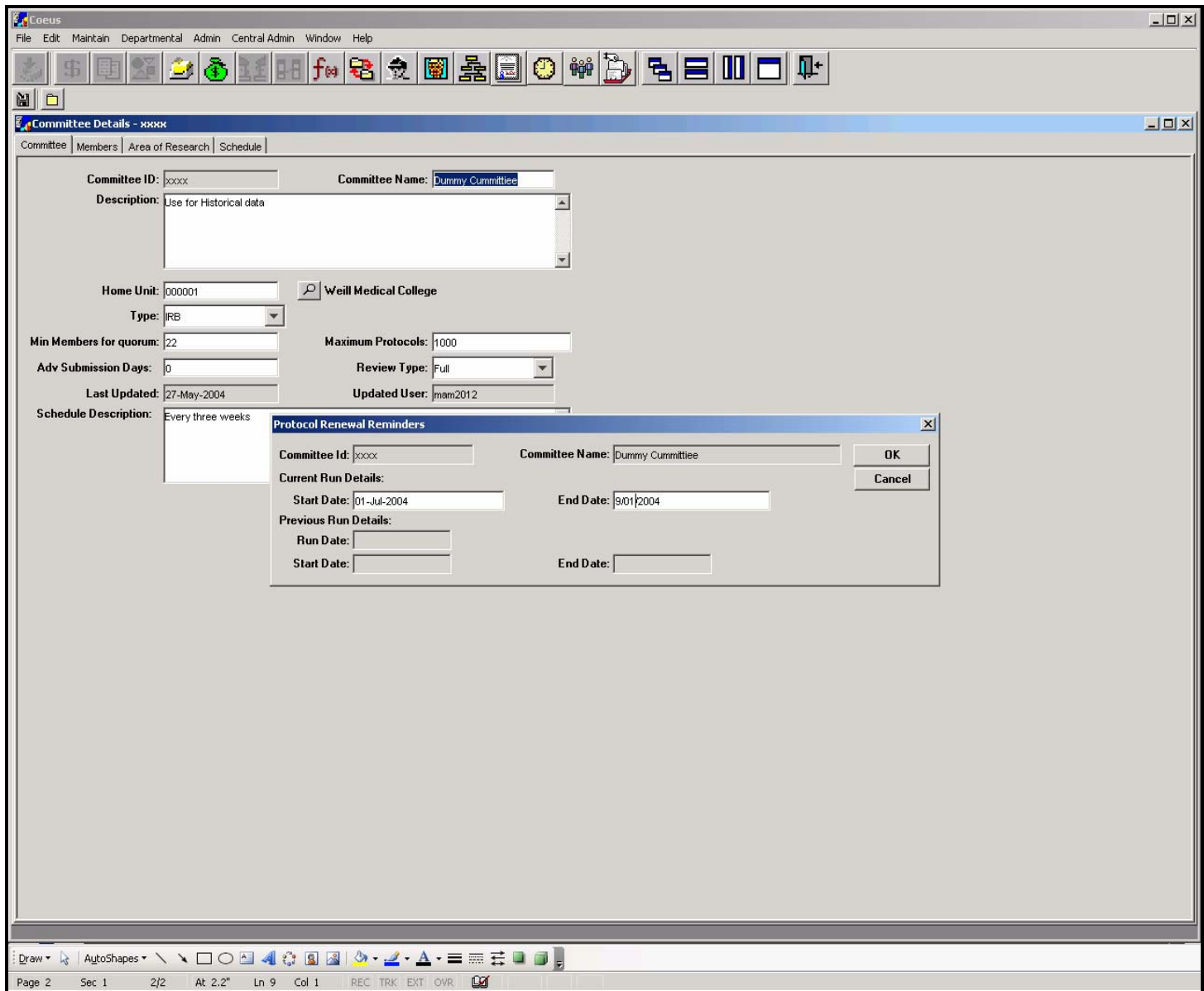
The screenshot shows the Coeus software interface. The top menu bar includes File, Edit, Maintain, Departmental, Admin, Central Admin, Window, and Help. A dropdown menu is open under 'Maintain', showing options: Generate Correspondence, Batch Correspondence (highlighted), Renewal Reminder, IRB Notification Reminder, and Batch History. The main window is titled 'Committee Details - xxxx' and has tabs for Committee, Members, Area of Research, and Schedule. The 'Committee' tab is active, showing the following details:

- Committee ID: xxxxx
- Committee Name: Dummy Committee
- Description: Use for Historical data
- Home Unit: 000001 Weill Medical College
- Type: IRB
- Min Members for quorum: 22
- Maximum Protocols: 1000
- Adv Submission Days: 0
- Review Type: Full
- Last Updated: 27-May-2004
- Updated User: mam2012
- Schedule Description: Every three weeks

The bottom status bar shows: Page 1, Sec 1, 1/1, At 3.6", Ln 11, Col 1, REC TRK EXT OVR.

# Creating Reminder Letters

5. To generate the Renewal reminder letters click on the Renewal Reminder selection, for reminders on an IRB Notification select IRB Notification Reminder. This will launch the appropriate “Reminders” window.
6. Coeus will auto-enter the Start and End dates for you. For example, if you run a batch on July 1, 2004 the Start Date you would enter is 07/01/2004 and the End Date would be 09/01/2004. Dates can be changed manually at any time. (Please note that this will be a once a month process.)



# Creating Reminder Letters

7. The system will then confirm that you want to generate the reminders. Click the *Yes* button.
8. Coeus will then launch all the reminder letters in a single separate window. Each reminder letter will be listed as a separate PDF file.