Dialysis Access Consortium (DAC)

Manual of Operations

Administrative

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Administrative
(03/22/05)

1. COMPUTING AND DATA ENTRY

1.1 Computing systems overview

Computing for DAC can be divided into two broad areas: computing at the Clinical Centers and computing at Data Coordinating Center (DCC). The purpose of this overview is to describe in general terms how these systems are organized.

Each Clinical Center has at least one personal computer. These PC's will be used, for study purposes, to run software for communicating over the Internet to the DCC. They may additionally be used for a variety of tasks useful for the centers' work related to the study, such as word processing.

To connect from your PC to the DCC (located in Cleveland, Ohio, at the Cleveland Clinic Foundation), you will be making use of the Internet, a world-wide network of computers, composed of and supported by primarily academic, governmental, and non-profit institutions. Using the Internet, you will be able to interact with the DCC's computers in Cleveland.

The PC that sits in your office is not directly connected to the Internet. You must first connect from your PC to a nearby computer that is on the Internet, and then from that computer to the DCC. This nearby computer is called an Internet "node." Just what kind of computer each center will connect to in order to access the Internet will vary from center to center. Some centers will be connected to computers at their institution that are an Internet node. This connection might be through a campus network, or it might involve dialing up the institution's computer over a phone line using a modem. Other centers will be utilizing a public provider of Internet access for a small monthly fee. Connecting to such a service will involve making a local phone call to connect using a modem. In either case, this manual will refer to the nearby computer to which the DAC center's personal computer connects to gain Internet access as the Local Internet Provider (LIP).

The DCC's computer is also connected to the Internet. Hence, connecting from your personal computer to your LIP allows you to reach the DCC across the Internet. In fact, you'll be using the DCC's computer directly when you enter data, and receive reports and mail messages from the DCC.

1.2 Your DAC Study personal computer

Each Clinical Center is required to have a minimum of one PC dedicated to the purposes of the DAC Study. The DCC's recommended specifications for your PC are as follows:

1.2.1 PC specification

A 500 Mhz or better PC is required.

1.2.2 Monitor

Color monitor.

1.2.3 Internet connection

A live connection to the Internet.

1.2.4 Browser software

Netscape Communicator 4.77 or Internet Explorer 5.5 or higher. Adobe Acrobat Reader 4.05. Oracle Jinitiator 1.1.8.14. These can be downloaded from the DCC’s website.

Web site downloadable utilities

The website https://clinapps.bio.ri.ccf.org/dac/download.html a number of files needed to fully utilize the DAC Consortium web application.

Included are:

(1) Netscape Communicator version 4.77 cc32d477.exe
(2) Adobe Acrobat Reader version 4.05 rs405eng.exe
(3) Oracle JInitiator version 1.1.8.14 jinit11814.exe

The following steps must be performed in the order given below:

1) If you do not have Netscape 4.77 already installed, install it by double-clicking on cc32d477.exe This is the latest version in the 4.x series. We've seen numerous problems with the 6.x Netscape and do not recommend it at this time.

2) Double-click jinit11814.exe to install (accept all defaults). This is a thoroughly debugged and Oracle-certified version of Sun Microsystems's Java Plug-In which replaces the browser's built-in Java Virtual Machine when the DAC application is run.

Once these components are installed:
Please go to https://clinapps.bio.ri.ccf.org/ and follow the links to DAC and then log in to the appropriate database.

NOTE: Using Netscape 6.x and Jinitiator

Aside from other directions in the computing section of the MOP and the above, the user still might not be able to run the application and gets the message to 'Get Plug-In' even after JInitiator had been installed. The problem is that the plug-in, NPJinit-11814.dll, may not have been copied to the correct directory. It needs to be in the Netscape → Plug-Ins directory along with other Java dlls. This seems particularly true for Netscape 6 and higher especially if there is a previous version of Netscape installed. To do to this, use the Windows 'Search' or 'Find' utility (Depends on which version of Windows OS). Once you have located 'NPJinit-11814.dll' copy it to the Plug-Ins directory under the current version of Netscape if it isn't there already.

1.3 Accessing the DCC website to enter data

See Appendix A for instructions on how to set up your PC to access the DCC's website.

The forms were designed assuming a user desktop area setting of 800 x 600.

There is currently a one hour idle time setting in effect. If the one hour idle time is exceeded, the user will see an error message containing the text "ORA-03114". To fix the problem, please log out and then log in again.

After you have successfully entered the website, you will see a menu titled "DAC Study". At this point, resize the window to the largest that will fit on the screen for optimal viewing. You can then

choose a form or report from the menu, or you can go to the “Query” menu to answer or view your queries.

1.3.1 Passwords

You will have an Oracle database username and password. The username is the first initial of your first name followed by the first seven characters of your last name. Please do not share passwords. Passwords will need to be changed every 75 days. Oracle passwords are NOT case sensitive; i.e., it does not matter if the cap lock is on.

Your new password must be at least 6 characters long.
Your password must contain at least two alphabetic characters.
Your password must contain at least one numeric character.
Your password must differ from your old password by at least 3 characters, or not match any of the three past passwords.
Your password cannot contain quotation marks OR ANY OTHER SPECIAL CHARACTERS.
Your password must begin with a LETTER.
Your password should not be a common word, a proper name, or a common phrase.

1.3.2 Selecting a good password

Here are some good references for picking a good password:

http://www.net.berkeley.edu/dcns/faq/good_pw.html

http://www.msc.tamu.edu/services/cops/security/goodpasswd.html and

http://www.cs.umd.edu/faq/Passwords.shtml

Please read them all as they all have good advice

1.3.3 Changing your password

There is a menu option available to change your password.

1.4 Instructions: How to enter study data into the database

Press enter, tab or click your mouse to move from field to field within a form. Note that you will see bubble help when you move your mouse over the top buttons. The upper left button should be the save button. When you are finished entering data for a form, click on the save button, or choose “Save” from the “Action” menu, or press the F10 (Accept or Commit) function key. The F10 key corresponds to the Oracle function “Accept” or “Commit”. You will see a message at the bottom of the screen indicating how many new records were added to the database. You can get out of a form by pressing the “Exit” button or choosing “Exit” from the “Action” menu. There is also a speed key for this. If you want to enter another form you should navigate to the top of the form, and press the “Insert Record” button. “Insert” can be selected from the “Record” menu. Unfortunately, you are not permitted to remove records once you have saved/committed them. You will need to send the DCC a query to do that. You are also not permitted to change certain key fields or fields that determine eligibility. Again, you will need to send a query to the DCC.

1.4.1 Keymappings

Ctrl+F1 means hold down the <Ctrl> key and then simultaneously press the <F1> key. Now release <F1> and then <Ctrl>. Another way to get to the key mappings is to choose “Keys” from the “Help” menu.

1.4.2 List of values (LOV)

Note that you may see messages on the bottom of your screen. If you see “List of Values”, that means you can choose “Display List” from the “Edit” menu, or press F9 to retrieve a list of values to your screen which you can scroll through and make a selection.

1.4.3 Editing

If the field is smaller than the text you are typing into it, you can choose “Edit” from the “Edit” menu, or press Ctrl+E when your cursor is in that field. This will open up a pop-up box containing a larger view of that field. Use this also for viewing.

1.4.4 Navigation

Other useful Oracle functions that you can use are “Next Record” and “Previous Record”. You can find buttons and speed keys for these and they are also on the “Record” menu. Use these to navigate between forms or detail records (for example, in medication forms).

1.4.5 Error messages

If you skip over a required field, you will see the error message:

Field must be entered.

If you enter a value that is not possible for that field, you will see the error message:

Invalid value for fieldname.

If you enter a non-numeric character in a numeric field, you will see the error message:

Legal characters are 0-9 - + E.

If you try to update previously entered data without using the [Change Value] button, you will see

Field is protected against update.

You will also see other various error messages as well. If you can’t figure out why you are getting that particular error message, please write down the complete message, and also choose Help->Display Error while the message is on the screen to see if a further explanation pops up before calling us. If you get stuck, it may help to use [Cancel Query] or Query->Cancel (if you see “Enter-Query” on the bottom of your screen), Action->Clear All or Record->Clear

1.5 Instructions: How to change study data in the database

1.5.1 Retrieving data

Once the data has been entered, you can retrieve it to your screen for viewing:

- Access the form # you want to view.
- Press the [Enter Query] key or button.

- Note the hint line will say “Enter-Query”.
- Enter the Patient ID and visit number. Note that visit number is not applicable for some forms.
- Press the [Execute Query] key or button.

1.5.2 Real-time changes

Clinical Centers can change data within 7 days and the new value is acceptable to the database:

Query the data from the appropriate from.
Position cursor on field to be changed, and then press the [Change Value] button.
Type in the new value.
If multiple fields within the same form need to be changed, repeat the above, starting with positioning your cursor in the new field.
You will receive a data change number for each field that you change.
You will need to save (commit) the data before you leave the form.
If a desired change does not pass an edit check, then none of the changes will be saved if you have made multiple changes. If you quit out of the form at this point the data change numbers will be discarded, but before you quit out of the form, you may be able to change the unacceptable value back to its original state, and then save the form again. Otherwise, you may need to quit out of the form and make the (acceptable) changes again, or make the changes one at a time, saving the form in between each change.
See the section entitled "Data Change Within 7 Days But the Database Will Not Accept It" for how to handle the changes that do not pass the edit checks.

1.5.3 Data change within 7 days but the database will not accept it

Retrieve the data.
Position the cursor on the field where changes were rejected.
Press the [Change Value] button.
Press [Enter] only.
A pop-up box will appear asking if you would like to send a query.
Answer “OK” to the popup box.
A new screen will appear that will allow you to enter a requested value and an explanation.
You will receive an inquiry number after you save the request. You can use this number to check to see if the DCC signed off on your inquiry.
After investigating, the DCC will take the appropriate action, and then use the DCC Sign-Off screen to indicate the final status of the request.
A “DCC Sign-Off to CC Initiated Data Inquiry” will be sent to the DCC and CC.
No further action is required.

1.5.4 Clinical Center change to data after 7 days

Retrieve the data.
Position the cursor on the field to be changed (only make one change per each inquiry).
Press the [Change Value] button.
A new screen will appear that will allow you to enter a requested value and an explanation.
Enter the new value as well as text describing the desired change. The DCC will use this response to investigate the request.
You will receive an inquiry number after you save the request. You can use this number to check to see if the DCC signed off on your inquiry. (Also document this number on the hard copy of the form).

The DCC will take the appropriate action, and then use the DCC Sign-Off screen to indicate the final status of the request.
A “DCC Sign-Off to CC Initiated Data Inquiry” will be sent to the DCC and CC.
No further action is required.

1.6 Instructions: How to initiate and respond to queries

1.6.1 Clinical Center Initiation of Queries

Queries can be initiated by the Clinical Center as described in the above section on changing data.

1.6.2 Clinical Center response to a DCC initiated inquiry

You will receive a DCC initiated inquiry report through e-mail, or you can go to the Main menu, choose "Forms" → "Inquiry Forms" → "Form 902 - Center Response to DCC Inquiry" to find unanswered queries.
When the screen appears you can press [Execute Query] to retrieve all unanswered queries, or press [Enter Query] and enter the query # and then press [Execute Query].
If you do not enter an inquiry number all unanswered queries will be retrieved. You need to press [Next Record] to navigate to the other queries. Keep pressing [Previous Record] to get back to a previous query.
Position your cursor on the “DCC text” field.
Choose Edit->Edit if you want to read the entire explanation from the DCC as to why you are being queried.
Navigate to “New Value”.
Type a new value for the field being inquired. If a different field requires changing, leave it blank or enter N/A for not applicable.
Navigate to “CC text”, and enter an explanation for your value. This field must be answered in order for the DCC to take action. Please make sure that your explanation is specific and complete. The explanation can be up to 2000 characters. Click on the [Save and Exit] button on the bottom of the screen to save the text. Click on [Exit and Don’t Save] if you do NOT want to save the text.
The DCC will then make the appropriate updates to the database.
It is very important that the CC respond within 3 business days.

1.7 E-mail alias lists

From your center's DACxxxx study account at the DCC, you will have access to several pre-defined distribution lists. These include:

access-all	-	lists every known e-mail address for any DAC study participants including the clinical centers, central labs, drug companies, NIH personnel, committee members, etc.
access-cc	-	lists all 9 clinical centers, plus the DCC
access-dcc	-	lists all DCC members

A complete list of these e-mail addresses can be found in the DAC address directory.

1.8 Retrieving data from forms

1.8.1 Introduction

Data can be retrieved in several ways from the form application. In order to "query" data available in the database for the information on a given form application, the [Enter Query] and [Execute Query] functions can be used. The screen will be populated with the first set of patient data for the form application being accessed. By using the [Next Record] or [Previous Record] functions (record menu or triangular buttons just below the menu), you will have the ability to view the next or previous set of data.

There are different ways to retrieve data. You can execute simple queries that meet specific criteria, as well as complex queries that satisfy several conditions. The following topics are discussed.

- Matching exact values
- Entering variable conditions
- Matching values that meet a specified pattern

1.8.2 Matching exact values

Suppose you want to check on all instances of visits of the follow-up type for a given patient ID (10001 for example). The data entry screens can retrieve the record(s) that contains specifically these values. The following are general steps for retrieving records that match exact values:

1) Access the appropriate form via the menu system.
2) Use the [Enter Query] function.
3) Type the values you want to match into the appropriate fields.
   For this example, cursor to the Patient ID field and type 10001.
4) Use the [Execute Query] function.
5) Use [Next Record] or [Previous Record] to view the retrieved data.

NOTE: If no data meet the specified criteria, the following message will be displayed on the status line of your screen:

"FRM-40301: Query caused no records to be retrieved. Re-enter."

You must use [Cancel Query] if you decide not to complete the initiated query.

1.8.3 Entering variable conditions

Sometimes it is not practical to enter the exact values that you want retrieved data to match. For example, you might want to retrieve the following:

- All Form 11's with visit type = FV and visit number >6
- All Form 11's after 12/31/2002

Rather than entering an exact data value, you can enter a relational operator before the data values in one or more fields.

The following table shows some relational operators typically used:

Operator	Meaning	Example
=	equal to	= '01/01/2003'
!=	not equal to	!=6
>	greater than	>6
>=	greater than or equal to	>=6
<	less than	<6
<=	less than or equal to	<=6

For example, to select data that have a visit number >6, press [Enter Query] and type >6 on visit number field and press [Execute Query]. To select any Form 11's after 01/01/2003, press [Enter Query], type >=01/01/2003, and press [Execute Query].

1.8.4 Using pattern matching

Pattern matching provides the capability to fetch data where a value for a field fits a certain pattern. This is useful when specifying search criteria on "string" or character value fields.

When specifying a pattern "_" represents any single character and "%" represents any combination of characters. The "_" and "%" symbols are referred to as wild cards.

For instance, suppose you are interested in all patients that have the letter “A” in their NAMECODE.

1) Access any data entry screen containing NAMECODE.
2) Use the [Enter Query] function.
3) Place your cursor on a blank NAMECODE field.
4) Type %A% (case sensitive).
5) Use the [Execute Query] function.
6) Use the [Next Record] and [Previous Record] functions to view the retrieved data.

To further refine the search, to find all patients with an “A” and a “B” (“A” is before “B”, but not necessary beside “A”), restart the process by using [Enter Query], type %A%B in the namecode field, and then use [Execute Query}.

1.8.5 Count query hits

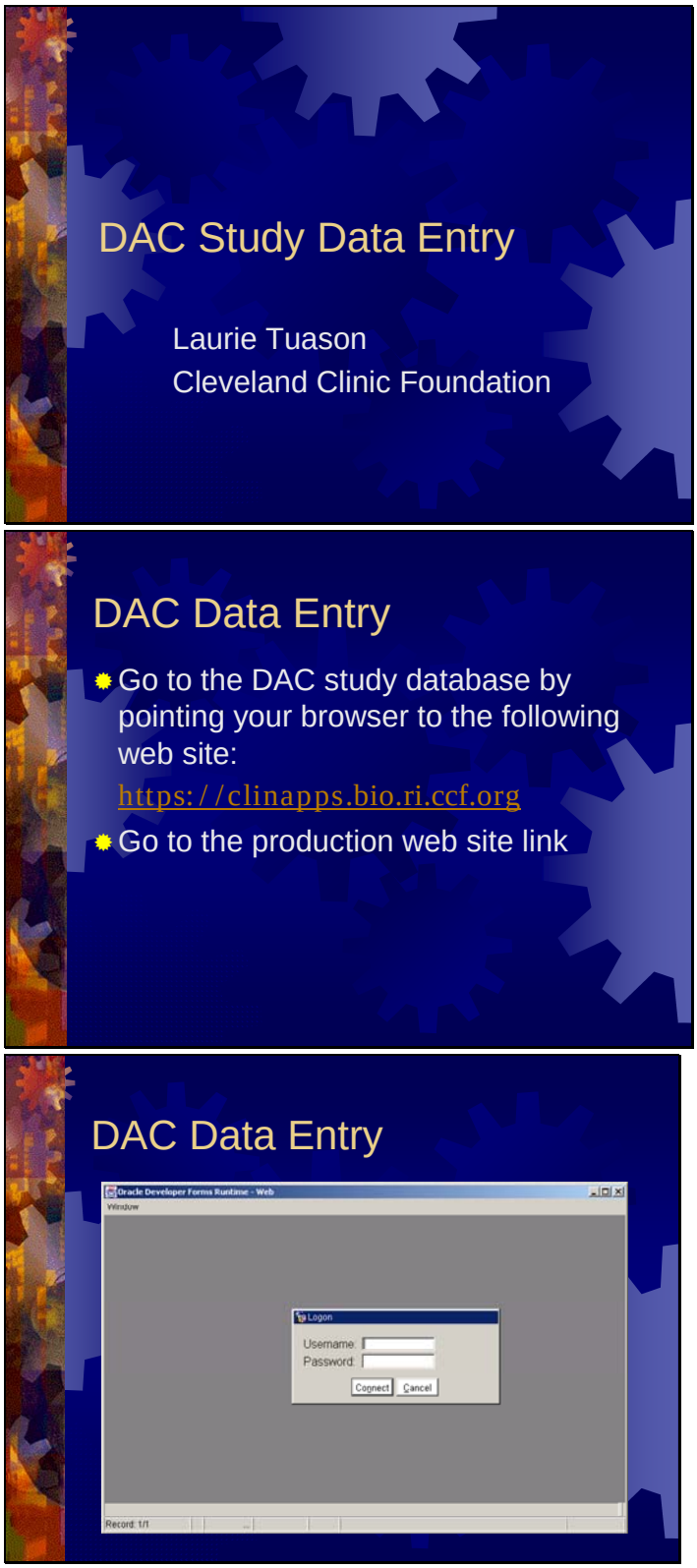
If you are interested in simply a count of how many records meet your search criteria, use the [Count Query Hits] function in place of the [Execute Query] function. Rather than having a screen full of data returned to your screen, you will receive a message indicating the number of "records" that meet the search criteria. For example, you will see something such as the following:

"FRM-40355: Query will retrieve 3 records"

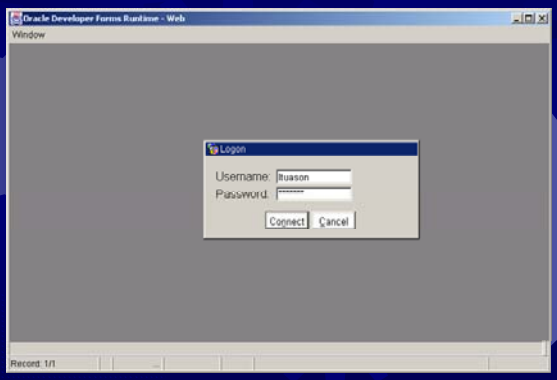
This function can be helpful if you are interested in determining a count of patients that meets some specific criteria.

Notes:
Queries can be issued in the first block of multi-block forms.

Appendix: Data Entry Presentation



DAC Data Entry



DAC Data Entry

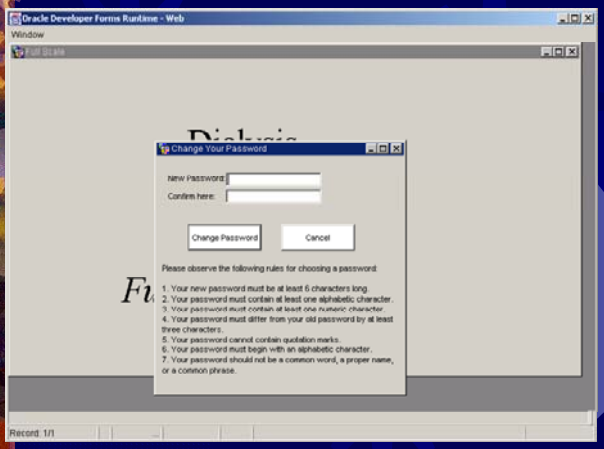
- Oracle username
  - First letter of first name
  - First seven characters of last name
  - Not case sensitive

DAC Data Entry

- Tab or click the mouse to get to the password field
- You will experience problems if you try to use the enter key here

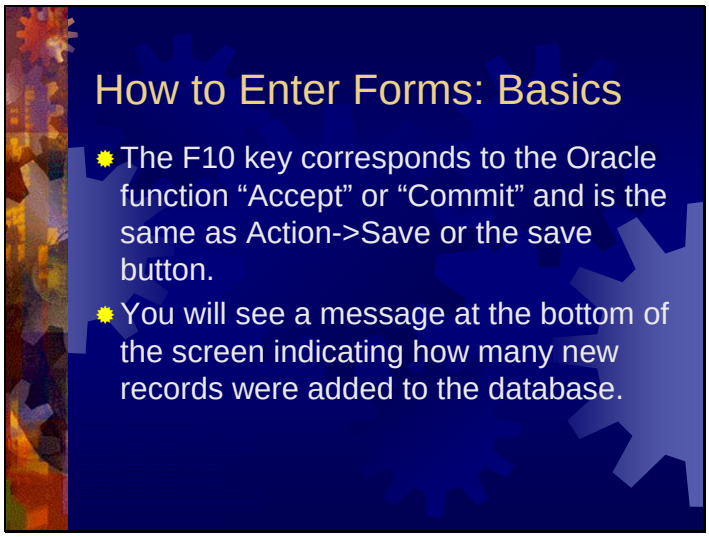
DAC Data Entry

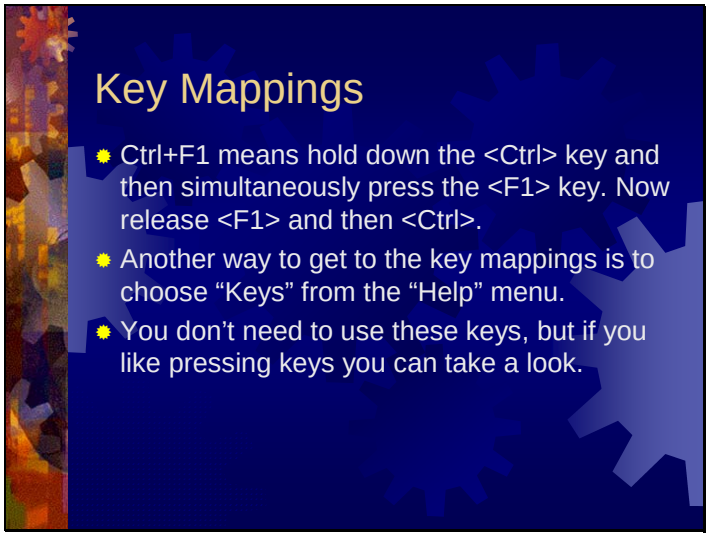
- Oracle password
  - Not case sensitive
  - Needs to be changed every 75 days
  - Must be at least six characters, start with a letter of the alphabet and contain at least one number
  - No special characters are allowed
  - Recycling is not allowed

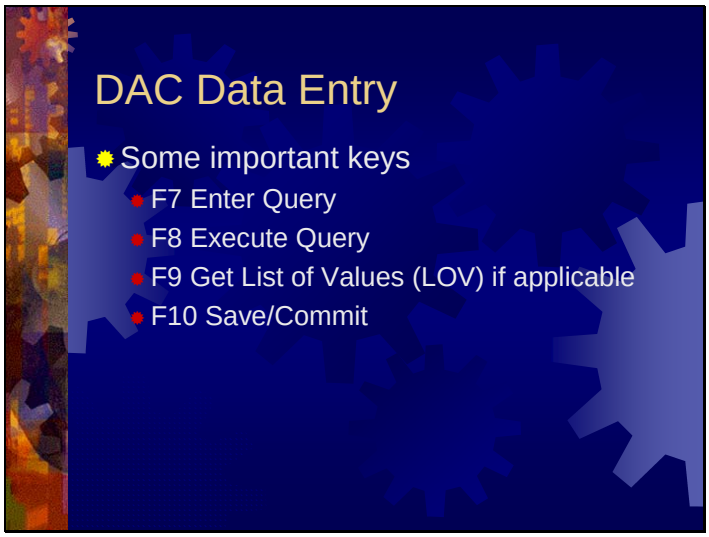


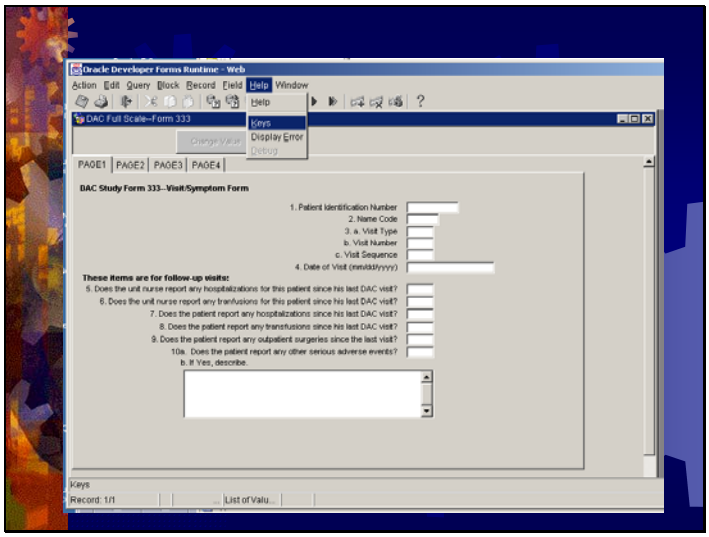
How to Enter Forms: Basics

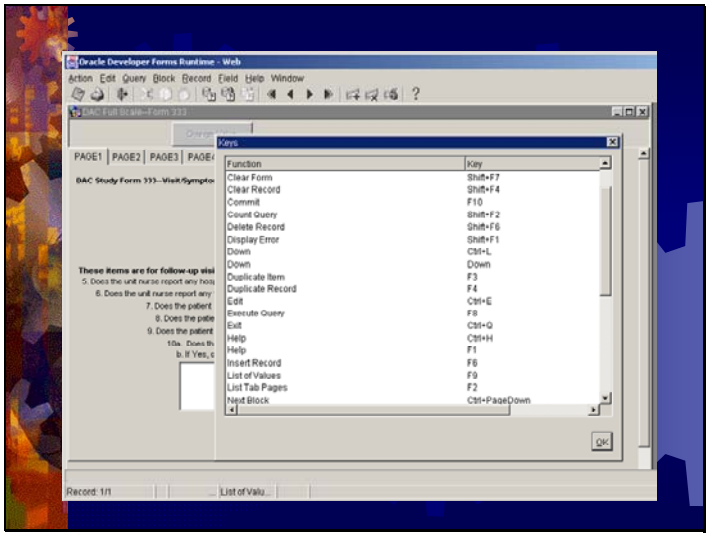
- You can hit enter, tab or click the mouse to move between fields on a form.
- Note that you will see bubble help when you move your mouse over the top buttons. The upper left button should be the save button.
- When you are finished entering data for a form, click on the save button, or choose “Save” from the “Action” menu, or press the F10 (Accept or Commit) function key.


How to Enter Forms: Basics
The F10 key corresponds to the Oracle function “Accept” or “Commit” and is the same as Action->Save or the save button.
You will see a message at the bottom of the screen indicating how many new records were added to the database.


Key Mappings
Ctrl+F1 means hold down the <Ctrl> key and then simultaneously press the <F1> key. Now release <F1> and then <Ctrl>.
Another way to get to the key mappings is to choose “Keys” from the “Help” menu.
You don’t need to use these keys, but if you like pressing keys you can take a look.

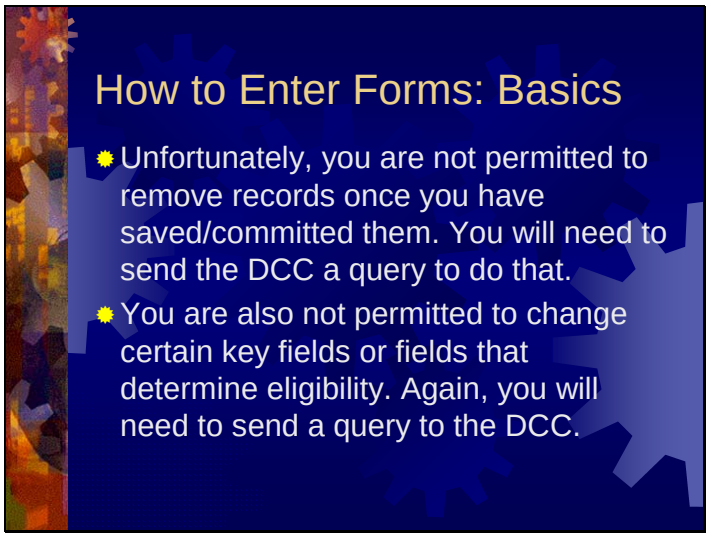

DAC Data Entry
Some important keys
F7 Enter Query
F8 Execute Query
F9 Get List of Values (LOV) if applicable
F10 Save/Commit

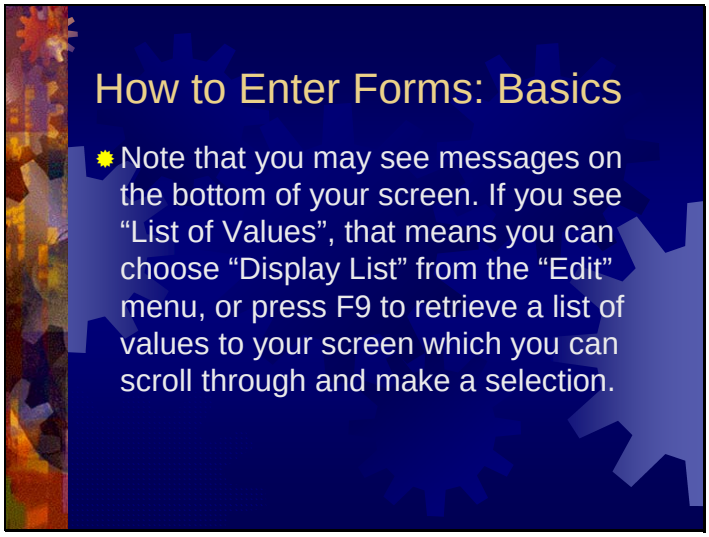




How to Enter Forms: Basics

- You can then get out of the form by pressing the “Exit” button or choosing “Exit” from the “Action” menu. There is also a speed key for this.
- If you want to enter another form you should navigate to the top of the form, and press the “Insert Record” button. “Insert” can be selected from the “Record” menu.


How to Enter Forms: Basics
Unfortunately, you are not permitted to remove records once you have saved/committed them. You will need to send the DCC a query to do that.
You are also not permitted to change certain key fields or fields that determine eligibility. Again, you will need to send a query to the DCC.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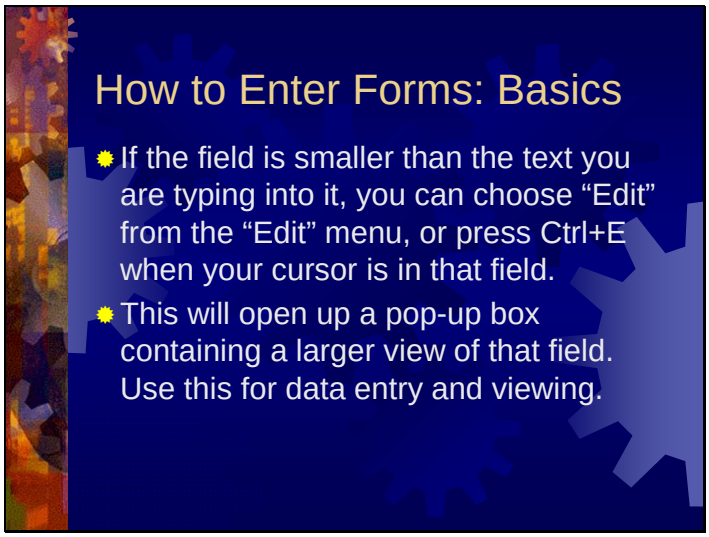
How to Enter Forms: Basics
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This will open up a pop-up box containing a larger view of that field. Use this for data entry and viewing.

How to Enter Forms: Basics

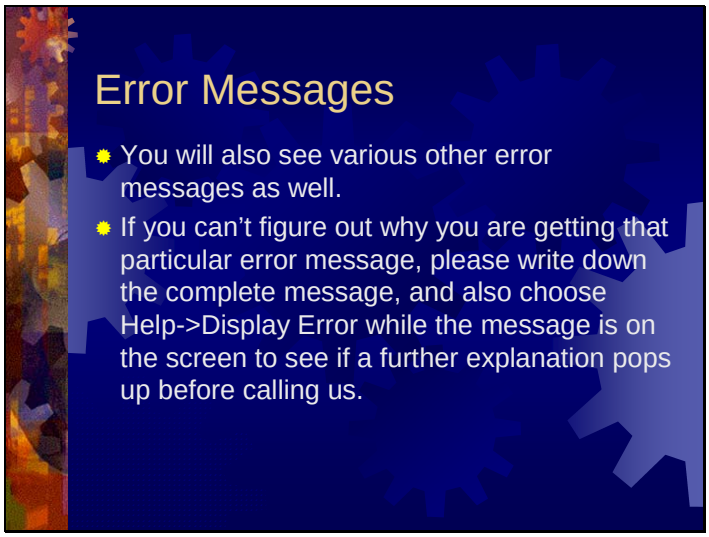
- Other useful Oracle functions that you can use are “Next Record” and “Previous Record”. You can find buttons and speed keys for these, and they are also on the “Record” menu.
- Use these to navigate between forms or detail records (contained in visit and medication forms).

Error Messages

- If you skip over a required field, you will see the error message:
  - Field must be entered.
- If you enter a value that is not possible for that field, you will see the error message:
  - Invalid value for *fieldname*.

Error Messages

- If you enter a non-numeric character in a numeric field, you will see the error message:
  - Legal characters are 0-9 - + E.
- If you try to update previously entered data without using the [Change Value] button, you will see
  - Field is protected against update.


Error Messages
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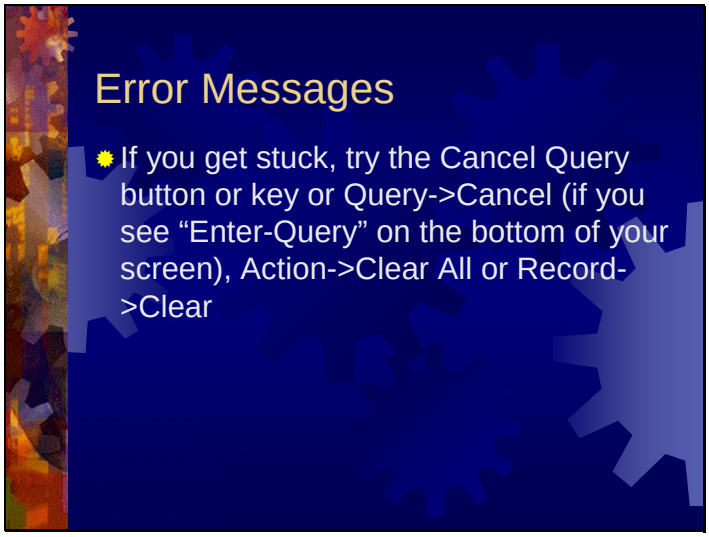
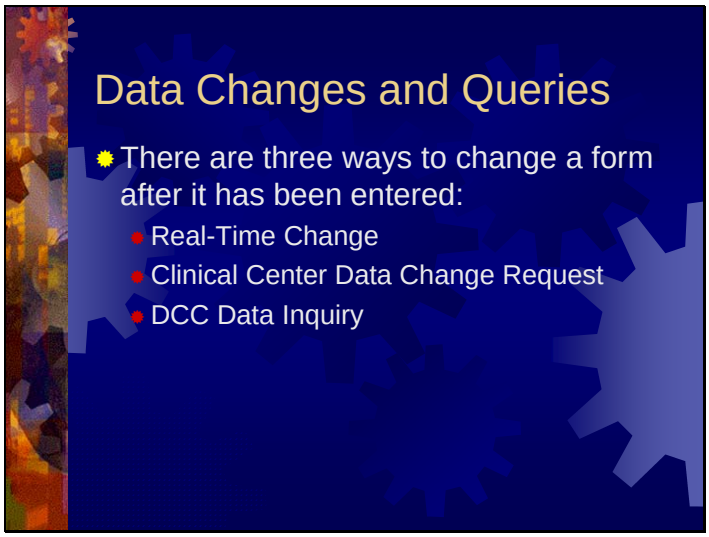
If you can't figure out why you are getting that particular error message, please write down the complete message, and also choose Help->Display Error while the message is on the screen to see if a further explanation pops up before calling us.


Error Messages
If you get stuck, try the Cancel Query button or key or Query->Cancel (if you see "Enter-Query" on the bottom of your screen), Action->Clear All or Record->Clear


Data Changes and Queries
There are three ways to change a form after it has been entered:
Real-Time Change
Clinical Center Data Change Request
DCC Data Inquiry

Retrieving Data

- Once the data has been entered, you can retrieve it to your screen for viewing.
  - Access the form # you want to view.
  - Press the [Enter Query] key or button.
    - Note the hint line will say “Enter-Query”.
  - Enter the Patient ID and visit number.
    - Visit number may not be applicable.
  - Press the [Execute Query] key or button.

Real-Time Changes

- Clinical Center change to data within 7 days, and the new value is acceptable to the database:
  - Query the data from the appropriate form.
  - Position cursor on field to be changed, and then press the [Change Value] button.
  - Type in the new value.

Real-Time Changes

- When you leave a field that you just changed you will receive a data change number.
- If the change does not pass the edit checks, change the value back to the original value, and then you will get a popup box that will ask you if you want to send a query to the DCC.

Data Change Within 7 Days But the Database Will Not Accept It

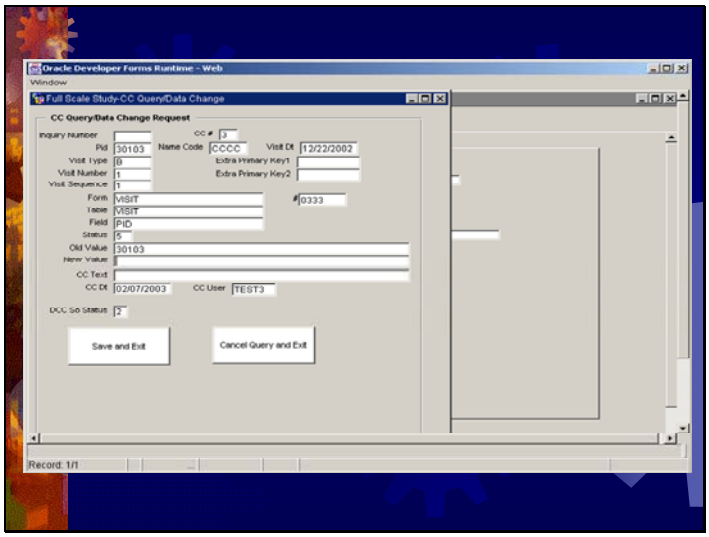
- Retrieve the data.
- Put the cursor on that field.
- Press the [Change Value] button.
- Press [Enter] only.
- A pop-up box will appear.
- Answer “OK” to the popup box.

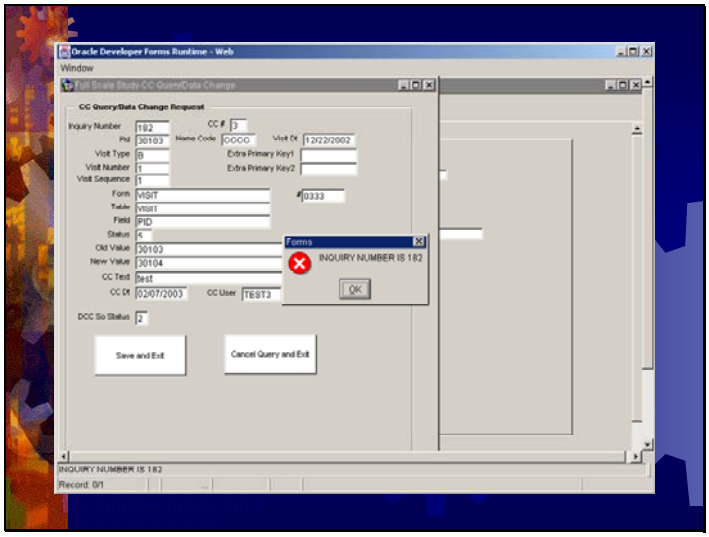
Data Change Within 7 Days But the Database Will Not Accept It

- A new screen will appear that will allow you to enter a requested value and an explanation.
- You will receive an inquiry number after you save the request. You can use this number to check to see if the DCC signed off on your inquiry.

Data Change Within 7 Days But the Database Will Not Accept It

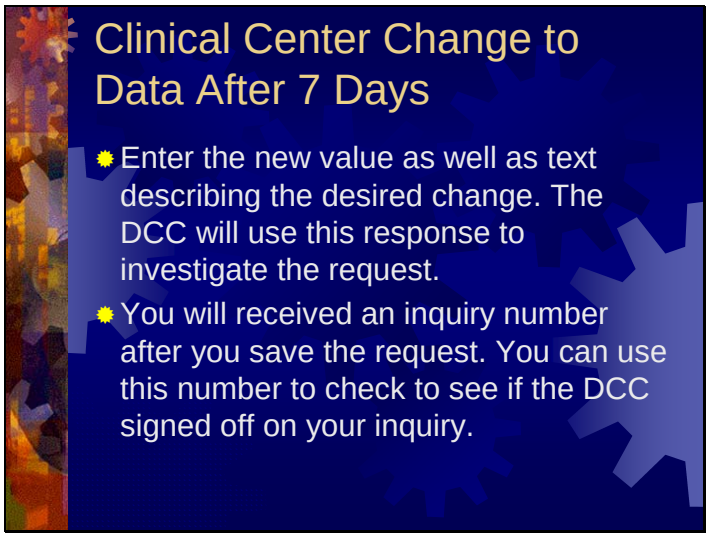
- After investigating, the DCC will take the appropriate action, and then use the DCC Sign-Off screen to indicate the final status of the request.
- A “DCC Sign-Off to CC Initiated Data Inquiry” will be sent to the DCC and CC.
- No further action is required.

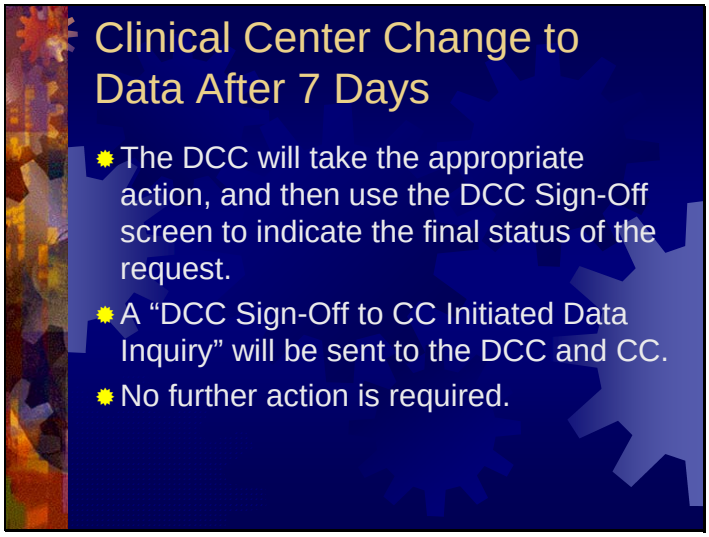


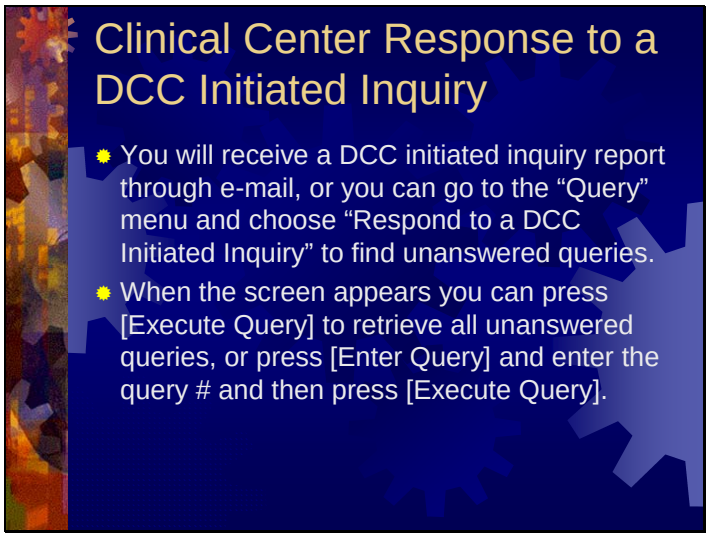


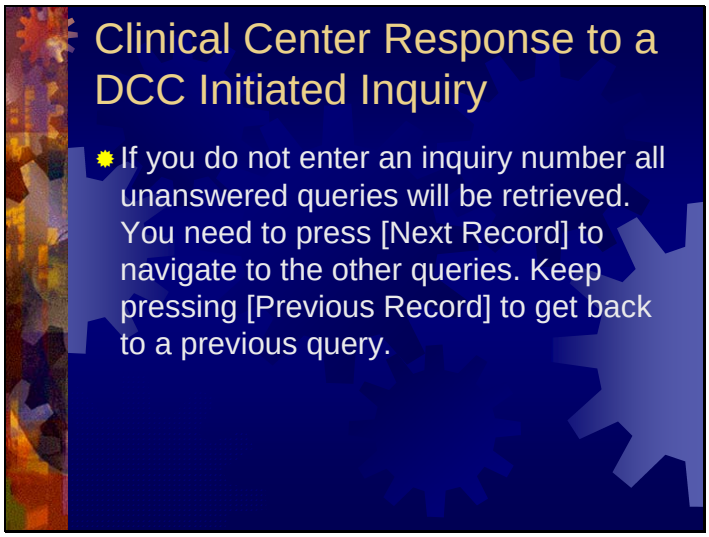
Clinical Center Change to Data After 7 Days

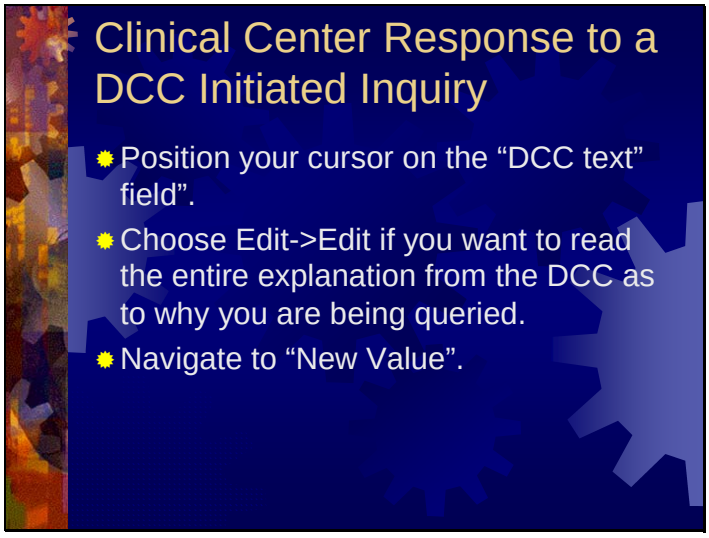
- Retrieve the verified data.
- Position the cursor on the field to be changed.
- Press the [Change Value] button.
- A new screen will appear that will allow you to enter a requested value and an explanation.

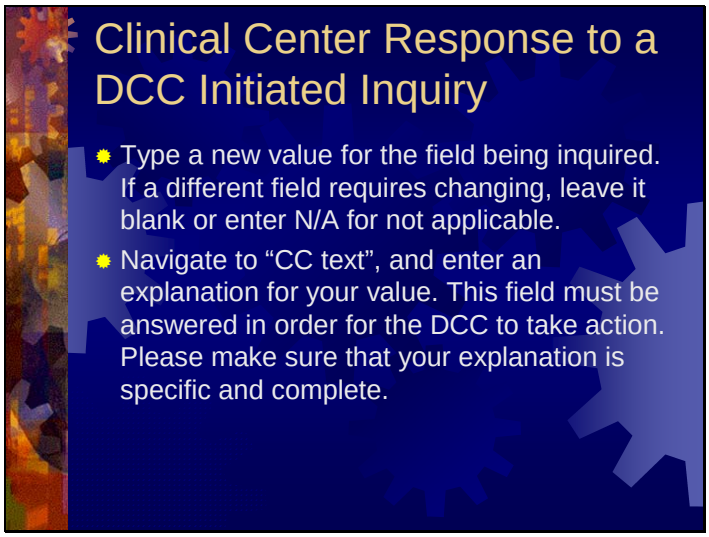

Clinical Center Change to Data After 7 Days
Enter the new value as well as text describing the desired change. The DCC will use this response to investigate the request.
You will received an inquiry number after you save the request. You can use this number to check to see if the DCC signed off on your inquiry.

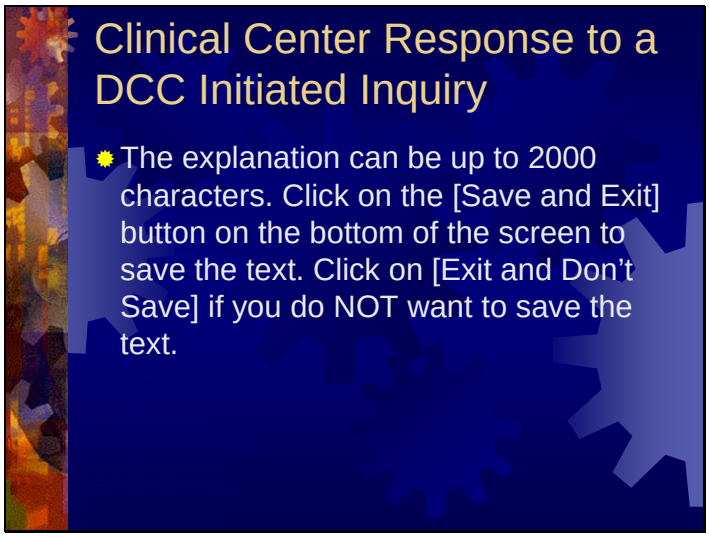

Clinical Center Change to Data After 7 Days
The DCC will take the appropriate action, and then use the DCC Sign-Off screen to indicate the final status of the request.
A “DCC Sign-Off to CC Initiated Data Inquiry” will be sent to the DCC and CC.
No further action is required.

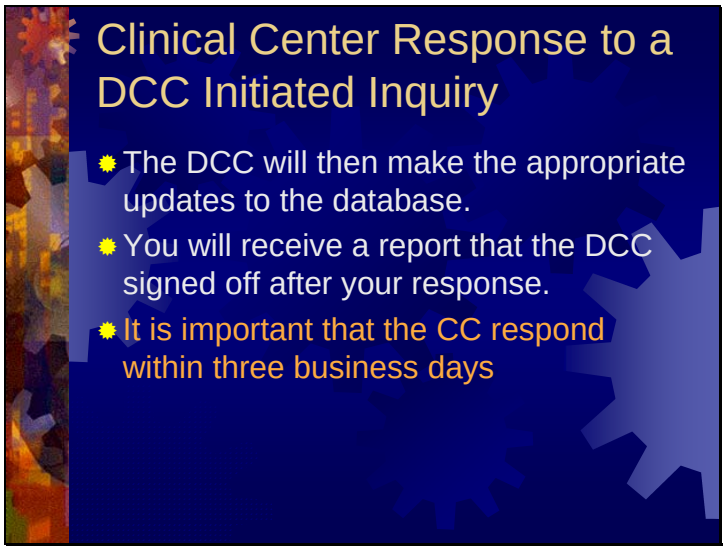

Clinical Center Response to a DCC Initiated Inquiry
You will receive a DCC initiated inquiry report through e-mail, or you can go to the “Query” menu and choose “Respond to a DCC Initiated Inquiry” to find unanswered queries.
When the screen appears you can press [Execute Query] to retrieve all unanswered queries, or press [Enter Query] and enter the query # and then press [Execute Query].


Clinical Center Response to a DCC Initiated Inquiry
If you do not enter an inquiry number all unanswered queries will be retrieved. You need to press [Next Record] to navigate to the other queries. Keep pressing [Previous Record] to get back to a previous query.


Clinical Center Response to a DCC Initiated Inquiry
Position your cursor on the “DCC text” field”.
Choose Edit->Edit if you want to read the entire explanation from the DCC as to why you are being queried.
Navigate to “New Value”.


Clinical Center Response to a DCC Initiated Inquiry
Type a new value for the field being inquired. If a different field requires changing, leave it blank or enter N/A for not applicable.
Navigate to “CC text”, and enter an explanation for your value. This field must be answered in order for the DCC to take action. Please make sure that your explanation is specific and complete.


Clinical Center Response to a DCC Initiated Inquiry
The explanation can be up to 2000 characters. Click on the [Save and Exit] button on the bottom of the screen to save the text. Click on [Exit and Don't Save] if you do NOT want to save the text.


Clinical Center Response to a DCC Initiated Inquiry
The DCC will then make the appropriate updates to the database.
You will receive a report that the DCC signed off after your response.
It is important that the CC respond within three business days

2. ADMINISTRATIVE STRUCTURE

The organizational structure of the Study will include:

1. The Data Coordinating Center (DCC)
2. 7 Clinical Centers (CCs)
3. The NIH Project Office

Representatives from the DCC, the CCs, and the NIH Project Officer will form the Steering Committee. The study will be overseen by a Data Safety Monitoring Board/External Advisory Committee. The DSMB/EAC will be composed of physicians and statisticians.

An Executive Committee made up of the NIH Project Officer, the Principal Investigator at the DCC, the Chair of the Steering Committee, and one Clinical Center Principal Investigator representative will have phone calls on a regular basis to discuss study progress and plan for meetings of the Steering Committee and the DSMB/EAC.

A Publications and Ancillary Studies (PAS) Committee will be appointed by the Steering Committee to review and approve proposed abstracts, presentations, and publications according to an established set of rules. For example, no participating institution may publish individual findings from the study without approval of the PAS Committee. This Committee will also review and approve all proposed studies which are ancillary to the Study. The PAS Committee will have conference calls as needed.

A Recruitment Committee will be appointed by the Steering Committee to revise tools and patient consent forms for recruitment. This committee will also monitor recruitment efforts.

A Forms Committee will be appointed by the Steering Committee to revise all Study Forms.

A Quality Control Committee will be appointed by the Steering Committee and will develop and monitor quality control of data collection.

Other committees will be formed by the Steering Committee as required.

3. PROTOCOL CHANGES

3.1 General principles

During the conduct of the Study, protocol changes are not desirable and should not be made unless patient safety is compromised or unless new information arises, strongly suggesting changes that would strengthen the scientific validity of the study. In the event that alterations are necessary, the following procedures will be followed.

3.2 Procedures

Recommendations for potocol changes may originate from the External Advisory Committee, the NIDDK, the Data Coordinating Center, or one of the working committees. All proposed changes will be submitted to the Executive Committee for consideration. The Executive Committee will make a recommendation to the Steering Committee as to whether the proposed modification merits consideration and the method of incorporating the proposed change into the protocol. Approval by

the Steering Committee must have support from two-thirds of the voting members. The recommendations of the Steering Committee will then be presented to the External Advisory Committee, which will advise the NIDDK as to whether the protocol change is advisable. The NIDDK may seek further advice from other experts outside the Study before making the final decision whether to approve the protocol change.

4. DAC STUDY PUBLICATION POLICY

4.1 Introduction

The policy of the Study concerning publications and presentations is designed to achieve five objectives:

1. To assure timely publication of the results of the Study to the appropriate professional audiences,
2. To avoid premature publication of results that might compromise the performance of the study (such as by publication of trends of results before such trends become statistically convincing) or that might compromise the ability to publish the results in high quality peer reviewed journals (as by premature release to the lay press),
3. To maintain high standards of quality of all material published by the Study,
4. To guard against duplicate publication of results by assuring absence of overlap of materials prepared by various writing committees, and
5. To assure equitable attribution of credit to all of the professionals participating in the Study.

To accomplish these ends, it is the policy of the Study that preparation of all publications or presentations, other than materials prepared for local publicity purposes, must be assigned by the Study Chairman after consultation with Chairman of the Publications and Ancillary Studies (PAS) Committee to specifically appointed writing committees, and that all such materials must be reviewed and approved by the PAS Committee and/or the Steering Committee before publication.

4.2 Scope of policy, and exception for local publicity materials

All material to be presented orally or submitted for publication or dissemination by individuals associated with the Study and dealing with any aspect of the Study must receive prior review and approval by the PAS Committee/Steering Committee with the following exception:

Material prepared for publicity purposes either nationally or within the recruitment region of a DAC Clinical Center, or presented orally or as handouts or posters to professional audiences solely for the purposes of informing the profession of the Study and its objectives, need not be reviewed by the PAS Committee. Such material must be limited to a background discussion of hemodialysis as a treatment for end-stage renal disease and a description of the Study organization, objectives, and entrance criteria, and to results of the study that have previously been presented to a scientific body or published in a scientific journal. It must not include discussion of any previously unpresented and unpublished Study outcomes or other citable professional reference.

4.3 Source of suggestions for publications of the study

Suggestions for topics appropriate for preparation of abstracts, peer reviewed papers, or chapters and reviews are made by the PAS Committee. In addition, all participants in the Study are invited to suggest topics appropriate for preparation as abstracts, peer reviewed papers, or chapters and reviews from the Study. Such suggestions should be made to the DCC and the Chair of the PAS Committee, who shall review the request to be certain that there is no overlap with materials

previously assigned to other writing committees. Where such overlap exists, the Chair of the PAS Committee may make recommendations to the Study Chair that the suggestion be referred to an existing writing committee, that additional study participants be added to existing writing committees, or make other suggestions to resolve the overlap. However, final decision in this matter will be made by the Study Chair after consultation with the Chair of the PAS Committee.

It is the policy of the Study to encourage non-physician professionals to prepare scientific presentations to their own professional meetings and to prepare scientific papers for their own professional journals in addition to participating in the preparation of papers for medical journals. Since the subject matter of these reports and papers may well overlap with material being prepared by writing committees for medical journals, it is the policy of the Study that under these circumstances, rather than forming a new writing committee, such non-physician professionals should be added to the existing writing committee concerned with related matters, specifically for the purposes of preparing such reports. The authors of these presentations and reports will be the members of the writing committee, with first author being the individual added to the committee for this purpose, using the appropriate authorship style described in section 4.6.

In addition, the PAS Committee will formulate and maintain a list of suggested topics that should be prepared for publication, to assure that all completed aspects of the work of the Study are reported to the scientific community in a timely fashion.

4.4 Assignment of writing committees

Topics suggested for presentation or publication that do not overlap with an existing committee will be circulated to the Principal Investigators of all clinical centers, DCC, and the NIH. These groups are requested to suggest and justify names for lead authors (Chair of writing committees) and co-authors. These names will be collated and reviewed by the PAS Committee. A recommendation for a writing committee will then be made to the Chair of the PAS Committee who will decide on the final composition of the writing committee. If a topic is suggested by a participant of the Study, the writing committee will be formed as just described except that the person making the suggestion will be considered as the potential lead author. The Principal Investigator of an ancillary study should be considered for lead author of material derived from this study. If only a subset of clinical centers participate in an ancillary study, only investigators from these centers should be considered to be on writing committees relating to this study. Appointments of writing committee chairmanships will be made in an equitable fashion to all professionals -- physicians, study coordinators, nurses, statisticians, and others -- in a fashion that recognizes the special contributions of each member of the Study to its performance. Any dispute about lead author or co-author will be settled by the Chair of the PAS Committee. In all cases, writing committees dealing with an issue that requires analysis of data by the Data Coordinating Center will have a member of the DCC assigned to it.

From time to time it may be expedient for the chairmanship of a writing committee to be reassigned to another member of that committee, or for members to be dropped from or added to a writing committee. The Chair of the PAS Committee is authorized to make such changes with the consensus of the members of the writing committee, or on his own authority where there is clear cause.

4.5 Classes of reports of the study

There are four classes of reports of the Study:

A. Reports of the major outcomes of the Study. It is assumed that there will generally be only one or two such reports derived from each Phase of the Study.

B. Reports addressing in detail one aspect of the Study, but in which the data are derived from the entire study.

C. Reports of data derived from a subset of centers by members of the Study (e.g., substudies or ancillary studies), or originally conceived analyses of data from the entire Study (original analyses).

D. Reports of investigations initiated outside the Study, but using data or samples collected by the Study. The investigators may be DAC or other investigators, but the source of the ideas and the funding for the study will have been derived outside the Study itself. Writing committees for this type are formed and presentations and publications made in accordance with the general policy rules for DAC publications. However, the Principal Investigator of an ancillary study should take primary responsibility in publishing the results of the study.

4.6 Authorship policy

The authorship policy of the Study must achieve two somewhat conflicting goals. First, it is recognized that the findings of the study, especially the findings reported in Type A and B reports, are derived from the efforts of the entire DAC professional staff. Thus, all reports, of whatever Type, must give recognition to all the participants of the Study, and reports of Types A and B must give primary recognition to the entire study professional staff. On the other hand, it is recognized that the preparation of a manuscript places special demands on the assigned writing committee, and especially on the Chair of the writing committee. Further, recognition of special effort and achievement is important in the professional careers of the study staff, and specific listing as an author is a significant motivating factor that will help assure prompt completion of writing assignments and timely publication of the results of the Study. The DAC authorship policy attempts to recognize each of these goals. The authors of DAC publications will be listed as detailed below for each type of publication.

Type A publications:
abstracts: the Dialysis Access Consortium (DAC) Study Group[1], presented by XXXX.
papers: the Dialysis Access Consortium (DAC) Study Group[1], prepared by XXXX.
[1]The DAC participant box, detailed below, must be included in these papers. If a journal's publication policy does not allow authorship by a group, the authors will be listed first as in Type B publications.

Type B publications:
abstracts and papers: Authors' names, and the Dialysis Access Consortium (DAC) Study Group[1]
[1]The DAC participant box will be included in all papers if this can be arranged with the publisher. Otherwise it will be referenced in one of the Type A papers. It will not be practical to publish the entire list of participants in abstracts.

Type C and Type D publications:
abstracts and papers: authors' names and the DAC Study
[1]The participant box will be included in all Type C papers if this can be arranged with the publisher. Otherwise it will be referenced in one of the Type A papers. In Type D papers, the list of participants will be referenced in all cases. It will not be practical to publish the entire list of participants in abstracts.

4.7 Listing of professional participants in the participant box

The DAC participant box will list all professionals who have participated in the Study for a minimum of one year. The participants for each participating center will be listed together, with the center Principal Investigator listed first, and identified as "P.I." followed by the other center staff

listed alphabetically. Each participant will be listed only by his/her professional and academic degrees, not by the specific position that he/she held in the study. The centers will be listed in the following order:

NIH
Study Chair
Clinical Centers (in alphabetical order)
DCC

Prior to the publication of any papers from the Study, each center will be asked to confirm and approve the listing of the personnel from that center in the Participant Box.

4.8 Acknowledgement of support and reprint addresses

Acknowledgement of grant support to be used in all papers reporting results of the Study. (In the case of ancillary studies, additional sources of support should be cited as appropriate).

The Study is supported by the Division of Kidney, Urologic and Hematologic Diseases of the National Institute of Diabetes and Digestive, and Kidney Diseases, NIH. Additional support is provided by the (list of any industrial or other support).

The following information regarding reprint requests should be included in all papers prepared for the Study. The DCC will maintain an inventory of all Study publications and will mail out the reprints.

Requests for reprints should be addressed to:

DAC Data Coordinating Center
Department of Biostatistics and Epidemiology, Wb4
Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195

4.9 Schedule for completion of writing assignments and resolution of overlaps between writing committees

At the time that a writing committee is constituted, the PAS Committee will establish a timetable for the completion of the writing assignment that takes into account deadlines for the publication, the amount of time that will be required for data analysis, the other commitments of the DCC, and the priority of the publication. The Chair of the Writing Committee should provide the Chair of the PAS Committee a general outline of the proposed publication within a month of receiving its assignment, to permit the PAS Committee to identify any overlap with the assignments of other writing committees, and to permit establishment of an appropriate timetable. Where overlaps of materials to be covered by different writing committees are detected, the Chair of the PAS Committee will attempt to resolve these informally with the chairs of the involved writing committees. In the event that this effort at mediation fails, the issue will be resolved by the Chair of the PAS Committee. The Chair of the PAS Committee will report at each meeting of the Steering Committee on the progress of the various writing committees.

4.10 Review of abstracts and presentations by the PAS committee

To expedite review of abstracts, oral presentations, and any other material for which there is an explicit deadline for submission, the following procedure will be used:

1. The writing committee wanting to submit an abstract, give a talk, or submit other material for which there is an explicit submission deadline shall contact the Chair of the PAS Committee. In the event that the Chair is unavailable, the Vice Chair may be contacted. The Chair (or Vice Chair) will name a subcommittee of two members of the PAS Committee to review the submitted material and will inform the submitter and this subcommittee of their appointment. The submitted material should be sent by the submitter directly to these two reviewers so as to reach them no fewer than seven (7) days prior to the deadline for submission.
2. The members of the subcommittee shall review the material and notify the Chair solely of their approval or disapproval. If there is unanimous approval, the PAS Committee Chair (or Vice Chair) shall inform (through the DCC) the submitter that he/she has Study approval for the submission.
3. All materials submitted for approval in this fashion will be distributed, together with notice of the disposition, to all members of the PAS Committee and to the Chair of the Steering Committee. All approved materials will also be forwarded to the NIH Project Officer, and for record purposes to the Principal Investigator of the Data Coordinating Center, and will be distributed to the entire membership of the Steering Committee at the next meeting of that Committee.

Approval for submission of an abstract or oral presentation does not automatically grant approval of the material ultimately to be presented. This material must also be submitted for review and approval in accordance with the above rules at least seven (7) days prior to the scheduled oral or poster presentation. Normally this review will be done by the same subcommittee of the PAS Committee that reviewed the initial abstract.

1. In the case of an oral presentation, an outline of the talk and a copy of any slides to be used must be submitted for review.
2. In case of a poster presentation, the content of the poster material must be submitted for review.

4.11 Review of papers by the PAS committee

All materials for which there is no explicit deadline, and all full papers that may result in a citable scientific reference, whether or not there is a deadline for submission, must be submitted to the Chair of the PAS Committee for formal review by the entire Committee. If there is a deadline for submission of a formal paper, it is the responsibility of the submitter to be certain that it is submitted to the Chair, PAS Committee, at least 30 days prior to the deadline, to permit such review. This review will be conducted as follows:

1. The Chair, PAS Committee, shall appoint a panel of two primary reviewers, one of which must be a PAS Committee member, and one of whom may be any professional member of the Study Group with appropriate expertise. The Chair (through the DCC) shall distribute the material to all members of the PAS Committee and to the Principal Investigator of each center participating in the Study. The two members of the review panel shall each prepare and send to the Chair a written critique of the submitted material for distribution to the entire PAS Committee. The P.I.s of the various clinical centers will be given a deadline by which any comments or critiques that study personnel at their center may wish to make must be received by the Chair, PAS Committee. This mechanism will assure that each professional participating in the Study will have an opportunity to review

any materials that will be submitted for publication bearing his/ her name as a participant and co-author.

2. The Chair, PAS Committee shall schedule a meeting of the Committee (generally by conference call), including review of papers and other non-time critical materials as Agenda items. The reviews of the panel members and any comments received from the center P.I.s will be distributed to the committee with the agenda.
3. While discussion of the submitted papers and other materials will be led by the two appointed reviewers, all members of the Committee will be invited to participate and all shall vote on final disposition.
4. In keeping with medical editorial traditions, there are three possible dispositions: approval of the material as submitted (possibly with some recommendations for revision that do not require re-review), non-acceptance of the material as submitted but with recommendations to the authors for revisions and resubmission, and disapproval of the material.
5. The Chair of the PAS Committee shall be responsible for communicating the decision of the Committee to the authors, together with a summary of suggestions for revision, if any. If the Committee has recommended non-acceptance of the material as submitted but with suggestions for revision and resubmission, he and the writing committee may agree not to proceed with a report to the Executive or Steering Committees at that time, pending revision and resubmission.
6. If there is a recommendation for approval or final approval or final disapproval of submitted material, or if there is a recommendation for revision which is contested by the author(s), the Chair, PAS Committee shall report this outcome in writing to the Executive Committee for final action. In the case of a dispute between the PAS Committee and the author(s), the Chair, PAS Committee shall provide a copy of the submitted material and a summary critique to the Executive Committee, and the chair of the writing committee shall be given an opportunity to submit a rebuttal.
7. The authority to grant final approval for a formal scientific paper of the Study rests with the Steering Committee, or the Executive Committee in the interim between meetings of the Steering Committee.
8. All materials submitted for approval in this fashion will be forwarded, together with notice of disposition, to the Chair of the Steering Committee. All materials receiving final approval by the Executive or Steering Committee will also be forwarded to the NIH Project Coordinator, and for record purposes to the Principal Investigator of the DCC.
9. In the event that editors of a scientific journal to which an approved DAC scientific manuscript is submitted suggest or require revisions of the manuscript, the revised manuscript must be reviewed again by the PAS Committee prior to resubmission in the same manner as described above. Generally, the Chair will appoint the same reviewers who first read the paper to review the revision, and every effort will be made to expedite such repeat reviews.

4.12 Criteria for review of materials by the PAS committee

All materials submitted to the PAS Committee will be reviewed for acceptability on two grounds:

1. Materials shall be evaluated for scientific accuracy, quality, importance, and style. The intent is to assure that all approved DAC materials reflect well on the Study.
2. Materials shall be reviewed to assure appropriateness of the content. The material shall be reviewed to assure that it conforms to the assignment to the writing committee, addressing satisfactorily the assigned topics and not encroaching on material assigned to other writing

groups. In addition, the material shall be reviewed to assure that it does not divulge prematurely the outcomes or findings of the Study or compromise the eventual publication of DAC findings in high quality peer reviewed journals. In this later regard, it must be remembered that publication of reports of more than 400 words are generally taken to constitute prior publication of a body of material and will generally preclude subsequent publication of the material in a peer reviewed journal.

4.13 Maintenance of records of publications and presentations

The DCC will maintain a record of all official publications and presentations of the DAC Study, separated into the following categories:

1. Peer reviewed papers accepted and published in professional journals
2. Invited editorials, reviews, chapters, and books
3. Abstracts published in citable journals
4. Other presentations at regional or national meetings that do not result in a citable abstract

This listing will be updated at least every six months and will be distributed to the P.I. of each center participating in the Study, together with reprints or copies of any papers, chapters, or abstracts accepted for publication since the last update. This is intended to facilitate the updating of curricula vitae and the timely submission of reports to CRCs and other such organizations within the participating centers.

4.14 Acknowledgement and acceptance of DAC Study policies on publications and presentations by the professional participants in the study

To assure that all professionals involved with the Study know and understand the policies of the Study, and to preclude the possibilities of misunderstandings after initiation of the Study, each professional member will be given a copy of this Chapter and will be asked to sign a Statement of Understanding Form (see next pages) listing the major provisions of the Chapter and attesting to his/her acceptance of these policies. The original of the signed Statement of Understanding Form should be returned to the DCC for record purposes. The copies of the Chapter and the signed Statement of Understanding Form should be kept by the DAC professional participant for reference.

DAC STUDY

Statement of Understanding of Policy
Concerning Publications and Presentations

To assure that all professionals involved with the DAC Study know and understand the policies of the DAC Study regarding publications and presentations, and to preclude the possibilities of misunderstandings after initiation of the Study, each professional member will be given a copy of protocol section XX detailing these policies and will be asked to sign this form attesting to his/her acceptance of these policies, which are summarized below.

I. Material Covered by These Policies

All material to be presented orally or submitted for publication or dissemination by individuals associated with the DAC Study and dealing with any aspect of the DAC Study must receive prior review and approval by the Publications and Ancillary Studies (PAS) Committee with the following exception:

Material prepared for publicity purposes either nationally or within the recruitment region of a DAC Clinical Center, or presented orally or as handouts or posters to professional audiences solely for the purposes of informing the profession of the DAC Study and its objectives, need not be reviewed by the PAS Committee. Such material must be limited to a background discussion of the issue involved and a description of the DAC Study organization, objectives, and entrance criteria, and to results of the Study that have previously been presented to a scientific body or published in a scientific journal. It must not include discussion of any previously unpresented or unpublished DAC Study outcomes or results, and must not itself result in publication of an abstract or other citable professional reference.

II. Assignment of Writing Committees for Publications

The PAS Committee will solicit volunteers for each writing committee for abstracts and publications and make a recommendation on the writing committee and topic to the DAC Steering Committee Chair. The DAC Steering Committee Chair will decide on the final composition and topic of the committee after consultation with the Chair of the PAS Committee. All interested individuals will be given a chance to request appointment to the various writing committees, but the final appointments will be by the Chair of the Steering Committee.

III. Authorship

The DAC policies specify the authorship for each of the four different classes of publication or abstract (See Section 4.5 of the protocol). These policies are binding and must be followed in all publications derived from the DAC Study.

IV. Review of Abstracts

All abstracts must be reviewed and approved by members of the PAS Committee before being submitted (See Section 4.10 of the protocol). These abstracts must be delivered to the reviewers at least seven (7) days before the submission deadline to permit time for this review. Abstracts not approved in this fashion will be withdrawn by the DAC Study.

V. Review of Materials for Presentations

Approval for submission of an abstract does not automatically grant approval of the material ultimately to be presented. This material must also be submitted for review and approval by members of the PAS Committee at least seven (7) days prior to the scheduled oral or poster presentation.

VI. Review of Papers

All materials for which there is no explicit deadline, and all full papers that may result in a citable scientific reference, whether or not there is a deadline for submission, must be submitted to the Chair of the PAS Committee for formal review by the entire Committee (see Section 4.11 in the protocol). If there is a deadline for submission of a formal paper, it is the responsibility of the submitter to be certain that it is submitted to the Chair of the PAS Committee at least 30 days prior to the deadline, to permit such review.

VII. Certification by DAC Study Participant

This is to certify that I have read the above statement of policies of the DAC Study with regard to publications and presentations, understand it, and agree to abide by it in matters of all publications and presentations derived from the DAC Study.

_____ _____

(Signature) (Date)

_____

(Print or Type Name and Institution)

5. DAC STUDY ANCILLARY STUDIES

5.1 Definition

Ancillary studies are defined as research studies employing participants, biological specimens or the database from the main study which have relevance to the overall objectives of the main study, but are not part of the mainstream protocol for all centers.

5.2 Funding of ancillary studies

Ancillary studies will not be funded by the main study, but will require an independent source of funding.

5.3 Approval procedures

1. Proposals may be generated by a participating clinical center or by other interested investigators providing at least one center is included as a co-investigator. These applications are submitted to the Data Coordinating Center for review by the Publications and Ancillary Studies Committee.

2. There will be a two-step review by the Publications and Ancillary Studies Committee. The first step is to have the proposal reviewed for its concept and general acceptability. This will be done in 2-4 weeks. A short description of the study including the following information should be submitted.

   a. Hypothesis to be tested.
      Specific outcome variables that will be assessed.
      Need for data from the DCC.

   b. Significance of the proposed ancillary study.
   c. How will performance of this ancillary study affect the main Study? Specifically:

      i. Will there be any deviations from the main Study protocol? If so, what will they be?
      ii. How much additional participant, staff and DCC time will be required to complete this ancillary study?
      iii. Will additional funds be requested for the study and what will their source be?

3. If this proposal is acceptable in concept to the Publications and Ancillary Studies Committee, a more detailed proposal should be written and submitted for review. This proposal should include detailed information on:

   a. Hypothesis to be tested.
   b. Significance of the study.
   c. Conduct and performance of the study including specifying the study population and the data to be collected.
   d. Sample size justification.
   e. Quality control of the data.
   f. Data analysis methods.

4. The Publications and Ancillary Studies Committee will make its recommendation within 2-4 weeks and submit it to the Steering Committee. The proposal will be discussed and voted upon at the next Steering Committee meeting. At that time, the applicant has the option to discuss his or her proposal before the Steering Committee.

5.4 Publication of ancillary study results

The policies regarding publications and presentations of the result of ancillary studies are the same as those governing the publications and presentations of results of the main study (see section 16). These policies are designed to:

1. Assure timely publication of the results to the appropriate professional audiences.
2. Avoid premature publications of results that might compromise the performance of the main study or that might compromise the ability to publish the results in high quality peer reviewed journals.
3. Maintain high standards of the published material.
4. To guard against duplicate publication of results.
5. Assure equitable attribution of credit to all of the professionals participating in the ancillary study and the Study.