

Committee on Clinical Investigations (CCI)

**Protocol  
Application &  
Tracking  
System**

**Researcher Handbook**

[Last Updated: 12/9/08]

Frequently Asked Questions:

[www.aecom.yu.edu/cci/page.aspx?ID=9706](http://www.aecom.yu.edu/cci/page.aspx?ID=9706)

For questions about PATS, technical difficulties, or

to report bugs, please contact Hegulka Scheiman at: 718-430-2776 or  
[hscheima@aecom.yu.edu](mailto:hscheima@aecom.yu.edu).

For questions about CCI policies and procedures, please call the CCI  
office at: 718-430-2237.

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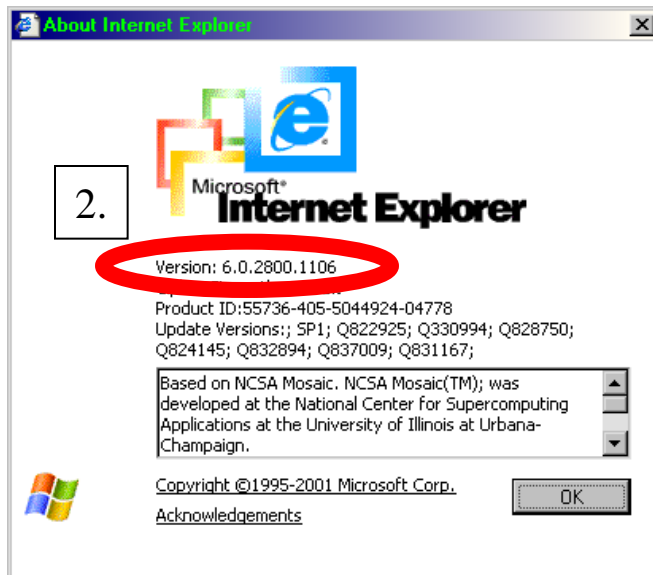
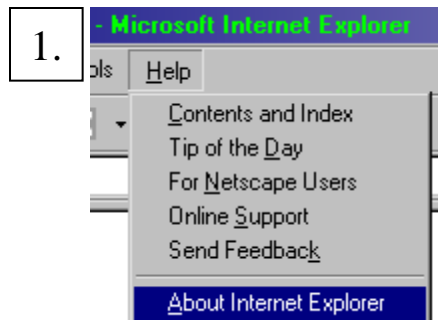
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# Required System Settings

- PATS requires Internet Explorer 6.0 or 7.0.
- To check the version of IE on your computer, open IE.

1. Click on “Help | About Internet Explorer.”
2. Check the version in the window that opens.

- To download IE 6.0, visit <http://www.microsoft.com/windows/ie>



## 3. Headers and Footers

NOTE: The settings below are only required if:

- a. Your research involves written consent.

AND

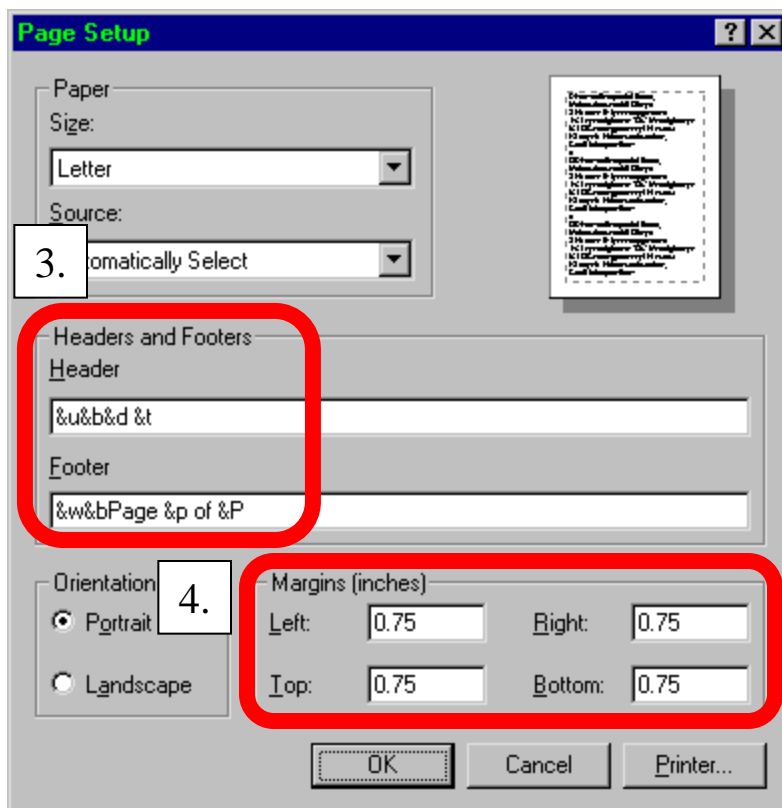
- b. You need to enter specific text in the footer of the Informed Consent Document(s).

Settings:

- Click on “File | Page Setup” to access the header/footer settings.
- The “&w” code represents the Window Title. To have this print as the footer, change the settings in your browser to reflect those at the right.

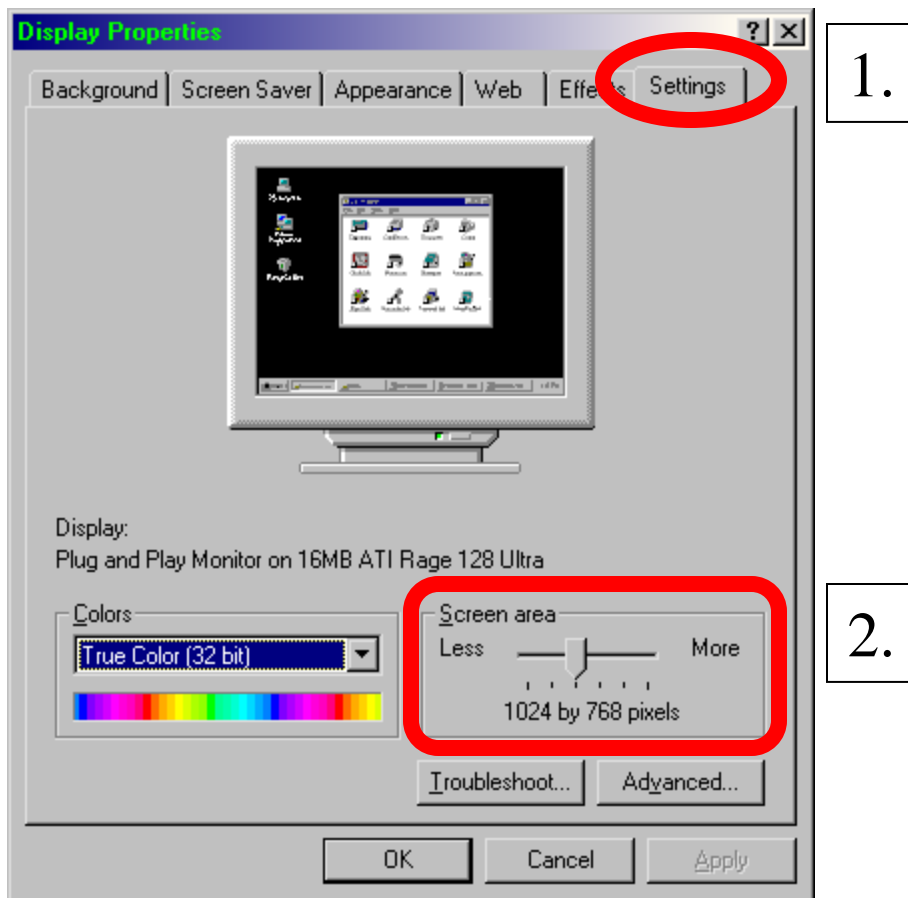
## 4. Margins

In order to ensure consistency, set your margins to 0.75 inches on all sides (Left, Right, Top, and Bottom).



# Recommended System Settings

- The recommended screen resolution is 1024 x 768. To check/modify your settings:
  - Click on “Start | Settings | Control Panel.”
  - Open “Display.”
    1. Click on the “Settings” tab.
    2. In the “Screen area” section, choose 1024 by 768 pixels.



**Spell Checking** is available in PATS. However, you need to download a free third-party program, called **ieSpell**, that will allow you to spell check all of the PATS forms (NOW INCLUDING ICDs). It is available for download at: <http://www.iespell.com/download.php>

# Introduction to PATS!

## Forgot Your Password?

If you forget your password, click the “here” link [1]. Upon providing PATS with your username, a temporary password will be emailed to your email address on file with the CCI.

https://door.adm.yu.edu/pats/ - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Refresh Print Mail Stop abc Select

Address https://door.adm.yu.edu/pats/ Go Links Convert Select

**EINSTEIN** Science at the heart of medicine  
Albert Einstein College of Medicine  
OF YESHIVA UNIVERSITY

**Welcome To PATS**  
Protocol Application & Tracking System

**CCI System Login**

Username:

Password:

Login

[Forgot your Password? Click here.](#)

**Note:**  
Only real (live) protocol data should be entered here - not testing/training data!  
If you have any questions, please contact Hegulka Scheiman at (718) 430-2776.

1.

http://webdev.misdevelop.aecom.yu.edu/cci/ccilogin.asp - Microsoft Internet ...

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Refresh Print Mail Stop

Address http://webdev.misdevelop.aecom.yu.edu/cci/ccilo Go Links Convert Select

**EINSTEIN** Science at the heart of medicine  
Albert Einstein College of Medicine  
OF YESHIVA UNIVERSITY

**Test System**

**CCI System Login**

UserName:

Password:

Login

[Forgot your Password? Click here.](#)

**Test System**

**Production Server (for real protocols):**

*https://door.adm.yu.edu/pats/*

NOTE: The production server URL begins with https.

**Test Server (for training and practicing):**

*http://misdev.aecom.yu.edu/cci/ccilogin.asp*

# Navigation: CCI System Menu

**SYSTEM MENU**

**Forms:**

- [Exempt Applications](#)
- [Full/Expedited Applications](#)
- [Amendments](#)
- [Internal Adverse Events](#)
- [External Adverse Events](#)
- [Group Adverse Events](#)
- [Progress Reports](#)

**Functions:**

- [Print Approval Letters](#)
- [Change Contact Information](#)
- [Delegate Assignment](#)
- [Report a Bug/Ask a Question](#)
- [Logout](#)

**SYSTEM MENU**

**Forms:**

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- [Group Adverse Events](#)
- [Progress Reports](#)

**Functions:**

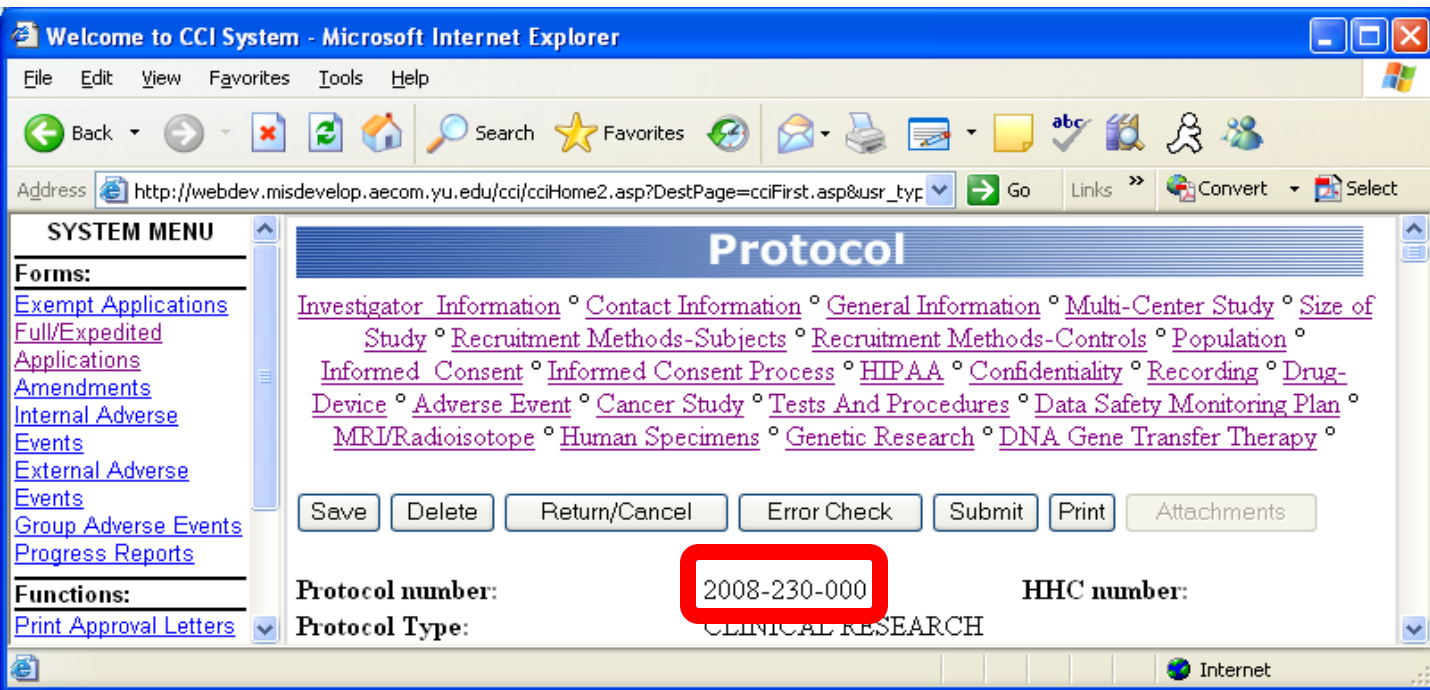
- [Print Approval Letters](#)
- [Change Contact Information](#)
- [Delegate Assignment](#)
- [Report a Bug/Ask a Question](#)
- [Logout](#)

*Upon successfully logging in, users are presented with a menu (left frame).*

## CCI System Menu:

- Exempt Application:** Create, Edit Print New Applications for Exempt Research.
- Full/Expedited Applications:** Create, Edit, Print New Applications for Full or Expedited Review. Print ICDs (Pending, Approved, and Expired).
- Amendments:** Create, Edit, Print Amendments.
- Internal Adverse Events:** Create, Edit, Print Internal AEs.
- External Adverse Events:** Create, Edit, Print External AEs.
- Group Adverse Events:** Create, Edit, Print Groups of External AEs.
- Progress Reports:** Create, Edit, Print Progress Reports
- Print Approval Letters:** View/Print approval letters for transactions completed in PATS. (NOTE: Letters for some early transactions completed in PATS and for transactions submitted prior to conversion to PATS and are not available through this feature.)
- Change Contact Information:** Update the contact information in PATS applications without doing an amendment.
- Delegate Assignment:** PI ONLY: Add “Delegates” to your account (allows other accounts access to your protocols).
- Report a Bug/Ask a Question:** Send an email to the CCI office.
- Logout:** Log out of PATS.

# PATS CCI Numbers



In PATS, CCI numbers now begin with a 4 digit year (e.g. 2004), instead of a two digit year. The second portion is still a 3 digit serial number. The largest change is the addition of a 3-4 digit transaction number, which is appended to the end. For new applications, the transaction number is always “000.” (Amendments follow: 001, 002, 003).

NOTE: These numbers may not match the Sponsor’s amendment numbers.

Old Style:

New (PATS) Style:

04 – 21 *or* 04 – 021 → 2004 – 021 – 000

Year application was started

Serial Number

Transaction Number

**NOTE: The CCI number for an application is assigned when the application is created.**



# Navigation: New Applications

The screenshot shows a software interface for creating new applications. At the top, a blue header contains the word 'Applications' in orange. Below this is a form with several sections:

- Investigator:** A dropdown menu with 'Select Investigator' as the current selection. A callout '1.' points to this field.
- Application No.:** Three empty text input boxes.
- Application Types:** A list of four radio button options:
  - Chart Review/Database Study Application
  - Behavioral/Observational Study Application
  - Specimen Study Application
  - Clinical Research Study ApplicationA callout '2.' is placed to the right of this list.
- Application Selection:** A table with two columns. The left column lists actions (a-i) and the right column is a large empty box. A callout '3.' points to the list, and a callout '4.' points to the empty box.
- Protocol Title:** A large text input field. A callout '5.' points to this field.
- Buttons:** 'Continue' and 'Cancel' buttons at the bottom. A callout '6.' points to the 'Continue' button.

## Application Types

**Chart Review/Database Study Application:** Study Examples: Medical Records review, Hospital Databases, Public Database, Data Analysis, etc.

**Behavioral/Observational Study Application:** Study Examples: School based research, or research using Focus Groups or questionnaires, etc.

**Specimen Study Application:** No direct research intervention by PI. Study Examples: research on leftover specimens, identifiable previously collected specimens, prospective specimens, etc.

**Clinical Research Study Application:** Direct research intervention by PI. Study Examples: blood drawing, MRI's, radioisotopes, drugs, or devices, etc.

1. Select an Investigator. Do not enter anything in the “Application No. fields.
2. Select an application type. See “Applications Types” (top right) for an explanation of what types of research are covered by each application. **It is important to select the right type – there is limited to no ability to change types if the wrong type is selected!**  
NOTE: Hovering the mouse over each application name will display a pop-up explanation of each application.
3. Select a function (explained in detail on page 9).
4. Select an application number in the “Application Selection” box.
5. (Optional) Double click on the application number in the “Application Selection” box (4) to display the Protocol Title.
6. Click the “Continue” button to proceed.



# Navigation: Applications Menu

a. New Application: Create a new application.

- Clicking this button will *immediately* create a new Application.

**NOTE: Since CCI numbers are assigned at the time of application creation, please avoid starting new applications unnecessarily.**

b. New – From Template: Create a new application, based on an existing application.

- If you frequently create many similar protocols (e.g. same key personnel, protocol sites, funding sources, etc.), start a new protocol, enter only the information that is repeated, then save the application, noting the CCI #. To create new applications, use the New – From Template feature to start new copies of your own custom template.
- If you have a new protocol that is similar to an existing protocol, use this feature to copy the entire application. Note that everything is copied, including funding sources, Informed Consent Documents, etc.

c. Edit Application: Edit an existing (but not approved) application.

- Use this button to access converted protocols in need of population (see page 26) as well as to access protocols that you have begun to work on, but are not yet approved. For information on editing a submitted application, see “Modifying a Submitted Transaction” (page 20).
- **NOTE: This button is not used for creating or accessing Amendments.**

d. Assent/Consent Form: Create and edit ICDs.

- Clicking this button will load the PATS ICD editor. See “ICD Creation” (pages 12-16) for more information.

e. Submit Application: Electronically submit the application & ICDs to the CCI.

- After clicking this button, the application is checked for errors. If none are found, the application can be submitted.
- **NOTE: Paper submissions are still required at this time.**

f. Print: Print the application to obtain a copy that can be signed and submitted to the CCI.

- At this time, the requirements regarding the number of copies for paper applications apply to PATS protocols as well.

g. Print Approved Assent/Consent Form: Print current, stamped, approved ICDs.

h. Print Expired Assent/Consent Form: Print expired ICDs.

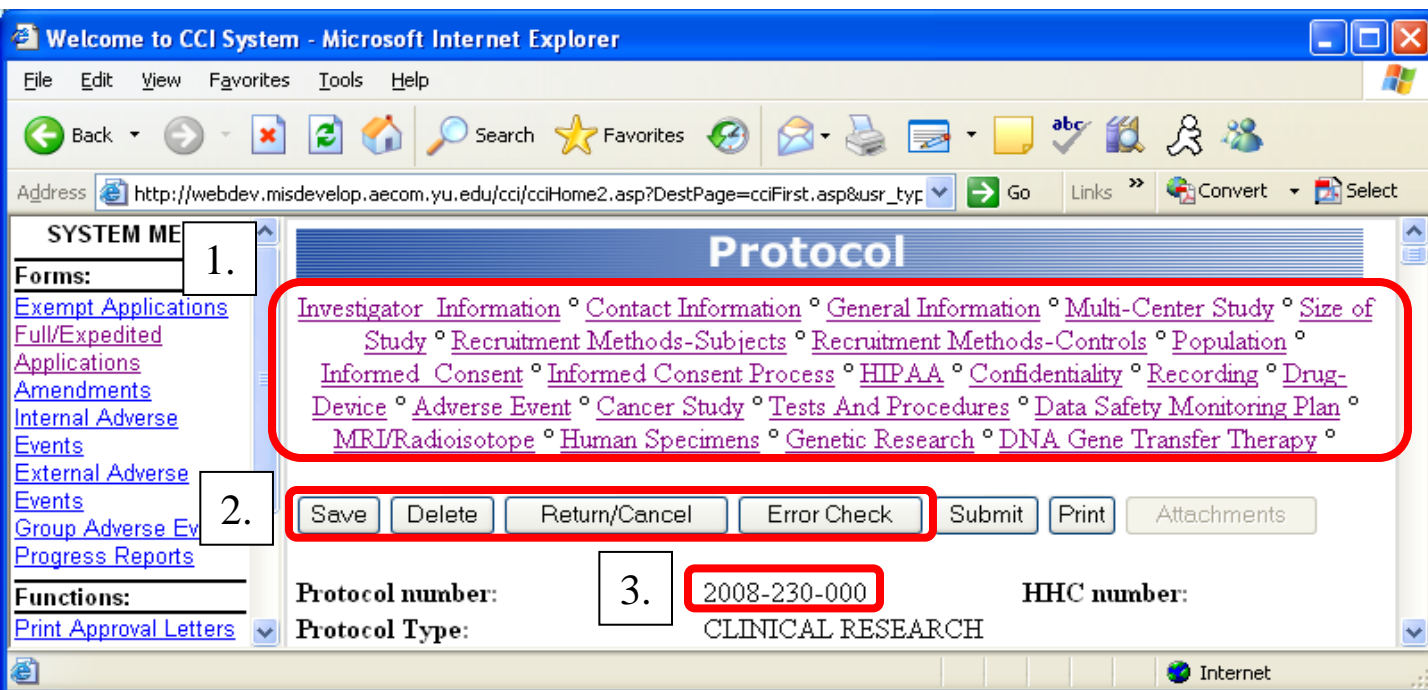
- Select the “transaction number” (see page 7 for more information on PATS CCI Numbers) to access the ICDs corresponding to that transaction.

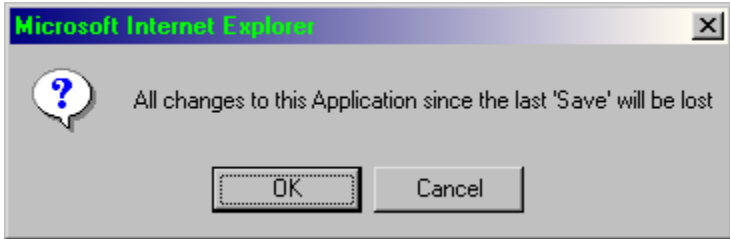
i. Un-Delete Application:

- Applications that are deleted (accidentally) can be undeleted within 14 days.

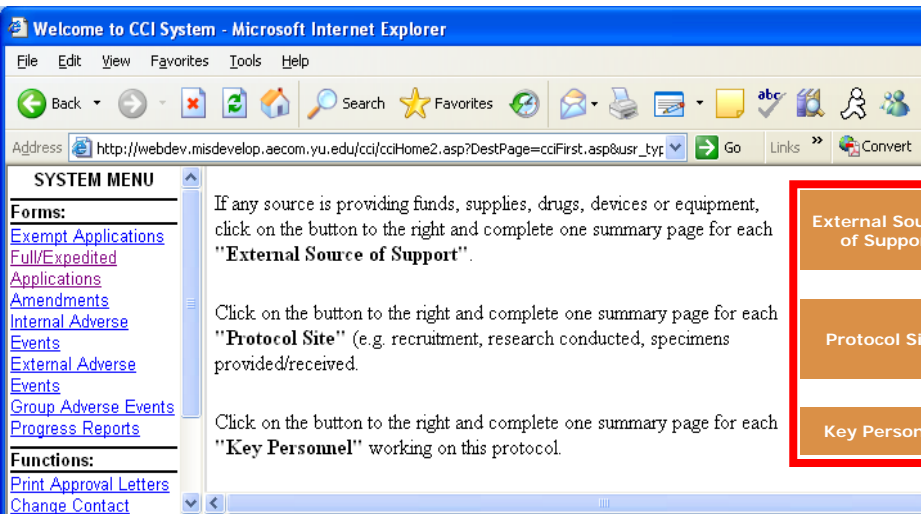
a.	New Application
b.	New - From Template
c.	Edit Application
d.	Assent/Consent Form
e.	Submit Application
f.	Print
g.	Print Approved Assent/Consent Form
h.	Print Expired Assent/Consent Form
i.	Un-Delete Application

# Navigation: Application Form

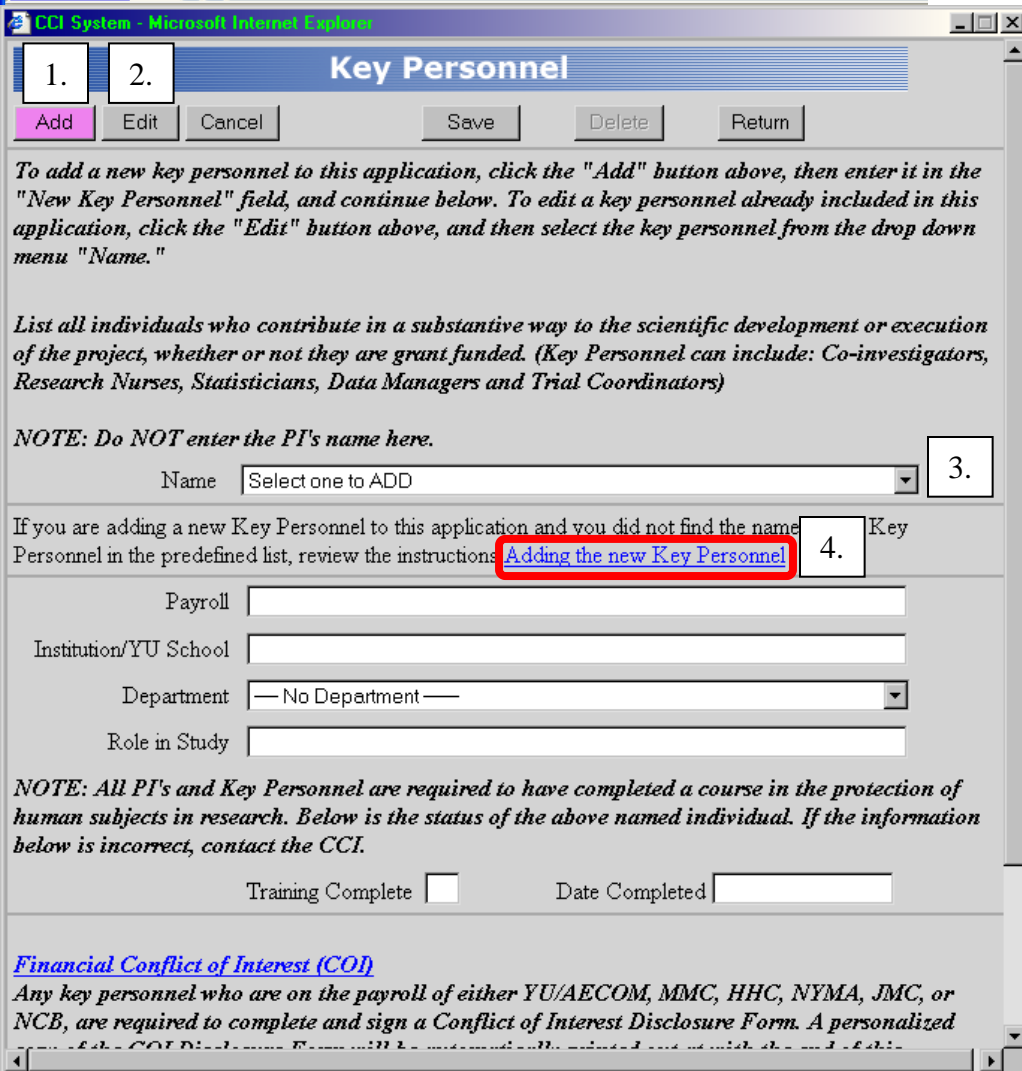


1. Shortcuts to the various sections of the application.  
NOTE: It is generally best to work your way straight through the application. Use the links only to return to your place in the application after saving or when attempting to locate and resolve errors from the error check (see 2d, below).
2. Application Function Buttons (these buttons are repeated after each section of the application):
  - a. **Save:** Save the entire application.
  - b. **Delete:** Delete the entire application (not just the section where the button is located).
  - c. **Return/Cancel:** Return to the Application Menu. If you have made changes, make sure to click on “Save” first to avoid losing your changes.  
NOTE: The following dialog box will always pop-up to remind you to save. (Even if you haven’t made any changes, or if you’ve already saved.)  

  - d. **Error Check:** Run an application error check, which lists two types of errors:
    - Omitted fields.
    - Logical conflicts.
3. The CCI Number of the application, which is assigned as soon as the application is created, is displayed on the application form for your reference (see page 7 for more information on PATS CCI Numbers).

# Navigation: Application "Child Pages"



Clicking on any orange buttons (such as these) in PATS will open a "Child Page" in a new window.



Child Pages are used in two cases:

- To ask specific questions that only apply in certain circumstances (e.g. drug/device information, Informed Consent Waiver Form, etc.)
- When multiple items are possible (e.g. Protocols Sites, External Sources of Support, Key Personnel, etc.)

On Child Pages where multiple items are possible, there are two modes:

1. Add: To add a new item.
2. Edit: To edit an item that was already added.

NOTE: One of these buttons is highlighted in color at all times to indicate the current mode.

## In "Add" mode:

3. Select an item to add from the pick list.
4. If the item you would like to add is missing, click the link for adding a new item.

## In "Edit" mode:

3. Select an item to edit from the pick list. The list will contain only the items that you have added (in "Add" mode).

# ICD Creation

## View/Edit Consent Form

Application: 2001-287-000

Consent Form Title:

Footer:

last modified by on

Forms **Templates** 1.

[AaBbCcDdEeFfGgHhIiJjKkLlMmNnOoPpQqRrSsTtUuVvWwXxYyZz](#)

description



Forms **Templates**

3.

2.

[AaBbCcDdEeFfGgHhIiJjKkLlMmNnOoPpQqRrSsTtUuVvWwXxYyZz](#)

description

Select Preview [ \*\*\* Updated 12/20/05 \*\*\* ] Important Informed Consent Information - Please Read

Select Preview **Blank** 5.

Select Preview Behavioral Research - Individual Informed Consent Document

Select Preview Behavioral Research - 3rd Party Permission for Participation in Research

Select Preview Behavioral Research - Child Assent Form

Select Preview Behavioral Research - Parental Permission and Young Adult Assent

Select Preview Behavioral Research - Parental Permission for Child's Participation in Research

Select Preview Behavioral Research - Simplified Informed Consent Document - No Help Text 6.



Forms **Templates**

4.

[AaBbCcDdEeFfGgHhIiJjKkLlMmNnOoPpQqRrSsTtUuVvWwXxYyZz](#)

description

Select Delete \_Blank\_

Creating a new ICD:

1. Click on Templates
2. (Optional) Click on the description of the ICD to preview it.
3. Click on the orange "Select" button to the left of an ICD you wish to use.
4. The template will be copied to the "Forms" section.
5. Use the "Blank" template for converting ICDs. (See instructions on "How to Convert an ICD from MS-Word to PATS," page 16.)
6. ICDs appended with "No Help Text" are usable, but simply lack help text. For assistance in preparing ICDs using these templates, reference the MS-Word templates on our website: <http://www.aecom.yu.edu/cci/page.aspx?ID=9676>

# ICD Editing

## View/Edit Consent Form

Application: 2005-621-000

Consent Form Name:

Footer:

*last modified by on*

Save

Open

Cancel

Return

Forms

Templates

[All](#) [a](#) [b](#) [c](#) [d](#) [e](#) [f](#) [g](#) [h](#) [i](#) [j](#) [k](#) [l](#) [m](#) [n](#) [o](#) [p](#) [q](#) [r](#) [s](#) [t](#) [u](#) [v](#) [w](#) [x](#) [y](#) [z](#)

1.  description

Select

Delete

\_Blank\_



## View/Edit Consent Form

Application: 2005-621-000

2. Consent Form Name:

3. Footer:

*last modified by d.  on 12/20/2005*

4. Save

Open

Cancel

Return

Forms

Templates

[All](#) [a](#) [b](#) [c](#) [d](#) [e](#) [f](#) [g](#) [h](#) [i](#) [j](#) [k](#) [l](#) [m](#) [n](#) [o](#) [p](#) [q](#) [r](#) [s](#) [t](#) [u](#) [v](#) [w](#) [x](#) [y](#) [z](#)

description

Select

Delete

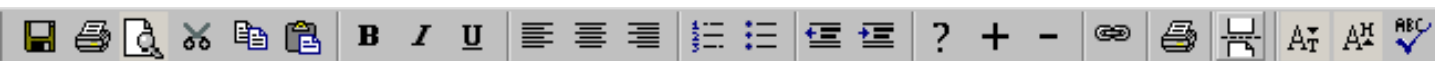
\_Blank\_
























### Editing an ICD:

1. In “Forms” mode, click on the orange “Select” button to the left of the ICD you wish to edit.
2. The ICD name is loaded in the “Consent Form Name” field, and can be modified.
3. The ICD “Footer”\* can be added/edited.
4. After modifying the “Consent Form Name” and/or the “Footer,” click the orange “Save” button.
5. Click the orange “Open” button to open the selected ICD.

\*ICD Footer: PATS uses the “Window Title” field to print the “Footer.” The location of this field on the printout is based on a browser setting. If the footer is not printing in the location desired, see the “Headers and Footers” section on page 3, “Required System Settings,” for instructions on modifying the browser settings.

# ICD Toolbar



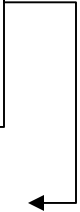
-  Save
-  Print (excluding help text)
-  Print Preview
-  Cut
-  Copy
-  Paste
-  Bold
-  Italic
-  Underline
-  Left Justify
-  Center
-  Right Justify
-  Numbered List
-  Bulleted List
-  Decrease Indent
-  Increase Indent
-  Mark/Unmark as Help Text
-  Mark/Unmark as Added Text
-  Mark/Unmark as Removed Text
-  Insert Hyperlink (not used)
-  Print (including help text)
-  Insert Page Break
-  Subscript
-  Superscript

**Spell Checking is now available in PATS! See Page 4 regarding IE plug-in that must be downloaded in order to make use of this feature.**

**IMPORTANT REMINDER:**  
All changes to consent forms must be tracked when the consent forms have previously been submitted to the administrative office. (Added consent forms do not require tracking.)

To track text that was added, highlight the added text and click on the [+] button.  
(Sample: Added Text)

To track text that is to be deleted, highlight the text and click on the [-] button.  
(Sample: ~~Deleted Text~~)



# ICD Page Breaks & Print Preview

Blank

Return

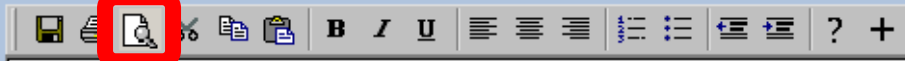
All changes to consent form(s) must be tracked when the consent form(s) have previously been submitted to the administrative office. Added consent form(s) do not require tracking

To track text that was added, highlight the added text and click on the [+ ] button.

(Sample: **Added Text**)

To track text that is to be deleted, highlight the text and click on

(Sample: **1. Deleted Text**)



Black text is normal text.

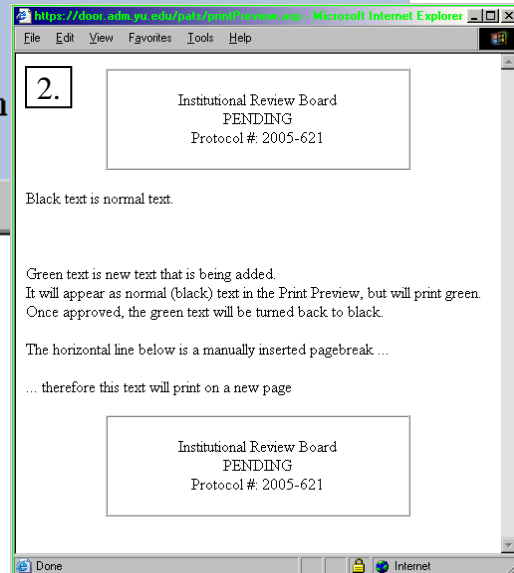
Blue text is "help text" and will NOT print.

~~Red text with strike-through is text that is being removed. It will not appear in the Print Preview, but will print. Once approved, the red text will be deleted.~~

Green text is new text that is being added. It will appear as normal (black) text in the Print Preview, but will print green. Once approved, the green text will be turned back to black.

The horizontal line below is a manually inserted pagebreak ...

... therefore this text will print on a new page

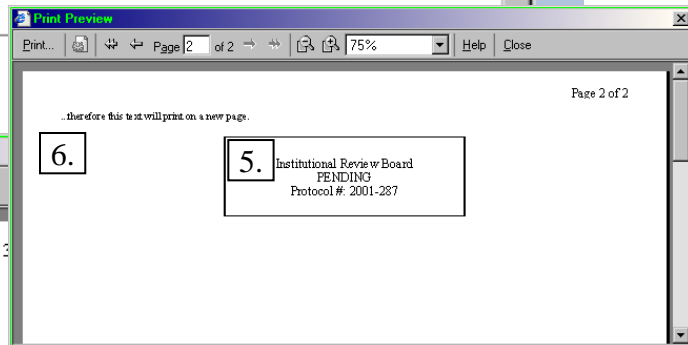


Black text is normal text.

Green text is new text that is being added. It will appear as normal (black) text in the Print Preview, but will print green. Once approved, the green text will be turned back to black.

The horizontal line below is a manually inserted pagebreak ...  
... therefore this text will print on a new page

Institutional Review Board  
PENDING  
Protocol #: 2005-621



3. The ICD will display as it will print.  
**NOTE:** ICD margins are controlled by the browser (Internet Explorer), not by PATS. Therefore, ICDs printed from different computers (with different margin settings) may appear differently when printed.
4. Click on the single Right Arrow to advance to the next page [6].
5. The CCI stamp prints at the top and bottom of the ICD

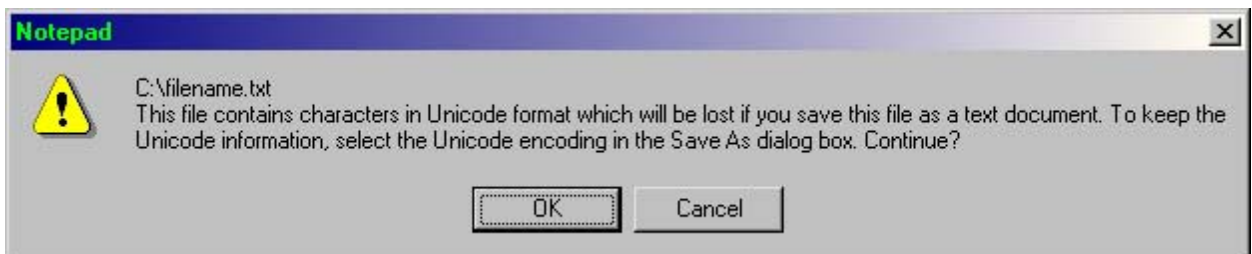
## Print Preview:


1. Click on the Print Preview button.
2. The ICD will open in it's own window. Click on "File | Print Preview..." in the new window to switch to print preview mode.



# Converting ICDs from MS-Word to PATS

1. In PATS, go to the ICD editor (see page 8, step 3 and page 9, step d), **Select** a “Blank” template (see page 12), then **Open** it (see page 13).
2. In MS-Word, **select** and **copy** (“Edit | Copy”) the text of the ICD (but not the “FOR OFFICE USE ONLY” boxes).
3. **Paste** (“Edit | Paste”) the text in Notepad (not Wordpad), usually found under “Start | Programs | Accessories | Notepad.”
4. **Save** (“File | Save”) the Notepad file in a convenient location.  
**NOTE: If while Saving you see a dialog box similar to the following, choose “OK,” then follow Steps A-B, below.**



- A. **Close** Notepad.
  - B. **Re-Open** “filename.txt” in Notepad.
5. In Notepad, **Select** (“Edit | Select All”) and **Copy** (“Edit | Copy”) the text.
  6. In PATS, **Paste** the text in the “Blank” template, using the “Paste” (  ) button. See NOTE #1, below.
  7. You may now delete the file you created when you saved the document in Notepad.

## NOTE #1:

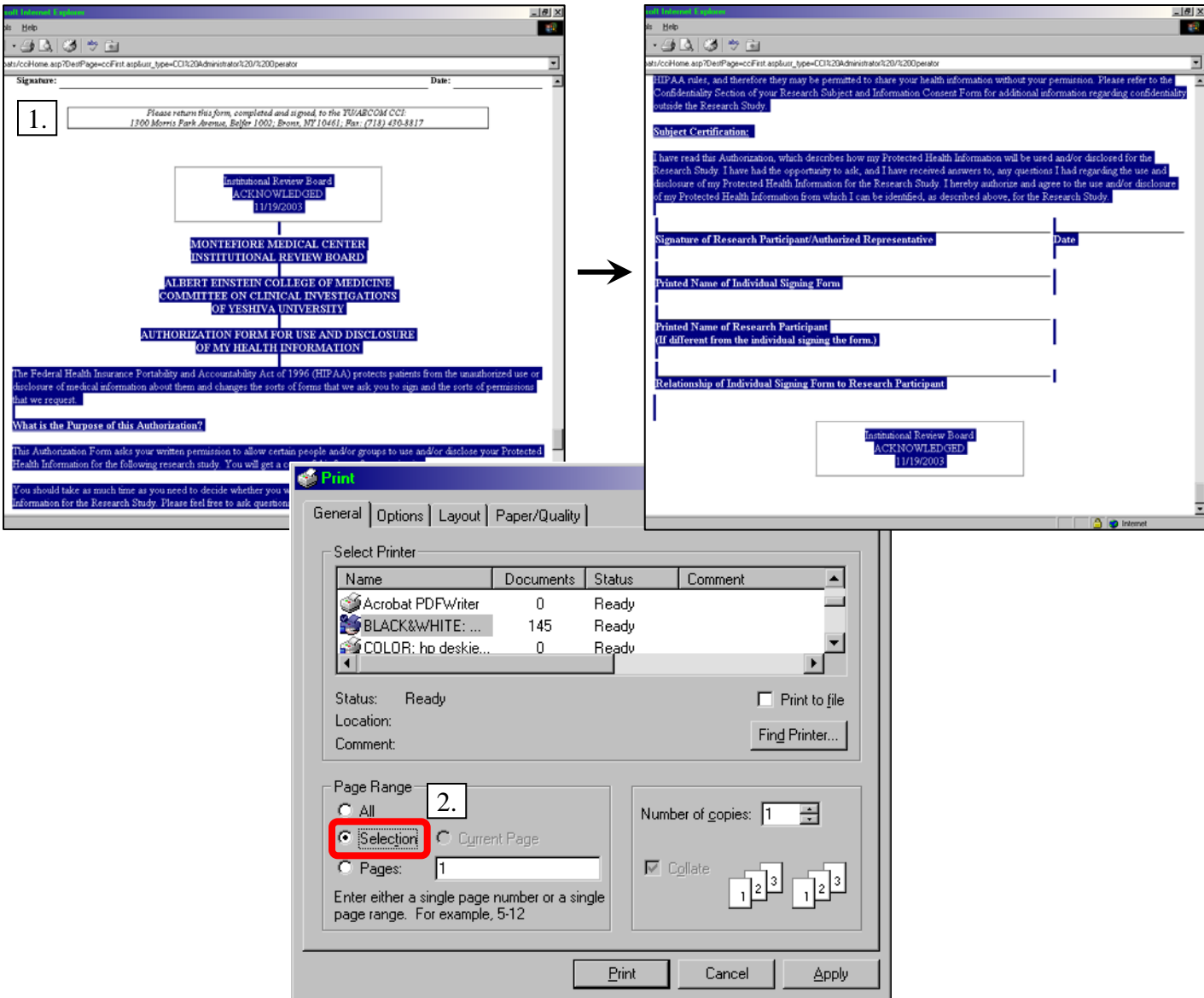
This procedure removes all of the formatting, good and bad. After pasting into PATS you must go through the document restoring the lost formatting (e.g. centering, bolding, and underlining).

## NOTE #2:

If your ICD includes tables and/or images (e.g. flowcharts, pictures, etc.), include a reference to them in the document (e.g. “See attachment #1”) and submit the printed tables/images to the CCI on paper.

# HIPAA Authorization Forms

- The text of the HIPAA Authorization forms is built into PATS.
- If written HIPAA Authorization is being sought, the application will ask a few questions to gather the information it needs to complete the Authorization form.
- Based on the information entered into the Application, PATS will include the following forms, as applicable:
  - English
  - Spanish
  - English – JMC/NCB
  - Spanish – JMC/NCB
- Once the application is approved, the forms are stamped “Acknowledged,” and can be accessed as follows:
  - Load the “Print” view of the Application (see page 8) or Amendment (see page 18).
    1. Using the mouse, select each HIPAA Authorization form (one at a time), including the stamps.
    - Click “File | Print...”
    2. In the “Print Range” section, select “Selection,” then click “Print.”
    - Repeat for each HIPAA Authorization Form.



# Navigation: Amendments

1. **Amendment Processing**

Investigator Wallach, David — Committee on Clinical Investigations

Application No. [ ] [ ] [ ]

Application Selection

a. New Amendment

b. Edit Amendment

c. Submit Amendment

d. Print

e. Un-Delete Amendment

2.

3.

4.

Protocol Title

5.

Continue Cancel

1. Select an Investigator.
2. Select a function.
  - a. New Amendment: Create a new amendment on an approved application.  
**NOTE: Only one unapproved amendment per protocol is allowed in PATS.**
  - b. Edit Amendment: Edit an existing (but not approved) amendment. For information on editing a submitted amendment, see “Modifying a Submitted Transaction” (page 20).
  - c. Submit Amendment: Electronically submit the amendment & ICDs to the CCI.  
**NOTE: Paper submissions are still required at this time.**
  - d. Print: Print the amendment to obtain a copy that can be signed and submitted to the CCI.  
**NOTE: PATS creates a custom form for each amendment, listing only the changes.**
  - e. Un-Delete Amendment: Undelete (accidentally) deleted amendments.
3. Select a CCI Number in the “Application Selection” box.
4. (Optional) Double click on the CCI Number in the “Application Selection” box (3) to display the Protocol Title.
5. Click the “Continue” button to proceed.

# Navigation: Amendments Cont'd

## New/Edit Amendments

**Application:** 2003-044  
**Principal Investigator:** Account, Testing  
**Protocol Title:** This is the test title of our test protocol #1. Look, I changed the title!  
**Protocol Review Type:** Full Review  
**Amendment:** 003

Amendment Justification/Explanation & Protocol Changes:

1.

Sponsor Amendment Information:

2.

**a.** Save

**d.** Cancel

**b.** Application Amendments

**e.** Assent/Consent changes

**c.** Change Principal Investigator

**f.** Return

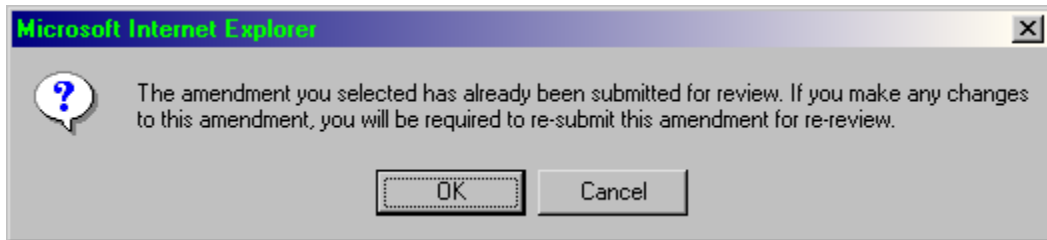
1. Amendment Justification/Explanation & Protocol Changes: In this section, enter a summary of what you are changing, and why. Also list any protocol changes that wouldn't be reflected in changes in the PATS application.

**NOTE: All changes must be explained/justified in this section.**

2. Sponsor Amendment Information: In this section list sponsor specific amendment/addendum numbers and dates, etc. (e.g. 'Addendum #2, dated 12/26/05).
- Save: Click this button to save updates to the "Amendment Justification/Explanation & Protocol Changes" and "Sponsor Amendment Information" fields.
  - Application Amendments: This button will load a complete copy of your application, which you can edit.
  - Change Principal Investigator: Change the PI of the protocol.
  - Cancel: Allows you to clear unsaved changes to boxes 1-2.
  - Assent/Consent changes: Add, remove, or modify consent forms.
  - Return: Return to the main Amendment menu.

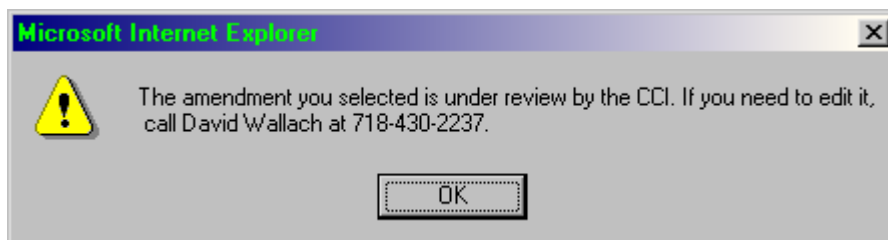
# Modifying a Submitted Transaction

1. PATS allows changes to transactions until the transaction is approved. (Exception: AEs may be modified even after “approval” to add follow-up information.)
2. If, after submitting a transaction, you need to modify it, attempt to access it via the “edit” function associated with that transaction.
3. If the CCI has not yet begun to review the transaction, PATS will display a message box stating that you may proceed with modifying the transaction. If you don’t make any changes, you do not need to resubmit (in fact, you won’t be able to).



**NOTE: You must resubmit the transaction when you are done modifying it.**

4. If the CCI has begun reviewing the transaction, PATS will display a message box indicating which CCI staff member is working on the transaction. Contact that person to request access to the transaction.



**NOTE: If a transaction is returned to you by the CCI Staff, you must resubmit it, even if you do not modify it.**

# Navigation: Adverse Events

**NOTE: The navigation for Internal and External Adverse Events (AE) is the same. To submit External Adverse Events in quantity, see “Navigation: Group AEs” (pages 22-23).**

The screenshot shows a software interface for navigating to Adverse Events. At the top, the title "Internal Adverse Events" is displayed in orange. Below the title, there are several input fields and a list of options. Callout 1 points to the "Investigator" dropdown menu, which is currently set to "Wallach, David — Committee on Clinical Investigations". Callout 2 points to a list of four options: "a. New Internal Adverse Events", "b. Edit Internal Adverse Events", "c. Submit Internal Adverse Events", and "d. Print Internal Adverse Events". Callout 3 points to a large empty box labeled "Internal Adverse Events Selection". Callout 4 points to the "Protocol Title" text input field. Callout 5 points to the "Continue" button at the bottom left of the interface. The "Cancel" button is visible at the bottom right.

1. Select an Investigator.
2. Select a function.
  - a. New Adverse Event: Create a new AE for an approved application.
  - b. Edit Adverse Event: Edit an existing (but not completed) AE. For information on editing a submitted AE, see “Modifying a Submitted Transaction” (page 20).
  - c. Submit Adverse Event: Electronically submit the AE to the CCI.  
NOTE: Paper submissions are still required at this time.
  - d. Print Adverse Event: Print the AE to obtain a copy that can be signed and submitted to the CCI.
3. Select a CCI Number in the “Adverse Events Selection” box.
4. (Optional) Double click on the CCI Number in the “Adverse Events Selection” box (3) to display the Protocol Title.
5. Click the “Continue” button to proceed.

# Navigation: Group AEs

**NOTE:** The Group AEs feature is designed for handling large quantities of External AEs. You are permitted to “collect” your AEs for submission in a single group, provided you comply with the External Adverse Event Policy (<http://www.aecom.yu.edu/cci/page.aspx?ID=9724>).

The screenshot shows the 'Group External Adverse Events' interface. At the top, the title 'Group External Adverse Events' is displayed in orange. Below the title, there is a form with several fields and buttons. Callout 1 points to the 'Investigator' dropdown menu, which currently shows 'Wallach, David — Committee on Clinical Investigations'. Callout 2 points to a vertical list of four buttons: 'a. New Group Adverse Events', 'b. Edit Group Adverse Events', 'c. Submit Group Adverse Events', and 'd. Print Group Adverse Events'. Callout 3 points to a large empty box labeled 'Group Adverse Events Selection'. Callout 4 points to the 'Protocol Title' text input field. Callout 5 points to the 'Continue' button at the bottom left of the form. The 'Cancel' button is visible at the bottom right.

1. Select an Investigator.
2. Select a function.
  - a. New Group Adverse Event: Create a new Group AE for an approved application.
  - b. Edit Group Adverse Event: Edit an existing (but not completed) Group AE. For information on editing a submitted Group AE, see “Modifying a Submitted Transaction” (page 20).
  - c. Submit Group Adverse Event: Electronically submit the Group AE to the CCI.  
NOTE: Paper submissions are still required at this time.
  - d. Print Group Adverse Event: Print the Group AE to obtain a copy that can be signed and submitted to the CCI.
3. Select a CCI Number in the “Group Adverse Events Selection” box.
4. (Optional) Double click on the CCI Number in the “Group Adverse Events Selection” box (3) to display the Protocol Title.
5. Click the “Continue” button to proceed.



# Navigation: Group AEs Cont'd

## Group Entry -- External Adverse Events

Protocol 2003-044   
Group Number 0002  
Title

1. Basic information about the selected protocol is displayed (CCI #, Group AE#, Title).
2. Enter general information about the AEs.
3. Enter the breakdown of the AEs.

Enter the date the first of these AEs was reported by the sponsor   
Total number of Adverse Events reported in this group

2.

### ADVERSE EVENTS DEFINITELY OR PROBABLY RELATED TO THE PROTOCOL

Number of Deaths\*  a.  
Number of Serious Events\*  b.  
Number of Unanticipated  c.

- a.\* Number of Deaths *Definitely or Probably Related to the Protocol*
- b.\* Number of Serious Events *Definitely or Probably Related to the Protocol*
- c. Number of Unanticipated *Definitely or Probably Related to the Protocol*
- d. Number of Deaths *All Others*
- e. Number of Serious Events *All Others*
- f. Number of Unanticipated *All Others*

### ALL OTHER ADVERSE EVENTS

3.

Number of Deaths  d.  
Number of Serious Events  e.  
Number of Unanticipated  f.

Comments

4.

5.

6.

*\*An individual External Adverse Event form must be completed for each Death and Serious Adverse Event that was definitely or probably related to the protocol. Click the button below to add an External Adverse Event form to this group.*

7.

### Edit External Adverse Events in this group

8.

**\*NOTE: An individual External Adverse Event form must be completed for each Death and Serious Adverse Event that was definitely or probably related to the protocol. Click the button [7] to add an External Adverse Event form to this group.**

4. Save Group External AE
5. Error Check Group AE
6. Return
7. Click the "Add New External Events to the Group" button to complete a full EAE form for each Definitely or Probably related Death or Serious Adverse Event.
8. To edit any of the individual External AE forms associated with the Group AE, select it from the pull down list, then click "Continue."

# Navigation: Progress Reports

The screenshot shows a software interface titled "Progress Report" in orange text. At the top, there is a dropdown menu for "Investigator" with the text "Wallach, David — Committee on Clinical Investigations" and a downward arrow. Below this is a field for "Application No." with three empty input boxes. The main area is titled "Progress Report Selection" and contains a large empty rectangular box. To the left of this box is a vertical list of four buttons: "a. New Progress Report", "b. Edit Progress Report", "c. Submit Progress Report", and "d. Print Progress Report". At the bottom of the interface is a "Protocol Title" field with a large empty text area. Below the text area are two buttons: "Continue" on the left and "Cancel" on the right. Numbered callouts are placed as follows: 1. points to the Investigator dropdown; 2. points to the list of function buttons; 3. points to the large empty box; 4. points to the Protocol Title field; 5. points to the Continue button.

1. Select an Investigator.
2. Select a function.
  - a. New Progress Report: Create a new Progress Report for an approved application.
  - b. Edit Progress Report: Edit an existing (but not completed) Progress Report. For information on editing a submitted Progress Report, see “Modifying a Submitted Transaction” (page 20).
  - c. Submit Progress Report: Electronically submit the Progress Report to the CCI.  
NOTE: Paper submissions are still required at this time.
  - d. Print Progress Report: Print the Progress Report to obtain a copy that can be signed and submitted to the CCI.
3. Select a CCI Number in the “Progress Report Selection” box.
4. (Optional) Double click on the CCI Number in the “Progress Report Selection” box (3) to display the Protocol Title.
5. Click the “Continue” button to proceed.

# Navigation: Exempt Applications

The screenshot shows the 'Exempt Protocol Applications' window. At the top, the title 'Exempt Protocol Applications' is displayed in orange. Below the title, there is a dropdown menu for 'Investigator' with 'Wallach, David — Committee on Clinical Investigations' selected. A callout '1.' points to this dropdown. Below the investigator field are three empty text boxes for 'Application No.'. To the left of the main area is a vertical menu with four options: 'a. New Application', 'b. Edit Application', 'c. Submit Application', and 'd. Print Application'. A callout '2.' points to this menu. The main area is titled 'Application Selection' and contains a large empty white box. A callout '3.' points to this box. At the bottom left is a 'Continue' button with a callout '4.' pointing to it. At the bottom right is a 'Cancel' button.

1. Select an Investigator/Advisor.

2. Select a function.

a. New Application: Create a new Exempt application.

NOTE: This will immediately begin to load a new application. No further steps are required.

b. Edit Application: Edit an existing (but not completed) Exempt application. For information on editing a submitted Exempt Application, see “Modifying a Submitted Transaction” (page 20).

c. Submit Application: Electronically submit the Exempt application to the CCI.  
NOTE: Paper submissions are still required at this time.

d. Print Application: Print the Exempt application to obtain a copy that can be signed and submitted to the CCI.

3. Select a CCI Number in the “Application Selection” box.

4. Click the “Continue” button to proceed.