

**CONFIDENTIAL**



**NAPRTCS**

**INTERNET USER'S GUIDE**

Prepared by:

Data Coordinating Center

The EMMES Corporation

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# 1 INTRODUCTION

The North American Pediatric Renal Trials Collaborative Studies (NAPRTCS) Advantage Electronic Data Capture System (EDC) can be accessed from any computer connected to the Internet. Advantage EDC allows participating sites to submit validated data forms and receive immediate feedback from NAPRTCS using secure transmission technology.

## 1.1 The NAPRTCS Advantage EDC User's Guide

This document explains the basic procedures for performing data entry over the Internet. This User's Guide provides information on accessing the software and entering data. Illustrations of the data entry screens, navigation bars, and system-warning messages are included throughout the User's Guide.

**For interested readers, the remainder of the Introduction Section includes additional background material, describes the advantages of using an Internet data entry system, discusses the functional requirements of the software, briefly describes the system architecture and addresses areas of future development.**

For instructions regarding access and use of NAPRTCS Advantage EDC, proceed to **Section 3, Getting Started**.

## 1.2 Additional Background Material

### 1.2.1. Advantages of Internet Data Entry

Advantages of an EDC system include computer platform independence, access to current data for both the sites and the NAPRTCS Data Coordinating Center (DCC) (read access only), immediate data validation, immediate access to project and software upgrades.

*Platform Independence.* Since data entry is done entirely within the user's web browser, any computer with Internet access capable of running Internet Explorer 5.5 or higher can be used for entering data. Macintosh, IBM PCs running Windows, Windows 95, Windows NT, or UNIX-based computers may be used to enter data.

*Immediate Data Validation.* Each field that is entered is selected immediately (as described in the next section) for format and validity. Error messages notify the user of invalid values.

*Access to Current Data.* Computers at each site are used for data entry, however the data resides on a computer at the DCC. Each site has immediate access to its data, but the DCC is able to read and analyze data from all sites. The time lag that occurs in a paper or fax-based system (i.e., sending data forms to the DCC, performing data entry at the DCC, and receiving query reports) is eliminated. In the future, both the individual sites and the DCC will have access to up-to-the-minute reports reflecting currently entered forms, missing forms, expected forms, and other reports.

*Upgrades.* Internet data entry also facilitates the distribution of software upgrades. After the DCC has implemented, tested, and approved a new feature/upgrade/fix, any site that accesses the software automatically uses the newest version.

### 1.2.2. Functional Requirements

This section discusses the functional requirements of the NAPRTCS Advantage EDC system, including software design issues such as system access, data entry features, reporting features, data integrity features, and application timeouts. Specific issues that relate to the overall security of NAPRTCS Advantage EDC are highlighted.

*System Access.* System access is restricted by use of usernames and passwords. Each system user has a unique username and password that is distributed by the site Administrator. The only way to access the data entry system is through a login screen. A user is allowed into the system only after entering a valid username/password combination. Other screens do not function if the user has not logged in properly. ***Accessing the system through a single login page is an important security feature of the NAPRTCS Advantage EDC System.***

Upon successful login, information regarding the user (e.g., full name and site code) is loaded from a user information database. The date, time, and IP (Internet) address of the user's computer is captured at login. The user's name is displayed on every screen accessed while using the system. This process is helpful because it identifies the individual working on the system (e.g., if a user leaves the computer temporarily to obtain information needed for data entry). Each user is limited to viewing forms from his/her site. Specific functions may be restricted to certain users. (Multiple users can access the system at the same time; however, an error message will be displayed if two users simultaneously access the same record and attempt to save it.) ***Capturing login information, displaying the user's name and restricting access to some functions are significant security features of NAPRTCS EDC. As an additional security feature, if necessary, it is possible to restrict specific users to accessing the software from specific IP addresses (e.g., being able to access the software only from a specific computer).***

*Data Entry Features.* Several data entry features facilitate finding and entering valid data. Users are able to page (browse) through forms for all of their site's participants by clicking appropriate buttons located on the data screens. In addition, users are able to clear the record displayed on the screen, type data in keyfields, display specific records, or add a record that has not been entered. Keyfields are selected as they are entered to prevent duplication of records. Key databases are updated as the form is saved.

*Reporting Features.* Reports will reflect the up-to-the-minute status of data that have been entered. If a form has **been added or modified**, the changes will be reflected in a freshly generated report.

*Data Integrity Features.* Data fields are validated during the data entry process. Fields are selected for format (proper date, time, or numeric format) and values (within the expected range). Some fields are restricted to a list of valid choices. An audit trail exists for all data – i.e., every time a record is added, modified, or deleted, the current user, date, and time is recorded. In addition, changes to modified fields are tracked. Users are able to indicate missing values and provide a reason for the missing data. Users are notified of out of range values and asked to confirm the value.

*Application Timeouts.* Information pertaining to the user's session is tracked by an application server at the DCC. If the system is idle for 20 minutes, the user will be automatically logged out of the application and required to login to continue using the system.

### 1.2.3. System Architecture

This section discusses the three-tiered nature of the system architecture and server configuration issues, such as web server, encryption, application server, and data access.

*Three-tiered Architecture.* There are three independent tiers on which the NAPRTCS Advantage EDC System operates:

The computer being used at the site is referred to as the *client*, the computer data entry web pages are contained on is referred to as the *server*, and the computer database files are contained on is referred to as the *database server*. The client may be any computer connected to the Internet, capable of running Internet Explorer 5.5 or higher. Interactive processes, such as prompts for improperly formatted data or out of range data, occur on the client. When the user clicks a button or a link on a page, an action is triggered on the server. The server sends the appropriate pages to the client. The server also sends the data entered on the client to the database server. All access to the database files is through communication between the server and the database server. The data are then sent to the client when the next page is generated dynamically. The server and the database server can be located on the same computer or on different computers. The server communicates between the client and the database server. The client cannot communicate directly with the database server.

*Web Server.* The web server software allows connection to the server by other computers via the Internet. The currently installed web server is the Microsoft Internet Information Server. The web server software can be changed or upgraded as system usage increases without affecting the functioning of the data entry software.

*Encryption.* All data transferred between the client and the server across the Internet is encrypted using Secure Sockets Layer (SSL) technology. ***Encryption is another important security feature of NAPRTCS EDC.***

*Application Server.* The application server controls all interactions between each client and the server. The application server dynamically generates each page the user sees. The application server connects to actual data files and keeps track of all relevant information during a data entry session. ***The application server enables several security features described in the software design section.***

*Data Access.* Access to the database files is through an Open Database Connectivity (ODBC) connection. The ODBC connection allows the application server to read and write data in the database files. The database files can only be accessed through the application server and are not visible directly from the Internet. ***Connecting to the data files through the application server is another important security feature of the NAPRTCS Advantage EDC system.***

### 1.2.4. Other Features

Other features include on-demand reports, such as missing and expected forms, accrual and site reports. Each site is able to download copies of data files and export these data into the NAPRTCS Advantage EDC system.

## **2 POLICIES, DOCUMENTATION, AND DATA MANAGEMENT**

### **2.1 Regulatory Requirements**

Centers participating in NAPRTCS must follow applicable regulatory and institutional requirements and Good Clinical Practice (GCP) guidelines.

### **2.2 Source Documentation**

Documentation of participant consent and source documentation for all data must be on file at the participating NAPRTCS site. Sites are responsible for ensuring that all data submitted are collected from source documents and entered accurately into the system.

### **2.3 Data Management**

Data will be collected and entered into the database according to study specifications, regulatory requirements and institutional policies. When possible, data entry should be performed directly from a medical record, laboratory report or similar source document. In order to expedite data entry, paper copies of NAPRTCS data screens may be used as source documents. Designation of source documents for data entry is the responsibility of the clinical staff. All forms used for data entry should be maintained in a secured file.

When recording data on source documents, use black ink and write as legibly as possible. Any modifications or corrections should follow standard documentation procedures. Always initial and date any changes. Use a single line to cross out errors. Correction fluid “white out” or obliteration of original entries is not allowed – original data should always remain readable to provide an audit trail for the data. An explanation for the modification may also be recorded.

### **2.4 Data Item Exceptions**

If a laboratory value, date field, or other text field cannot be obtained, place an asterisk in the field and enter the reason the item cannot be obtained. (Note that text fields are those that the user types a value in a field.)

### **2.5 Forms Exceptions**

If a form cannot be submitted, use the Request Forms Exception from the Missing Forms Report listing. Select the box “Request Exception”. Specify the reason the data is not forthcoming using the pick list. If none of the reasons are applicable, select NEW and specify the reason. The DCC reviews and grants/rejects all requests for form exceptions.

### **2.6 Missing Data/Data Anomalies**

Sites will receive data discrepancy reports including missing and expected forms. Data discrepancies (data anomalies and missing data items) will be posted regularly. Missing forms should be entered prior to the 15<sup>th</sup> of the next month or a forms exception should be requested. Data corrections are made directly in the EDC system.

## 2.7 Study Materials

Additional study materials may be obtained by contacting the DCC at the address listed below or via the contact information provided in the NAPRTCS roster.

NAPRTCS Data Coordinating Center  
The EMMES Corporation  
401 N. Washington Street, Suite 700  
Rockville, MD 20850

## 2.8 NAPRTCS Procedures

### 2.8.1. Patient Eligibility Criteria

- 1) Patients who have chronic renal insufficiency on or after January 1, 1994 who have not reached their 21st birthday,
- 2) Patients initiating maintenance dialysis therapy on or after January 1, 1992 who have not reached their 21st birthday, and
- 3) Patients receiving a renal allograft on or after January 1, 1987 who have not reached their 18th birthday.

OR

Patients receiving a renal allograft on or after January 1, 1992 who have not reached their 21st birthday.

### 2.8.2. Data Submission

The NAPRTCS Data Entry System has checks programmed to ensure accuracy. The Registration data for each participant is entered during the enrollment process. No other data can be entered until enrollment is completed. Status forms in the dialysis or transplant registry cannot be processed until a Dialysis Initiation or Transplantation Report Form, respectively, has been received. Data reported on the initial CRI Status Form must satisfy all entry criteria for the CRI registry.

Sites that opt to submit data to the DDC will complete the new NAPRTCS Case report forms and submit them to the following address:

The EMMES Corporation  
401 N. Washington Street, Suite 700  
Rockville, MD 20850  
Attn: NAPRTCS Database Administrator

### 2.8.3. Data Reports

NAPRTCS Annual Reports (of all data collected to date) are distributed to all participating sites in June. Site-specific Reports are distributed to all participating sites on a periodic basis.

### 2.8.4. Payments

Payments for new patient registrations are made semi-annually, in June and December. Personnel, address, or taxpayer information changes that affect the disbursements should be reported to the DCC immediately. The deadlines for forms received at the DCC are mid-May and mid-November, or at least one month prior to checks being generated.

### 2.8.5. Lost to Follow-Up

Once follow up information can no longer be obtained for a participant, the Lost to Follow-Up form should be completed. Submission of this form prevents subsequent data from being entered in the system. If a participant is re-entering the Registry, the Lost to Follow-up form must be deleted.

## 3 GETTING STARTED

### 3.1 Access to the Internet

When people speak of the Internet, they are usually referring to the World Wide Web, a graphical interface to the Internet. The World Wide Web is accessed through a browser program such as Internet Explorer. For best performance, use Internet Explorer 5.5 or higher. You may be able to access the system using earlier versions of Internet Explorer, however they are not supported and performance may not be optimal. If you are unsure of what browser version you are currently using, select the **HELP** menu of your browser.

### 3.2 Access to the NAPRTCS Advantage Electronic Data Capture System

#### 3.2.1. NAPRTCS Advantage EDC

The DCC will issue username/password accounts to all participating site staff. Staff should contact the DCC to obtain training on the system and their own access information. When staff no longer required access to the system, please contact the DC so that account status may be updated.

#### 3.2.2. User Rights

Users are assigned rights to the system by the DCC. The types of rights include:

- **Add/Modify:** User's assigned add/modify data entry rights are able to add and modify patient clinical and laboratory data.
- **Delete:** User's assigned delete data entry rights are able to delete patient clinical and laboratory data.

### 3.3 Navigation

After establishing an Internet connection, start Internet Explorer. In the location box, type [www.naprtcs.org](http://www.naprtcs.org) and press ENTER. Additionally, you may go to [www.emmes.com](http://www.emmes.com) select Projects and a list of projects will be displayed. Click [**North American Pediatric Renal Trials Collaborative Study (NAPRTCS)**] and the home page will display as shown on the next page:



# Home



- ▶ Home
- ▶ Announcements
- ▶ Resources
- ▶ Study Documents
- ▶ Directory
- ▶ Study Login
- ▶ Training System
- ▶ Coordinators
- ▶ Other Studies
- ▶ Other Information

*PLEASE NOTE: To access the Directory, please type **NAPRTCS** in the User Name box and **WELCOME** in the Password box when you are prompted. (The ID and password are case sensitive - all caps.)*

Welcome to the NAPRTCS Website

**NAPRTCS is now known as the North American Pediatric Renal Trials Collaborative Studies**

The North American Pediatric Renal Trials Collaborative Studies (NAPRTCS) is a research effort organized in 1987.

At the outset of the study, the operational objective of this group was to obtain the voluntary participation of all renal transplant centers in North America in which multiple (>4) pediatric patients received renal allografts annually. Scientific objectives include capture of information about current practice and trends in immunosuppressive therapy with an ultimate goal of improving care of pediatric renal allograft recipients in North America.

In 1992, the study was expanded to include pediatric patients who receive maintenance hemodialysis or peritoneal dialysis therapy. In 1994, data collection began on patients with chronic renal insufficiency (CRI), defined as a Schwartz calculated creatinine clearance < 75 ml/min/1.73 m<sup>2</sup>.

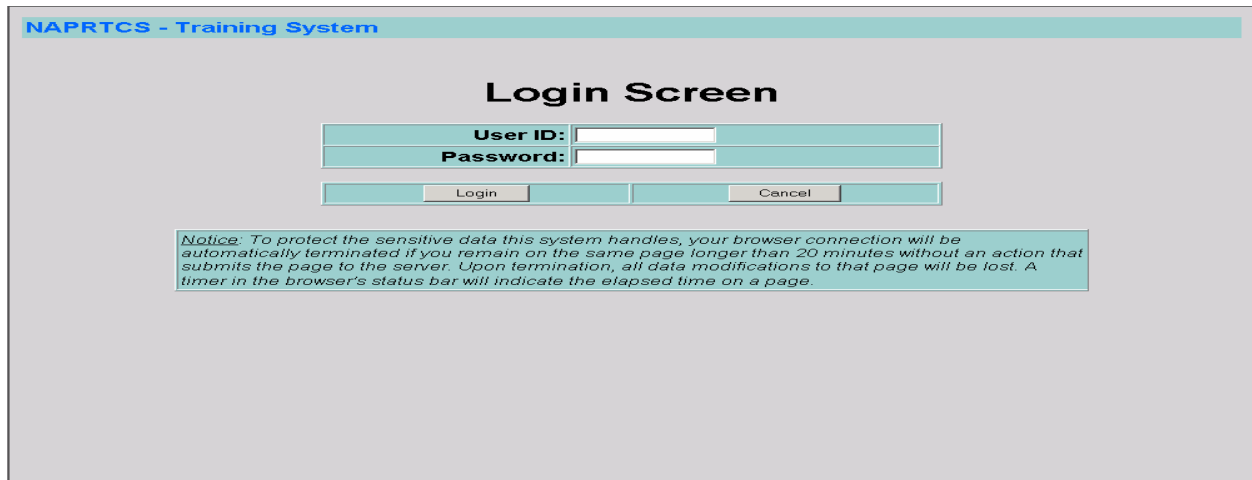
Now, not only do we hope to register and follow greater than 80% of

### 3.4 Training System

The NAPRTCS training system is a “mirror” of the live site and is provided to familiarize and train potential users of the EDC system with system features. The training system should be used to provide a means to “practice” using system utilities and data entry functions. There is no link between the training site and the live EDC system so you may use the functions of the system freely without concern that your actions will have an impact on study data.

The main menu is located on the left side of the home page (see above). To enter the training site, click [**Training System**].

A valid username/password has been assigned by the DCC and is required for access to the NAPRTCS EDC Training Site.



## 4 LOGIN AND MAIN MENU

### 4.1 NAPRTCS Advantage EDC

To access the NAPRTCS Advantage EDC, select Study Login from the NAPRTCS Home Page, [www.naprtcs.org](http://www.naprtcs.org).



**NAPRTCS Online**

# Home

**PLEASE NOTE:** To access the Directory, please type **NAPRTCS** in the User Name box and **WELCOME** in the Password box when you are prompted.  
(The ID and password are case sensitive - all caps.)

Welcome to the NAPRTCS Website

**NAPRTCS is now known as the North American Pediatric Renal Trials Collaborative Studies**

The North American Pediatric Renal Trials Collaborative Studies (NAPRTCS) is a research effort organized in 1987.

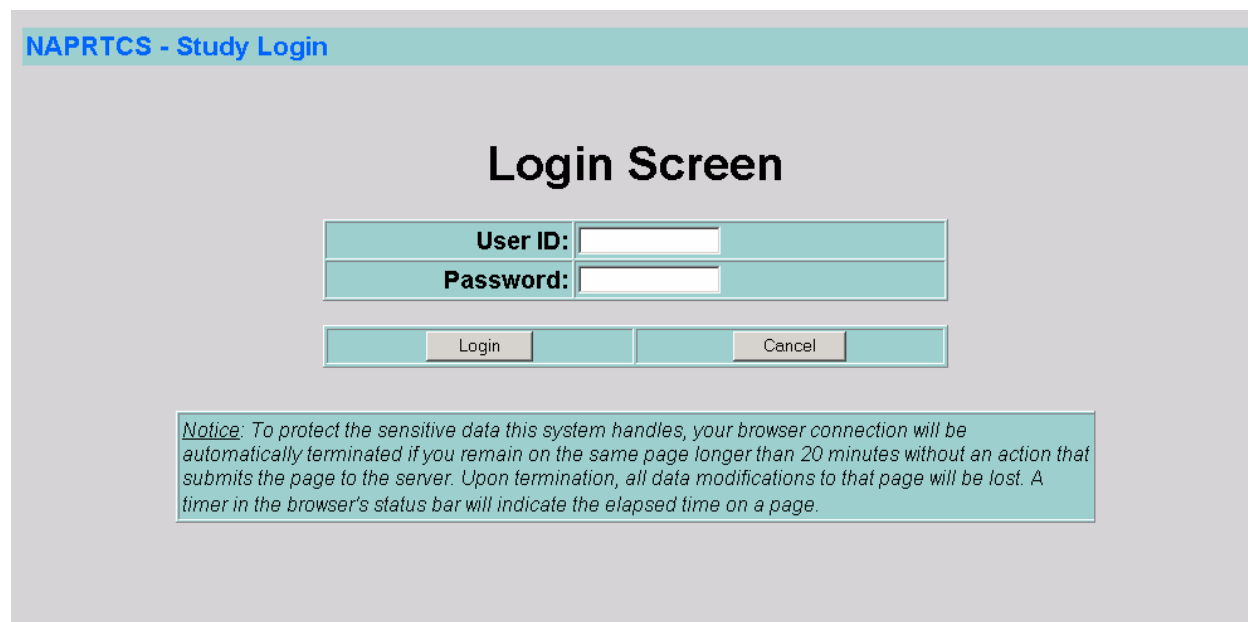
At the outset of the study, the operational objective of this group was to obtain the voluntary participation of all renal transplant centers in North America in which multiple (>4) pediatric patients received renal allografts annually. Scientific objectives include capture of information about current practice and trends in immunosuppressive therapy with an ultimate goal of improving care of pediatric renal allograft recipients in North America.

In 1992, the study was expanded to include pediatric patients who receive maintenance hemodialysis or peritoneal dialysis therapy. In 1994, data collection began on patients with chronic renal insufficiency (CRI), defined as a Schwartz calculated creatinine clearance < 75 ml/min/1.73 m<sup>2</sup>.

Now, not only do we hope to register and follow greater than 80% of

**Note:** *Bookmark this location so that you can easily return in the future.*

The NAPRTCS Advantage EDC login screen will be displayed. The Login screen prompts the user to enter a username and a password. Enter the assigned username and password in the appropriate fields and select [Login]. If [Cancel] is selected, you will not be logged into the system.



**NAPRTCS - Study Login**

## Login Screen

User ID:

Password:

Login Cancel

*Notice: To protect the sensitive data this system handles, your browser connection will be automatically terminated if you remain on the same page longer than 20 minutes without an action that submits the page to the server. Upon termination, all data modifications to that page will be lost. A timer in the browser's status bar will indicate the elapsed time on a page.*

The Log In screen prompts the user to enter a username and a password. The username identifies the user with a particular site and restricts IDES access to only that site's data and the functions to which the user has been granted rights.

***Instructions:*** Usernames and passwords are case sensitive (i.e., it makes a difference whether you use **UPPER CASE** or **lower case**) and limited to 8 characters.

In the **User Name** field, type your assigned username. Use your mouse or press Tab to advance to the **Password** field.

Type in your **Password** in the **Password** field.

Use the mouse to click on [**Log In**] or tab and press ENTER. If you click [**Cancel**], you will be logged out of the system automatically.

## 4.2 The Main Menu

NAPRTCS Advantage EDC has many components available to users. Once you have logged into the EDC system, you will be able to move from screen to screen, or navigate from the Main Menu. The Main Menu is the gateway to patient registration, data entry, access to utilities including missing and expected forms, study documentation including the Manual of Procedures, User's Guide, and data download capabilities.

All NAPRTCS Advantage EDC functions are accessed via the Main Menu. The following options are displayed on the Main Menu:

- Data Entry - Data entry by patient and enrollment
- Utilities and Reports-Maintain User ID's, Missing Forms, Data Download (site specific).
- Other Materials-Study materials such as the Internet User's Guide (for download), NAPRTCS forms, Manual of Operations, Publications such as Annual Report (for download). Please note that additional options may be added over time.

The screenshot shows a web application interface for the North American Pediatric Renal Transplant Cooperative Study. At the top, it displays the date and time 'Wed Jan 08 2003 11:54:19', the study name 'North American Pediatric Renal Transplant Cooperative Study', and the version 'Test Release 1.0a'. Below this, it shows 'Site/Center: Test Site' and 'User: Test User'. A 'Main Menu' section is centered, with a sub-menu 'Extend Session • Logout' to the right. The main menu is divided into three columns: 'Data Entry' (containing 'NAPRTCS Forms' and 'Enrollment'), 'Utilities and Reports' (containing 'Utilities' with 'Maintain User IDs', 'Change Site', and 'Data Download', and 'Reports' with 'Missing Forms Report'), and 'Other Materials' (containing 'Study Materials' with 'Users Guide\*' and 'Manual of Operations\*', and 'Publications' with 'Bibliography\*', 'Annual Report\*', and 'Special Studies Request Form\*'). A note at the bottom states: '\* These links open in a new window. Please close that window to return to this screen.'

### 4.3 Patient Identifiers

All forms must be identified with the following information:

#### 4.3.1 Site Name and Code

A three digit site the NAPRTCS DCC at site registration will be used for all sites.

#### 4.3.2 NAPRTCS Identification Number

Unique use of this identifier is essential and will provide the basis for communication between clinics and the DCC. Once a number is assigned to a participant, the same number must be used for that participant in **ALL** subsequent communications. There is a maximum of 9 characters allowed, both numbers and letters are permitted. Sites should conform to local requirements when designating a study identifier. **Participant names are strictly prohibited.**

Submission of data to NAPRTCS must follow local institutional requirements with respect to consent/assent and data authorization procedures. These documents should be maintained at the site, and should not be submitted to the DCC.

## 5 GENERAL GUIDELINES

Common guidelines that apply to all EDC screens are detailed below. Form-specific guidelines are detailed in Appendix 1.

### 5.1 Navigation

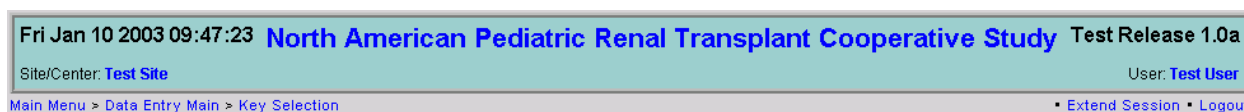
**Use only Advantage EDC navigation links or buttons to navigate throughout the system.** Use of the Browser buttons may cause unintended and unpredictable changes to the data and Advantage EDC functions. Use of browser selections may also cause loss of data and/or system problems.

Throughout the NAPRTCS EDC system, links are used to direct the action of the user. To direct the system to perform a specific function, use the mouse to click a button or tab to the button and press the ENTER key on your keyboard.

Once data entry is complete, click the [**Save**] button to save the data. The DCC recommends that you save data frequently. If you time out before saving data, any data entered since the last save will be lost.

### Navigation Bar Summary

#### Toolbars



#### Forms Navigation Toolbar

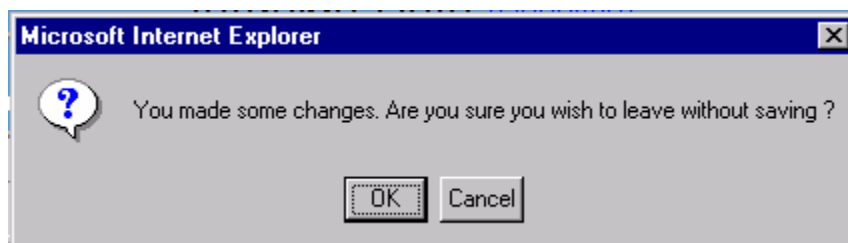
**Main Menu**: If selected, the Main Menu page will display.

**Date Entry Main**: If selected, the Data Entry Main page will display.

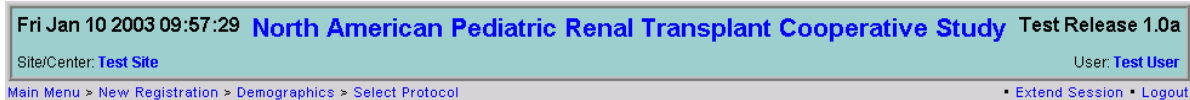
**Key Selection**: If selected, the Key Selection page will display. Key Selection page displays keyfields and Existing Records for the form selected.

**Extend Session**: If selected, extends the session time to 20 minutes.

**Logout**: If selected, logs the user out of the system. If you have changed data on a screen and have not saved the changes, you are asked during log out – “Are you sure you wish to leave without saving” (see message below). If no data have been changed, this message is not displayed.



Click [**OK**] to leave without saving or [**Cancel**] to return to the screen.



## Registration Navigation Toolbar

**Main:** If selected, the Main Menu page will display.

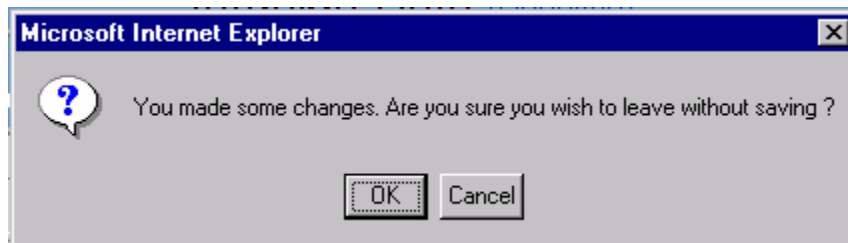
**New Registration:** If selected, New Registration page displays to begin the registration process.

**Demographics:** If activated and selected, the Demographics page will display for that participant.

**Select Protocol:** If activated and selected, the Select Protocol page will display.

**Extend Session:** If selected, extends the session time to 20 minutes.

**Logout:** If selected, logs the user out of the system. If you have changed data on a screen and have not saved the changes, you are asked during log out – “Are you sure you wish to leave without saving” (see message below). If no data have been changed, this message is not displayed.



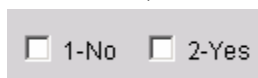
Click **[OK]** to leave without saving or **[Cancel]** to return to the screen.

## 5.2 Screens

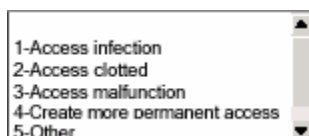
### 5.2.1 Data Entry Formats

The following formats are used to capture data:

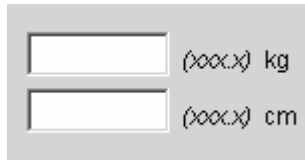
- Select boxes are often used when pre-specified codes or options must be chosen (e.g., “Yes” or “No”). Note: Only one choice is allowed.



- Drop down boxes are used when multiple options are listed. Note: Only one choice is allowed.



- Text boxes are used for data that must be typed. Text boxes are most commonly used to capture dates and numeric values.



Two text input boxes are shown. The top box is followed by the text "(xxx.x) kg" and the bottom box is followed by the text "(xxx.x) cm".

## 5.2.2 Print Screen

Print screen is a convenient mechanism to provide documentation of how Advantage EDC is functioning.

- To print a screen, position the cursor on the screen and press CTRL-P (PC) or Command-P (Macintosh). You may also print by selecting **File** on the browser toolbar and clicking **Print**. In both cases, a print menu will display with print options for your local printer.
- If an error message is displayed, the print screen command described above will not work. Press the **[Print Screen]** button on your keyboard, move to a word processor (e.g., Microsoft Word or Word Perfect) document and paste the selection into the document. You may print the selection from the word processor.

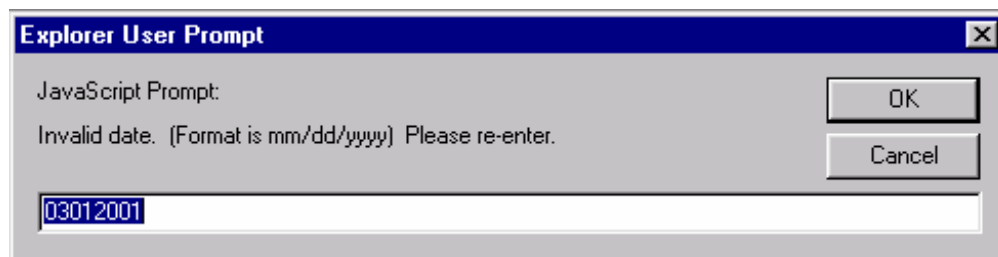
## 5.3 System Messages

### 5.3.1 Consistency Checks/Field Validation Error Messages

During data entry, the system performs field validation checks on certain fields (e.g., checks the format of dates, times, and numeric values) and consistency checks between select fields. If your entry fails the validation check, or the data do not meet the specified requirements, you will be prompted by a message indicating the problem. You must resolve this problem by deleting the incorrect data and entering valid data in the space provided on the error. Examples of consistency checks and field validation error messages are shown in the following sections.

#### 5.3.1.1 Date Field Formats

Below is an example of a date field, the required format is indicated in parentheses next to the textbox. In the example, a date has been entered without the required format of forward slashes between the month, day and year. If a date is entered in an invalid format, the following error message will appear:



Correct the invalid format by re-entering the date in the proper format and click **[OK]**. The system will enter the date in the field as shown below.

The message will not disappear if **[Cancel]** is selected from the error message box. The date must be corrected or deleted.

Below is an example of the date field formatted correctly.



05/10/2002 (mm/dd/yyyy)

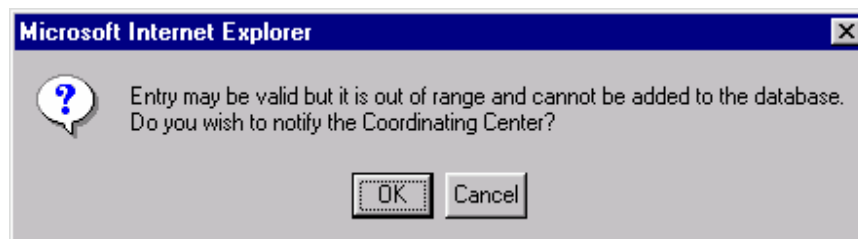
### 5.3.1.2 Date Field Ranges

The latest date that may be entered in a date field is the current date. In the example above, the date entered is beyond the date allowed by the system. When a future date is entered the following consistency select message will appear:



The error message shown above will also display if the date is too far in the past. If the data are correct as entered, click **[OK]** and a carat “^“ will appear in the field. The carat informs the DCC of the extreme value. To correct the data, click **[Cancel]**.

When **[Cancel]** is selected, the following prompt will appear on the screen:

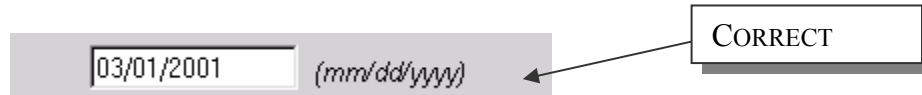


Enter the correct date in the textbox, click **[OK]** and the form will display with the new date.

When **[Cancel]** is selected at this prompt, the date must be changed or the error message cannot be canceled.

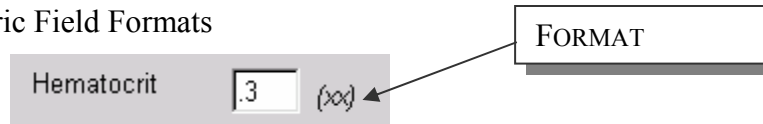
Correct the invalid format by entering the date in the text box with the proper format (in the example, use forward slashes 03/01/2001) then, click **[OK]**. The system will enter the date in the field as shown below.

If you select **[Cancel]** from the error message box, the system will take you back to the form with the date field blank.

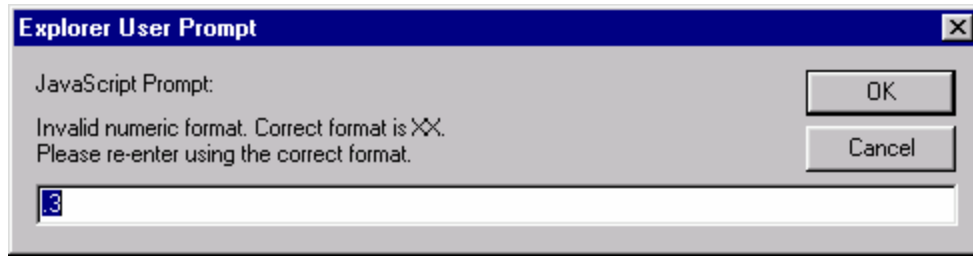


This is an example of the date field formatted correctly.

### 5.3.1.3 Numeric Field Formats



Above is an example of a numeric field. The form will indicate, next to the textbox the formatting required for the field. In the example, a number has been entered with a decimal point. However, the valid format for this field is a two-digit number with no decimal point. If an invalid number is entered, the following consistency check will appear:



Enter the correct numeric value in the textbox, click [OK] and the form will display with the corrected value.

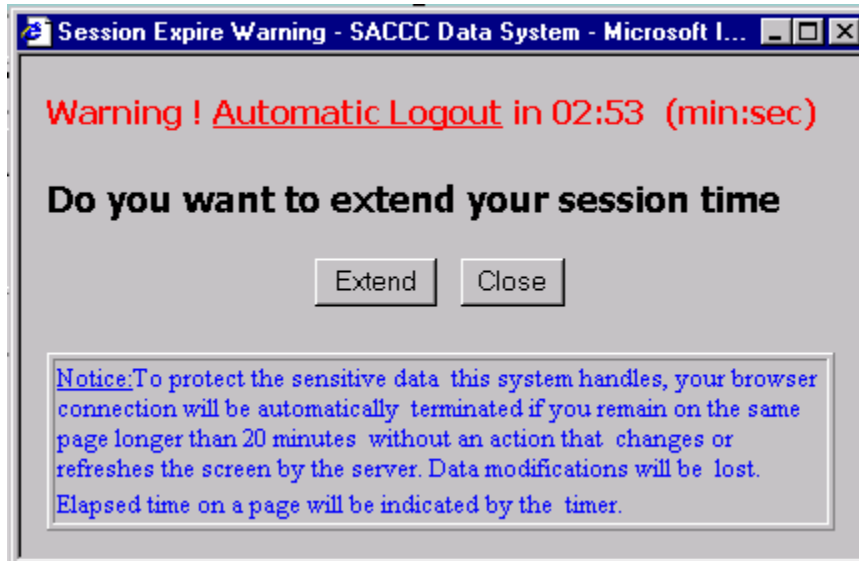
When [Cancel] is selected at this prompt, the form will redisplay with the date field blank.



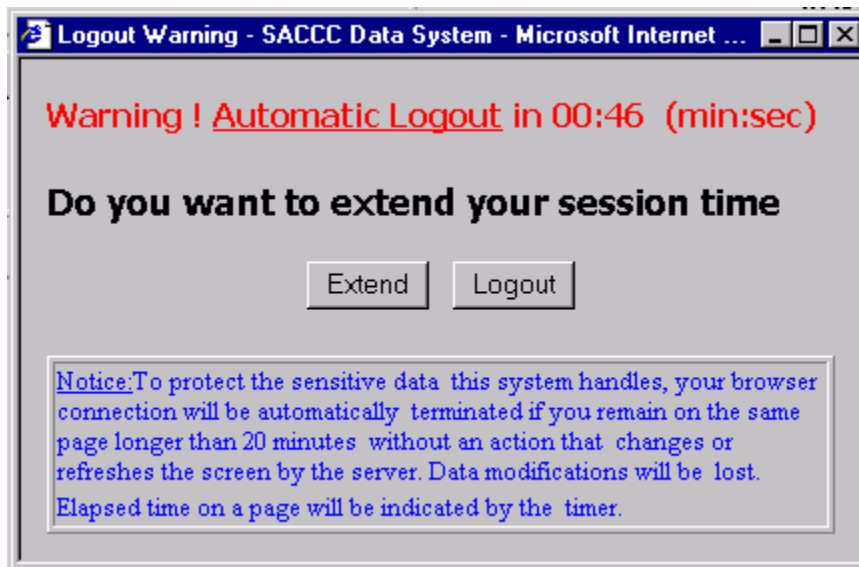
This is an example of the numeric field correctly formatted.

## 5.3.2 Timeout Warnings

The data entry system will log you out of the system automatically if there has been a period of inactivity lasting 20 minutes. The system displays a Session Expire Warning (see below) message after 17 minutes of inactivity that you have 3 minutes left before timing out.



Click on **[Extend]** to add an additional 20 minutes to your system login time or **[Close]** to clear the warning window.



This window will display when there is <50 seconds left before automatic logout. Click on **[Extend]** to add an additional 20 minutes to your system login time or **[Logout]** to log out of the system.

## 5.4 General Instructions

Please keep the following guidelines in mind when submitting data.

### 5.4.1 Participant Identification

Participant identification must be entered **consistently** on all data submitted for a patient. The patient ID number reported on the Registration form should be used on all subsequent data submitted to the Coordinating Center.

#### 5.4.2 Dates

Use the U.S. convention (month/day/year) to report dates. Use leading zeroes. For Internet use, you must type the “slash” as part of the date.

*EXAMPLE: July 4, 2003 should be reported as 07/04/2003.*

#### 5.4.3 Data Item Exceptions

If a laboratory value, date field, or other text field cannot be obtained, place an asterisk in the field and provide the reason the item cannot be obtained. (Note that text fields are those that the user types a value in a field.)

#### 5.4.4 Forms Exceptions

If a form cannot be submitted, use the Request Forms Exception from the Missing Forms Report listing. Select the box “Request Exception”. Specify the reason the data is not forthcoming using the pick list. The DCC will review and grant/reject all requests for form exceptions. Refer to section 7.3, Requesting an Exception, for more detailed procedure or you can use the Forms Grid and select Forms Exception.

### 5.5 Medications

All medications are listed by common name not tradename. Please record all medications in the specified fields unless the medication is not listed. Contact the DCC if there are questions regarding which medication to specify.

Generic/Common	Tradename
Methylprednisolone	Solumedrol
Cyclosporine	Neoral Sandimmune
Tacrolimus	FK506 Prograf
Azathioprine	Imuran 6-Mercaptopurine
Mycophenolate Mofetil	Cellcept
ATG/ALG	Rats

## 6 ENROLLMENT SYSTEM

### 6.1 Demographic Data, Component Selection, Eligibility Confirmation

The Registration System consists of three parts – collection of demographic data, protocol selection, and confirmation of eligibility. The process must be completed:

- After the participant has been screened, determined to be eligible for a NAPRTCS segment, and
- By an individual who has been granted specific user rights to the Registration module.

### 6.2 Registering a New Participant

#### 6.2.1 Accessing the Enrollment System

At the Main Menu, click on **Enrollment**. The following screen will appear:

TOOLBAR

Fri Jan 10 2003 10:25:27 North American Pediatric Renal Transplant Cooperative Study Test Release 1.0a  
Site/Center: Test Site User: Test User  
Main Menu • Extend Session • Logout

New Registration

Participant Registration  
  
Select an existing Participant  
  
Begin Registration

#### **Instructions:**

1. For a New Participant, click on [**Begin Registration**].
2. If the participant is already registered in another NAPRTCS segment, type in his/her Participant ID in the select **Existing Participant ID** textbox.
3. Use the mouse to click on [**Continue Registration**] button.

#### 6.2.2 New Registration Toolbar

The following is an explanation of the buttons located on the toolbar.

**Main:** Takes you back to the Main Menu screen.

**Extend Session:** Adds an additional 20 minutes to your login time on that screen (see the Remaining Session Time in the left hand bottom corner of the New Registration screen).

**Logout:** Logs you out of the IDES system.

## 7 FORMS STATUS/REQUEST EXCEPTIONS

### 7.1 Forms Status

All data for participants enrolled in NARPTCS will be reviewed for completeness, accuracy and timeliness. The NAPRTCS EDC Forms Grid details by participant/component/segment all forms and with corresponding visit schedule and status. The table represents the forms current status.

### 7.2 Scheduled Form Status

From Data Entry Main, click on **[Forms Grid]** and the **Forms Grid** page will display as shown below:

**Key:**

- Scheduled
- Scheduled and Overdue
- Received
- Received and Not Scheduled
- Exception Requested
- Exception Granted
- Requirement Removed

Data Entry  
 Request Exception

SEE NEXT PAGE FOR

**1st Transplant Sequence**

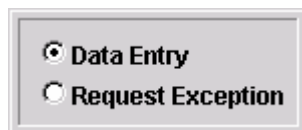
Form / Visit # - Target Date	01	02	03	04	05	06	07	08	09	10	11
Transplantation Status											

#### 7.2.1 Form Schedule Status Table

The table represents the forms visit schedule to indicate at what visit and date a particular form requires data to be entered and sent. Symbols within the table indicate the current status of a form for each visit. The meaning of each symbol is found above the table labeled **Key**.

You may also access a form from the form status table by the following steps:

**Step 1:** Select Data Entry function in the box in the upper left corner of the page.



**Step 2:** Click on the key symbol corresponding to the desired form and visit number.

### 7.2.2 Key Symbols:



Scheduled: Represents a form is required for the visit and date as shown in the column header.



Scheduled and Overdue: Indicates the form due date has pasted and no data has been entered into the form and a form exception has not been requested.



Received: Data has been entered into the form.



Received and Not Scheduled: Data has been entered into a form that was not scheduled.



Requirement Removed: The data for this form is no longer required.



Exception Requested: An exception (site has requested no data be sent in for a form) has been requested.



Exception Granted: An exception has been granted. Form is no longer required.

### 7.3 Requesting an Exception

In the event that data collected on a particular screen cannot be obtained (e.g., a missed visit), the user may request a form “exception.” All exceptions are executed by performing the following:

**Step 1:** Select Request Exception function in the box in the upper left corner of the page.

**Step 2:** Click on the key symbol corresponding to the desired form and visit number. After selecting the form, the **Request Exception** page will display as shown below:

Request Exception		
Component: Transplantation	Participant: 000364323	Form: Transplantation Status
Registry Sequence: 1st Transplant Sequence		
Visit Number: 17		
Exception Status: <b>None</b>		
Select Reason: <input type="text"/>		
<input type="button" value="Submit Request"/>		

**Step 3:** Select a reason for the exception from the **Select Reason** pull down list.

**Step 4:** Click [**Submit Request**] and the exception has been submitted to the NAPRTCS DCC for review. The system will indicate the Exception status as **Requested** and the toolbar will say **Exception Request Saved** as shown below:

The screenshot displays a web form titled "Request Exception" with a teal header. Below the title, the text "Exception Request Saved" is shown in red. The form is divided into three columns: "Component: Transplantation", "Participant: 000364323", and "Form: Transplantation Status". Below this header, the form contains the following fields and controls:

- Registry Sequence: 1st Transplant Sequence
- Visit Number: 17
- Exception Status: **Requested**
- Select Reason: Participant missed visit (dropdown menu)
- Submit Request (button)

Return to the **Forms Grid** by selecting **Forms Grid** on the toolbar.

If the DCC is not able to grant the exception (for example, incorrect data were entered and caused the form to trigger initially), the exception may be rejected. In the event the exception is rejected, the **Exception Requested** symbol in the table will revert to whatever symbol was listed prior to the exception request.

## **8 DATA DOWNLOAD**

Data that your center has entered into the NAPRTCS system is available for electronic download by selecting [Data Download] from the Utilities section of the Main Menu. Files are ASCII, or XML format. You will be prompted with a secondary screen from which a form can be selected. You may specify the location (i.e. your hard drive). You may rename this file once it is downloaded. For additional assistance with this feature, contact the DCC.

## 9 DATA ENTRY PROCEDURES

### 9.1 Keyfields

Key points to remember about keyfields:

- Keyfields are the fields (data items) that make an individual data record (form) unique from all others.
- For forms that are visit-based, the keyfields usually consist of Component, Participant ID and Visit Number.
- For forms that are not visit-based, keyfields typically consist of Component, Participant ID, Event (e.g., adverse event) and Start Date for the Event. When these fields are keyed in, they will display at the top of the form and cannot be modified.
- Once entered, keyfields are displayed at the top of the form and cannot be modified. If you make a mistake, the record must be deleted and the keyfields entered with the correct information. Then reenter the remaining data for the form.

### 9.2 Form Selection Menu

The **Data Entry Main** menu allows you to select forms to be entered for a selected protocol. Additionally, you may also select a Participant ID number for any participant enrolled in the specified protocol at your site. To select a Participant ID, either click on the down arrow and choose a listed Participant ID number or enter a valid ID in the adjacent box at the right.

The screenshot shows the 'Data Entry Main' interface. At the top, there is a header bar with the date and time 'Wed Jan 08 2003 01:50:32', the study name 'North American Pediatric Renal Transplant Cooperative Study', and the version 'Test Release 1.0a'. Below this, the site is identified as 'Test Site' and the user as 'Test User'. A 'Main Menu' link is visible on the left, and 'Extend Session' and 'Logout' links are on the right. The main content area is titled 'Data Entry Main' and contains a 'Select Component:' dropdown menu set to 'CRI'. Below that, there is a 'Select Participant:' dropdown menu set to 'EXB000033' and an adjacent text input field also containing 'EXB000033'. A 'Forms' section displays a list of form types: 'Chronic Renal Insufficiency Status', 'Chronic Renal Insufficiency Termination', 'Demographics Review', 'Lost to Follow Up', 'Patient Death', 'Registration Review', and 'Targeted Adverse Event'. At the bottom, there are three buttons: 'Data Entry', 'Forms Grid', and 'Forms Report'.

Wed Apr 10 2002 04:07:04	<b>SACCC Data System</b> TOL	Jane R. Doe, RN-Clinic
Site/Center: Test Clinic		
Main Menu > Data Entry Main		• Extend Session • Logout
<b>Key Selection</b>		
<b>Protocol:</b> New Medication for Diabetes - XXX01	<b>Participant:</b> XXX01XXX01001	<b>Form:</b> Adverse Events
Date event occurred	<input type="text" value="04/02/2002"/> (mm/dd/yyyy)	
Adverse event description	<input type="text" value="Wrist fracture"/>	
<input type="button" value="Add Record"/>		
<b>Existing Records</b> No existing records.		

**[Add Record]:** After the key fields are populated, click on **[Add Record]** to enter the form selected.

### 9.3 Data Entry Notes

- To choose data entry for the same type of form for the same participant, click on the Key Selection on the top toolbar in the form.
- Unless otherwise specified, all data on each form is required at the visits at which the form is required.
- Each form includes a Comments field, which you may use to provide additional documentation if appropriate. Note, however, that text in the comment fields is generally not useful for analysis purposes.

## 10 DATA MANAGEMENT/FORMS INSTRUCTIONS

### 10.1 Special Data Entry Instructions

**Estimated dates:** Dates entered into the IDES must be complete to be valid (e.g., "--/08/2000" is not a valid system date). Because exact dates are sometimes unknown, a convention has been developed to provide estimated dates in a format acceptable to IDES:

If the **month of the year** is estimated: Enter "06".

If the **date of the month** is estimated: Enter the 15th.

If the **year** is estimated: Enter the mid-year of the decade, e.g., "1975".

**Document the estimation** in the Comments field of the form.

**For example:** A participant remembered that he started taking a particular medication "sometime last year". Efforts by the clinic staff to elicit a more precise response were unsuccessful. The date would be estimated as "06/15/2000" and a note of the estimated date added into the progress notes in the participant's chart and in the **Comment** section of the form.

## 11 MISSING FORMS

### 11.1 Missing Forms Report

All NAPRTCS data will be reviewed for completeness, accuracy, and timeliness. The NAPRTCS Advantage EDC Missing Forms Report details forms (by participant) that are expected for visits that should have occurred as of “today’s date.” Past due forms remain on this report until data are submitted or the form has been granted an exception (see Request Form Exception).

Missing Forms Report

Sort Order

Sort #1	Sort #2	Sort #3	Sort #4
Participant	Form	Protocol	Visit

Filter

Select Component: Dialysis

Select Participant: 000002038 or enter Participant ID: 000002038

Select to filter on Protocol     Select to filter on Participant

Report Options

Missing Forms   
  Expected Forms   
  All

**Enter Date Range** *(only applies for Expected Forms report)*

Begin Date:      End Date:  

*Please select Report Options and click Generate Report*

Generate Report

**Report Settings**

Sort #1: Participant  
 Sort #2: Form  
 Sort #3: Protocol  
 Sort #4: Visit #  
 Report Type: ALL  
 Protocol: ALL  
 Participant: 000002038

**Key:**

Scheduled                      Scheduled and Overdue

Exception Requested                      Exception Granted

Requirement Removed

Data Entry

Request Exception

Participant	Form	Status	Visit #	Trigger Date	Target Date	Component	Reason
000002038	Dialysis Status		03	08/28/2001	02/26/2003	DIALYA	Enrollment
000002038	Dialysis Status		04	08/28/2001	08/28/2003	DIALYA	Enrollment
000002038	Dialysis Status		05	08/28/2001	02/26/2004	DIALYA	Enrollment
000002038	Dialysis Status		06	08/28/2001	08/27/2004	DIALYA	Enrollment
000002038	Dialysis Status		07	08/28/2001	02/25/2005	DIALYA	Enrollment

There are two ways to access the missing forms report.

- Click on **Missing Forms Report** on the Main Menu (listed under “Utilities and Reports”)
- OR Click on **[Forms Report]** on the Data Entry Main

Forms may be accessed directly from the Missing Forms Report by clicking on the form name.

## 12 TRANSFERS

### 12.1 Reporting Participant Transfers

#### General Information

Complete and submit the Transfer form to the Destination Center and the DCC via fax (301-251-1355) when a patient transfers to another *Participating* NAPRTCS Center.

The Originating Center must complete the top half of the form and at least the Destination Center's name before submitting it to the DCC. **Use the same NAPRTCS number reported on the Registration Form.** The DCC will contact the Destination Center to verify they have received the patient and that the patient will continue to participate in the registry.

Do not submit this form to report a patient as lost to follow-up (i.e., transferred to the adult program). Patients that are no longer being followed should be reported on the Lost to Follow-up Form.

All data fields on this form must be completed unless otherwise specified.

#### Data Field

#### Instructions

#### ORIGINATING CENTER

Date of Last Evaluation

Date which corresponds to the last Status form submitted. For example, use the *Date of Creatinine Obtained* on the Transplant Status form for this date if the patient was in the Transplant registry. Otherwise, use the date of evaluation. This date determines when the Destination Center should submit the next Status form.

Last Form Submitted

Note the last Status form type submitted for this patient. For example, if the patient was in the Transplant registry, indicate *Transplant Status*.

Name of the Person Documenting Transfer

Record the name of the contact person at the Originating Center.

#### DESTINATION CENTER

Date of Transfer

Record the date the patient begins follow-up at this center. Note that this date cannot precede the Date of Last Evaluation at the Originating Center.

Name of Person Documenting Transfer

Record the name of the contact person at the Destination Center.

## 13 QUERIES

### 13.1 Data Query Reports

Data query reports identify missing data or identify potential data discrepancies on forms received at the DCC. They are posted online on an alternating monthly basis. The date of the report is provided in the upper left corner of each page of the report. Only the most recent report should be completed. Multiple pages of data queries may be generated for a given form for a patient. Additionally, multiple forms submitted for a single patient may generate multiple pages of queries. It is important to review all pages of the data queries, checking the patient name, form, and event date.

07/04/03

Page 1

NORTH AMERICAN PEDIATRIC RENAL TRIALS COLLABORATIVE STUDY  
**DATA QUERY**

- The Data Evaluation System has found the following anomalies in the NAPRTCS data listed below. This report displays the ID, date, form and data field(s) in question.
- Blanks or “. “ are listed if no data were received. Enter a dash to confirm if no data are appropriate. Confirm correct items by reentering on the line.
- You may call 1-301-251-1161 with any questions.

Return by: 07/04/03

CENTER  
 ID NUMBER  
 PATIENT NAME  
 NAPRTCS FORM  
 EVENT DATE

=====

Mycophenolate Mofetil initiated is missing.

FORM	FIELD	DATA SUBMITTED	MODIFICATIONS
TRANSP STATUS	MYCOPHENOLATE INITIATED	.	_____

=====

Data queries are sorted by center, identification number, patient name, form and date. Each individual query will provide a brief description of the problem. The form name, data field, and data submitted are provided next. The data query reports themselves should be used to provide the missing data, or information necessary to resolve the data discrepancy. If an item is correct as reported, repeat the data under the modification section of the form or write “**confirmed**”. If you are uncertain how to resolve the discrepancy, or unclear which data item is in question, contact the DCC.

Common Form Submission Errors:

- Dialysis Termination or CRI Termination form(s) submitted to report a patient as lost to follow-up or transferred (Lost to Follow-up or Transfer forms should be used instead).
- Multiple status form(s) submitted for a given follow-up period.