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Advantage EDC^{SM} User's Guide

For Duke Stem Cell Application Studies

Prepared by:

The Emmes Corporation

Version 1.0 – November 2015

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1. INTRODUCTION

The AdvantageEDC^{SM} electronic data collection system for protocols managed by the Duke Data Coordinating Center can be accessed from any computer connected to the Internet. The system allows participating transplant centers to submit validated data forms using secure transmission technology. Participating transplant centers will have access to reports showing expected and missing forms, and will also be able to download their data for internal purposes.

1.1. AdvantageEDC^{SM} User's Guide

This document explains the basic procedures for performing data entry over the Internet using AdvantageEDC^{SM}. 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.

1.2. Background Information

1.2.1. Advantages of Electronic Data Collection

Advantages of electronic data collection include computer platform independence, access to current data for both the sites and the Emmes Corporation (read only access), 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 the supported browsers (referenced in the Data Management Handbook) can be used for entering data.

Immediate Data Validation: Each field that is entered is checked immediately (as described in the next section) for format and validity. Error messages notify the user of invalid values, which are not allowed into the system (see Chapter 4).

Access to Current Data: Though data entry is done from computers at each site, the data resides on a server at the Emmes Corporation. Each site has immediate access to its data, whereas the Emmes Corporation is able to read and analyze data from all sites. Both the individual sites and the Emmes Corporation will have access to reports reflecting current data on entered forms, missing forms, expected forms, and other reports.

Upgrades: Internet data entry also facilitates the distribution of software upgrades. After the Emmes Corporation 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 AdvantageEDC^{SM} electronic data collection 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 AdvantageEDC^{SM} are highlighted.

System Access: System access is restricted with use of usernames and passwords. Each system user has a unique username and password that is distributed initially by the Emmes Corporation. 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 AdvantageEDC^{SM}.*** 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 to identify who is 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 AdvantageEDC^{SM}. As an optional 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 browse through forms for all of their site's patients by clicking appropriate buttons located on the data screens. In addition, users are able to clear the record currently on the screen, enter key fields (data items) that make an individual data record (form) unique from all others, and display a specific record if it has already been entered or add it if it has not been entered. Keyfields are checked as they are entered to prevent duplication of records. As the form is saved, other relevant databases are updated as necessary.

Reporting Features: When the reporting features of the system are implemented, missing values and missing forms will be displayed on the main menu. Reports will reflect the up-to-the-minute status of data that have been entered. If a form has just **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. Some fields are checked for format (proper date, time, or numeric format) and values (in the expected range). Other fields are restricted to a list of valid choices. All data entered will also have an audit trail – i.e., every time a record is added, modified, or deleted, the current user, date, and time is recorded. Upon modifying a record, changes to individual fields are tracked. Users are able to indicate values that are missing and provide a reason for the missing data. Users are notified if values are entered that are out of currently defined ranges and are asked to confirm that the value is appropriate.

Application Timeouts: Every time a user accesses AdvantageEDC^{SM}, information concerning the user's session is tracked by the application server at the Emmes Corporation. If a user has been "idle" for 20 minutes, he/she will be logged out of the application automatically and will be required to login again to continue using the system. Idle is defined as not sending data back to the Emmes Corporation server (only entering data on a screen and not saving the form). At 17 minutes of inactivity the system displays a warning indicating that "Your session will timeout in 3 minutes." This feature prevents an unauthorized user being able to view, add or modify data in the event that the authorized user has left the computer without logging out. ***Application timeouts are another significant security feature of AdvantageEDC^{SM}.***

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 AdvantageEDC^{SM} operates:

- The computer being used at the site is referred to as the ***client***;
- The computer the data entry web pages are contained on is referred to as the ***server***, and
- The computer the database files are contained on is referred to as the ***database server***.

The client can use any computer connected to the Internet capable of running the supported browsers (referenced in the Data Management Handbook).   Interactive processes, such as prompts about 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 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 AdvantageEDC^{SM}.***

Application Serve: The application server controls all interaction between each client and the server. The application server dynamically generates each page the user sees. The application server keeps track of all relevant information during a data entry session and it is the application server that is connecting to the actual data files. ***The application server enables several of the security features mentioned 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 AdvantageEDC^{SM}.***

1.2.4. Future Directions
Other features that are not part of the initial version of AdvantageEDC^{SM} can be added as the system is developed further.

2.   POLICIES, DOCUMENTATION, AND DATA MANAGEMENT

2.1.   Regulatory Requirements

Sites participating in Duke Stem Cell Application protocols must follow applicable regulatory and institutional requirements for collecting and submitting individual patient data to the Emmes Corporation. Good Clinical Practice (GCP) guidelines are to be followed in the conduct of studies. This includes maintaining IRB approval of the protocol(s) in which the site is participating. In the event of a lapse in approval, data entry and enrollment access will be removed to prevent data entry during the lapse period.

Reporting of adverse events (AEs) in Advantage EDC^{SM} will follow protocol specific requirements. Sites will also follow their particular institutional and regulatory requirements. Such events will be entered using an adverse experience reporting system linked to AdvantageEDC^{SM}. The data will be collected, maintained, and monitored by the Emmes Corporation. This system also allows for expedited reporting to the medical monitor and the Food and Drug Administration (FDA), when applicable. In addition to submitting AEs to the Emmes Corporation, transplant centers must report AEs to the appropriate regulatory and institutional authorities, in a timely manner.

2.2.   Patients

Patients enrolled into Duke Stem Cell Application protocols must meet all protocol inclusion/exclusion criteria. Chapter 9 discusses the enrollment process in detail.

Patients are identified by a unique eight-digit code supplied by AdvantageEDC^{SM} at the time of enrollment. To protect the confidentiality of the patients, the patient's name or any other information that would potentially make the patient's identity known (e.g., Social Security Number or hospital identification number) will not be required for study enrollment. Also, this information should never appear in uploaded documents. Site coordinators will be asked to remove any uploaded documents found to have personal identifying information and to redact or remove that information from the documents.

2.3.   Source Documentation

HIPAA (Health Insurance Portability and Accountability Act) authorization and documentation of patient consent/assent must be on file for each patient at the participating transplant center [if required by the local Institutional Review Board (IRB) or Ethics Review Board (ERB)]. Source documentation for all data also must be on file at the transplant center. Centers are responsible for ensuring that all data submitted are collected from source documents and entered accurately into the system.

2.4.   Data Management

Data for Duke Stem Cell Application protocols will be collected and entered into the database according to the Data Management Handbook, protocol specific requirements, sponsor SOPs, regulatory requirements, and institutional policies following the instructions in this User's Guide. Data entry, when possible, should be performed directly from a medical record, laboratory report or similar source documents. However, to expedite work flow and data entry, there may be

times when it is necessary to extract data from source documents, record on a paper copy of a data screen and then enter the data.

2.5.   Forms Submission Schedule

Forms Submission Schedule for a specific protocol can be found in the protocol specific Data Management Handbook.   The Forms Submission Schedule provides an outline of the data forms that are required for each protocol.   Form-specific instructions are also located in the protocol-specific Data Management Handbook.

2.6.   Required and Event Driven Assessments

2.6.1. Required Assessments
Follow-up for study patients is protocol-specific. Refer to the protocol and Data Management Handbook to view protocol form specific submission schedules.

2.6.2. Visit Numbers for Required Assessments
Visit Numbers are assigned to each study day for each protocol to simplify data management and statistical analysis and are key fields for entering most data forms – i.e., the form cannot be entered unless the Visit Number is specified.

Visit Numbers on the Duke Stem Cell Application platform consist of 3 characters – 007, 014, 028, etc. "Visits" may be actual physical visits to the clinic by the patients, assessments that patients report to study staff, or telephone/other contacts that study staff have with patients that result in a need to capture data.   Unless otherwise instructed, the following conventions apply to Visit Numbers:

- Visit D00: Date of infusion
- Visits D07, M03, M06, etc: Protocol-designated days post-transplant for follow-up assessments of therapy safety and efficacy (e.g., assessments by clinical staff at designated time points following therapy).

2.6.3. Event Based Assessments
Additional observations (i.e., assessments that do not have Visit Numbers) must be reported to the Emmes Corporation when the patient's condition dictates.   Such instances are protocol-specific and the submissions are considered to be "event based."   For example, if a patient develops an infection, the appropriate form (i.e., Infection Form) must be submitted.   The form submission schedule in the Data Management Handbook specifies which forms are event based.

3.   GETTING STARTED

3.1.   Access to the Internet

When people speak of the Internet, they are usually referring to the World Wide Web (WWW) – a graphical interface to the Internet. The World Wide Web is accessed through a browser program such as Internet Explorer. For best performance, the supported browsers (referenced in the Data Management Handbook) should be used to access AdvantageEDC^{SM}. Although you may access the system using earlier versions of internet browsers, they are not supported and performance might not be optimal. If you are unsure of what browser version you are currently using, click the [Help] menu of your browser and select [About Internet Explorer] or [About Mozilla Firefox]. A screen will then display with your version information (see images below). If no browser is installed on your machine, you should arrange to have Internet Explorer 5.5 or higher installed.

3.2.   Access to AdvantageEDC^{SM}

3.2.1. AdvantageEDC^{SM}
The AdvantageEDC^{SM} system is available only to individuals who have been authorized for its use by means of user rights granted by the Emmes Corporation, as described below. After starting the browser program, the user accesses AdvantageEDC^{SM} software via its Uniform Resource Locator (URL) – its Web address. Refer to Chapter 5 for detailed instructions for accessing AdvantageEDC^{SM} and performing data entry functions.

3.2.2. Usernames/Passwords
A username/password, assigned by the Emmes Corporation, is required to access the system. The username identifies who is working in the system and provides a record of who is responsible for adding, modifying or deleting data. This information is linked to the data in the database as part of an audit trail. **It is very important that you do not share your username/password for this reason.** Your name and site will appear in the header of each

screen that you access. Users are restricted to only their site's data and only to the functions associated with the rights the user has been granted.

3.2.3. User Rights
Users are assigned rights to the system, based on their responsibilities for Duke Stem Cell Application protocols. The types of rights include:

- Enrollment: Persons assigned enrollment rights are able to enroll patients onto protocols.
- Full Data Entry Rights: Persons assigned full data entry rights are able to access all parts of the data entry system, with the exception of the Enrollment module. They may add, delete and modify patient, clinical and laboratory data, as well as use system utilities.
- Read-Only Rights: Persons assigned read-only rights will have limited access to the data entry system and system utilities, and will not have access to the Enrollment module. They may view data, but are not able to add, delete or modify data.
- Administrative Rights: Persons assigned administrative rights have the ability to grant new users access to their sites' data and to manipulate their user rights.

3.2.4. User Certification
Certification by the Emmes Corporation is required prior to assignment of rights for individuals who request full data entry rights and/or enrollment rights. To be certified, the user must demonstrate sufficient knowledge of AdvantageEDC^{SM} and the responsibilities associated with the rights that have been requested.

At a minimum, certification will be granted after the potential user has:
- Read the sections of this manual that address the functions and responsibilities associated with the requested rights;
- Accessed the AdvantageEDC^{SM} training site and completed the training using the features of the system to which he/she will have access; and
- Participated in a discussion of these functions and responsibilities with Emmes Corporation staff.

Formal certification sessions may be held as part of site visits or other training activities, as appropriate for the circumstances.

3.3. Navigation

AdvantageEDC^{SM} has multiple components available to users. Once you are logged in, you move around the system from the **Main Menu**. The Main Menu is the gateway to enrollment, data entry of forms and access to system utilities (e.g., Download Data). The computer mouse or tab button is used to move from items on a screen and to activate the buttons on each screen. Instructions for use of these functions are provided in the remaining sections of this User's Guide.

Before data can be entered for an individual, the patient must be enrolled in the system using the **Enrollment** module (see Chapter 9), which requires entry of demographic information and completion of a protocol-specific enrollment form. The patient is enrolled based on this step and data entry functions then become available for this patient's data.

3.4. AdvantageEDC^{SM} Training System

To access the AdvantageEDC^{SM} training site, contact the Emmes Corporation for the URL.
The training site is a "mirror" of the live site (Data System) and is provided to familiarize potential users of the AdvantageEDC^{SM} system with its features and to provide a means to "practice" using system utilities and data entry functions. There is no link between the training site and the live AdvantageEDC^{SM} system, so you may use the functions of the system freely without concern that your actions will have any impact on actual study data.
A valid username/password has been assigned by the Emmes Corporation and is required for access to the AdvantageEDC^{SM} Training Site. The instructions for use of AdvantageEDC^{SM} functions in the remainder of this manual also apply to the training site.

Notes:
- The username/password for the training system is not valid for access to the "live" or production Duke Stem Cell Application AdvantageEDC^{SM} system.
- For future convenience, we recommend that you bookmark the URL for logging into the training system.
- The training system has a green background on the login page, differentiating it from the live data system login page which has a grey background.

4.   GENERAL GUIDELINES

Common guidelines that apply to all AdvantageEDC^{SM} screens are detailed below.   Form-specific guidelines are detailed in the Data Management Handbook.

4.1.   Navigation

Use only AdvantageEDC^{SM} navigation buttons to navigate throughout the system (e.g., do not use the BACK arrow in the browser navigation toolbar or BACK in the GO TO section of VIEW). Using the Browser buttons might cause unintended and unpredictable changes to the data and to AdvantageEDC^{SM} functions. If you do use the browser selections, you may lose data that you have entered and/or be "booted out" of the system.

- It is helpful to go to your Browser's "View/Toolbar/Standard Buttons" and click to turn the Standard Buttons 'off' to prevent the unintentional use of your Browser's buttons.

Throughout AdvantageEDC^{SM}, buttons are used to direct the action of the user. To direct the system to perform a specific function, use the mouse and click on a button, or tab to the button and press the ENTER key on your keyboard.

Once you have completed data entry on a screen, click the [Save] button. Data are not saved, and thus not entered into the database, unless you use this button. We recommend that you save your data frequently, especially if you are called away from your computer. If you "time out" before saving data (see Section 4.3.2), any data you have entered since the last save will be lost, and you will need to re-enter them.

4.2.   Screens
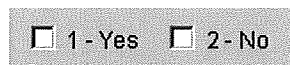
4.2.1. Screen Format

Most of the data screens are designed to be "single page," in which the data are captured on one screen. You may need to scroll down to reach the bottom of the page or scroll across to see the entire width of the page, but you do not need to use a button to move down the page of the screen.

4.2.2. Data Entry Formats

Within data entry screens, the data are captured using different formats.

- Checkboxes are often used when one of several pre-specified codes or options must be chosen – e.g., "Yes" or "No" or one of several easily displayed, short responses (see example below). Only one choice is allowed.

☐ 1 - Yes   ☐ 2 - No
Checkbox

- Pick lists (sometimes called "drop down boxes," "pull-down lists" or "combo lists") are also used when a list of possible choices is provided for a data field, but the list is too long to display efficiently or clearly on the screen. Depending on where the data field is located on the screen, the pick list may display upward or downward. Click on the appropriate option. It will be displayed in the box. Only one choice is allowed.

1 - Cyclosporine
2 - Tacrolimus
3 - Mycophenolate Mofetil (MMF)
4 - Not Given During Assessment Period
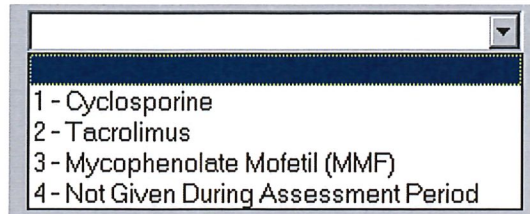
Drop down, pull-down or combo list

- Text boxes are used for data that must be typed in, rather than selected from a list. Text boxes are most commonly used to capture text, dates, and numeric values, such as laboratory values. Comments may also be entered on most forms using large text boxes called memo boxes.

(mm/dd/yyyy)

Text box

4.2.3. Data Entry Field Icons

On each case report form, there will be an icon to the left of each question. This icon will indicate the status of the field. The table below displays all the possible icons:

ICON	Description of Functionality
No Icon	The field is not required to be completed.
✔	The field is required and valid data has been entered. A missing value exception request cannot be submitted for a field when this icon is displayed.
○	The field is required to be completed and no data has been entered.
EX	The field is missing, a missing value exception has been requested, and the exception is pending review by a Data Manager at Emmes.
EX	The field is missing, and a missing value exception was requested, but the exception was denied by a Data Manager at Emmes.
EX	The field is missing, and a missing value exception was requested and granted by a Data Manager at Emmes.
OR	An out-of-range value has been entered in the field, and review of the out-of-range field by a Data Manager at Emmes is pending.
OR	The field has an out-of-range value and the value was denied for inclusion in the database by a Data Manager at Emmes.

4.2.4. Printing Screens

Printing screens is frequently a convenient mechanism to provide documentation of how AdvantageEDC^{SM} is functioning or for internal quality assurance purposes.

To print a screen, position the cursor on the screen and press **CTRL+P**. You may also print by selecting **File** on the browser toolbar and clicking on **Print**. In each case, a print menu will display with print options for your local printer set-up.

If an error message is displayed, the print screen command described above will not work. Instead, press the **[Print Screen]** button on your keyboard; switch to a word processor (e.g., Word or Word Perfect) document and paste. Then print from the word processor.

4.2.5. Navigation Bar Summary

4.2.5.1. Toolbars

Wed Nov 25 2015 10:46:51 AM EST	Duke Stem Cell Application - Dev - V.1.05 Sarah Nikles (20.0) IDES20.1.3	
	Site/Center: Duke Clinical	
Main Menu > Data Entry Main		• Extend Session • Preferences • Logout
	Forms Grid	
Protocol: Sibling Allogeneic UCB for Children with Cerebral Palsy		Recipient: SCP001

Forms Navigation Toolbar

Main Menu: If selected, the user will be returned to the main menu. From the Main Menu page you may choose from such categories as Data Entry, Utilities and Reports, and protocol-specific Other Materials.

Data Entry System: If selected, the Data Entry Main page will display. From the Data Entry Main page you have the options of selecting the protocol, patient ID and form for data entry.

Key Selection: If applicable, the Key Selection page will display. Key Selection page displays key fields (other than protocol and patient ID) applicable for a form to be submitted, as well as other existing records for the form and patient selected.

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

Session Preferences: If selected, allows the user to display the audit history. Also allows user to determine if they will return to the previous page after saving a form or if the form will be reloaded.

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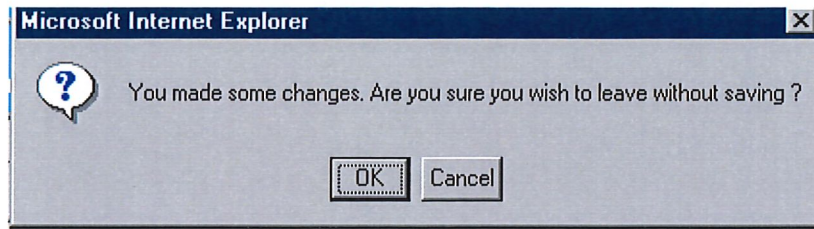
Click **[OK]** to leave without saving or **[Cancel]** to return to the screen.

The following is the toolbar for the *Enrollment Module*:
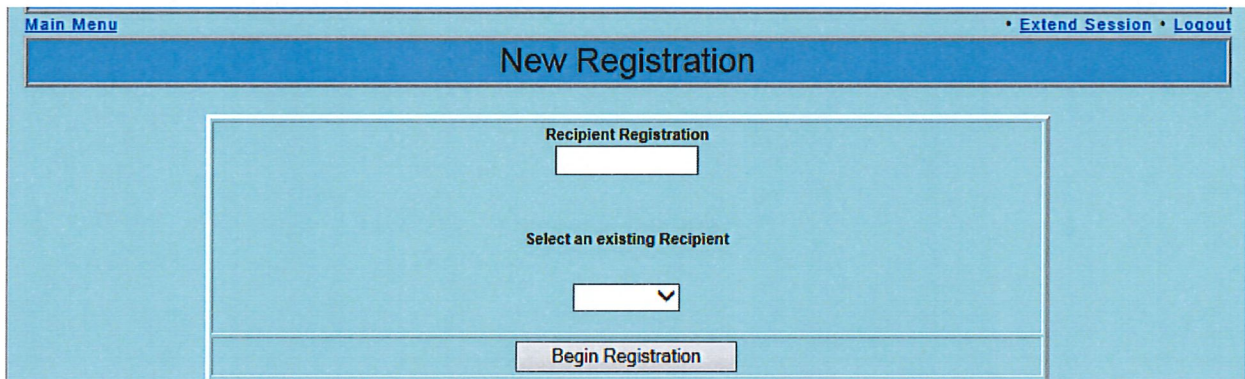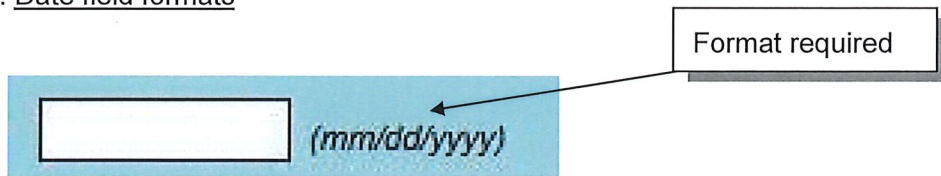

Enrollment Navigation Toolbar

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

Recipient Registration: If selected, the New Enrollment page displays to begin the enrollment process for a new patient; the Demographics screen is displayed for entering data.

Select an Existing Recipient: If selected, the New Enrollment page displays to continue the enrollment process for a patient previously enrolled in at least one segment of a protocol on the platform; the Demographics screen is displayed for verifying the data previously entered.

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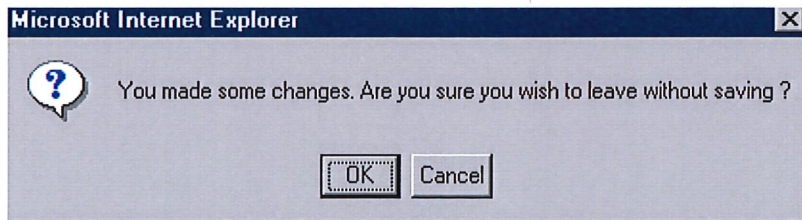
Click **[OK]** to leave without saving or **[Cancel]** to return to the screen.

4.3.   System Messages

4.3.1. Consistency Checks/Field Validation Messages

During data entry, the system performs field validation checks on certain fields (e.g., checks for format for dates, times, and numeric values) and consistency checks between select fields (e.g., end dates for a medication or adverse experience must be on or after the start date). If your entry does not pass the validation check, or the data do not meet the specified requirements, you will be prompted by a message indicating this check. You must resolve this inconsistency by deleting or modifying the data entered or performing some other action appropriate to resolve the situation. Examples of consistency checks and field validation messages are shown below.

4.3.1.1. Date field formats
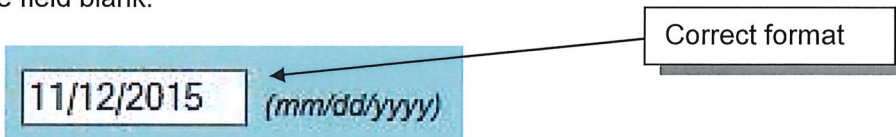
Format required

(mm/dd/yyyy)

Above is an example of a date field. The form will indicate, next to the textbox, the formatting required for the field. In the example, a date has been entered without the required format of forward slashes between the month and day and the day and year.

If a date is entered in an invalid format (e.g. *ddMMMyyyy*), the following field validation error message will appear:

Message from webpage

⚠ Invalid characters found and removed from date

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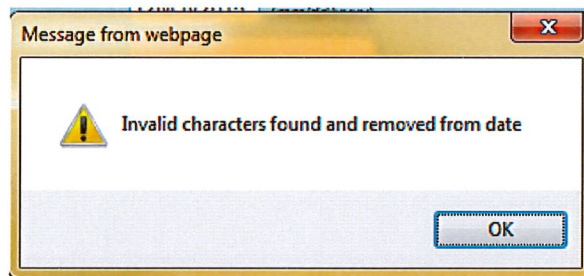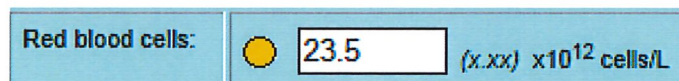
If you select **[OK]** from the error message box, the system will take you back to the form with the date field blank.

Correct format

11/12/2015 (mm/dd/yyyy)

Above is an example of the date field formatted correctly.

4.3.1.2. Numeric field formats

Red blood cells: ● 23.5 (x.xx) x10^{12} cells/L

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 too many characters

before the decimal point. However, the valid format for this field is a one-digit number with two places after the decimal point. If an invalid number is entered, the following consistency check will appear:
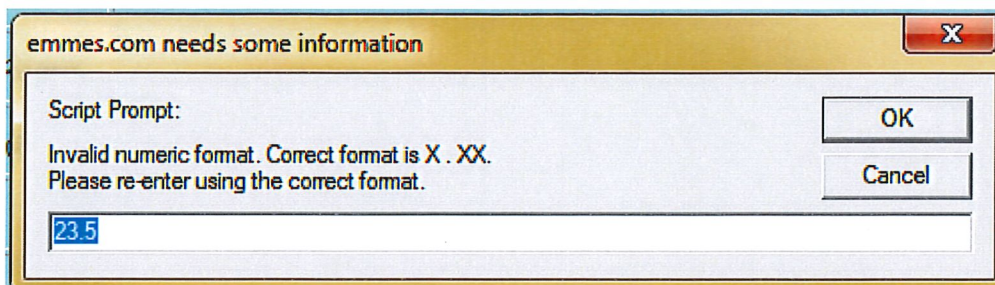

Enter the correct numeric value in the textbox, click [OK] and the form will display with the corrected value.

When **[Cancel]** is selected at this prompt, the form will redisplay with the field blank. The field is available for re-entry of a correctly formatted numeric.

4.3.1.3. Data Ranges

Ranges are programmed for most numeric and date fields to ensure data integrity. When data are entered into a field that falls out of the programmed range, a field validation error message will display.
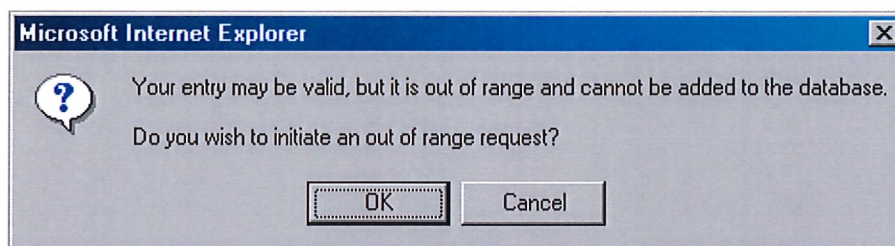
The consistency check message informs you that the data is not allowed because it is out of range. If the data are correct as entered, then click **[OK]** and the icon will appear to the left of the question, indicating that an out-of-range value has been entered and review by the Emmes Data Manager is pending. To change the data, select **[Cancel]** and then make modifications to the data.

At any time, an Emmes Data Manager can review the out-of-range value requests and either grant or deny the requests. When an out-of-range request is denied, the icon will change to the **OR** icon and the value will appear in the "Missing Value/Range Request Report". If an out-of-range value is approved, a production release will be completed to expand the range of the specified field to allow for data entry. Sites will be notified once the production release is complete, and the specified field is ready for data entry.

4.3.2. 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.
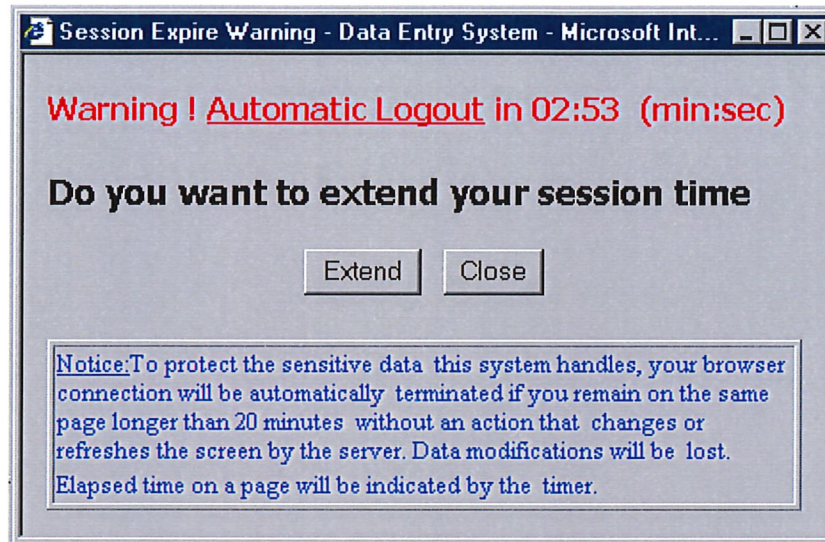
Click on **[Extend]** to reset your system login time to 20 minutes, or **[Close]** to clear the warning window.
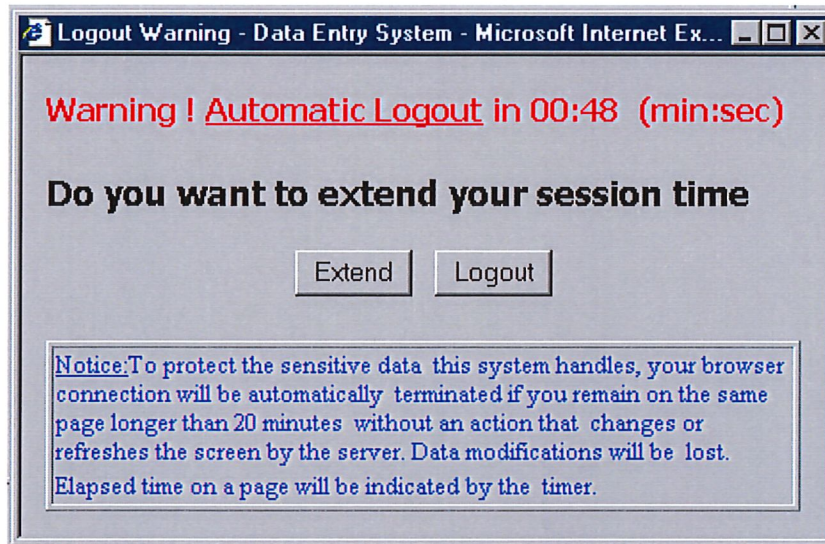
The window pictured above will display when there is <50 seconds left before automatic logout. Click on **[Extend]** to reset your system login time to 20 minutes, or **[Logout]** to log out of the system.
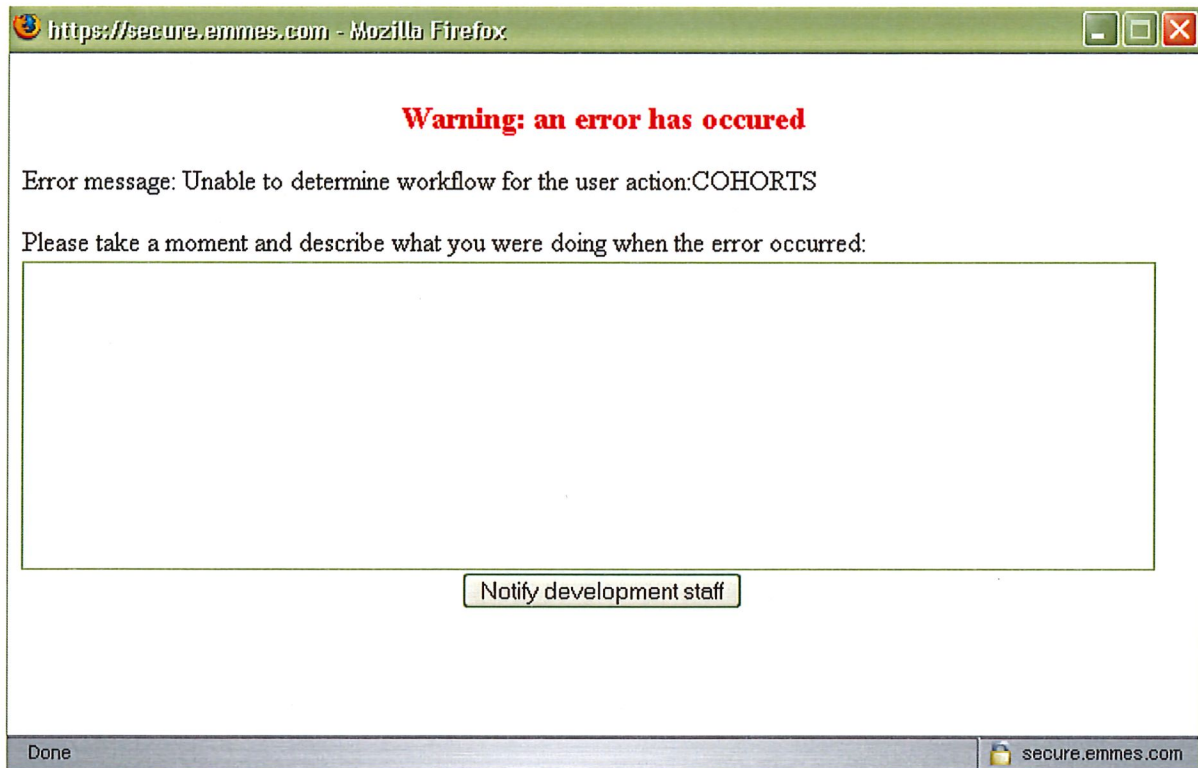
4.3.3. JavaScript Error Messages

If the system suddenly becomes unresponsive and beeps when you click the mouse, you have a buried JavaScript error. Press **Alt+F4** to close your browser. Then you will see a JavaScript

error box. Write down as much of the error message as possible (or capture as a print screen and paste it in a Word or Word Perfect document, as described in Section 4.2.3) and e-mail it as an attachment or fax it to the Emmes Corporation Data Manager. You will lose any unsaved data when this error occurred. Then click **[OK]**. You'll need to start your browser again to resume data entry.

5.   CUSTOM ERROR PAGE

The user now has the option to send an email directly to the Emmes computer systems development staff upon encountering an error in AdvantageEDC. When an error occurs, the warning box below will appear, pre-populated with the corresponding error message. In order to assist the programming staff in replicating and resolving the error, the user is requested to describe what he or she was doing when the error occurred in a brief email. To submit the email to the programming staff, click on the 'Notify development staff' button at the bottom of the window.

Warning: an error has occured

Error message: Unable to determine workflow for the user action:COHORTS

Please take a moment and describe what you were doing when the error occurred:

| Notify development staff |

6.   RETRIEVE PASSWORD / PASSWORD EXPIRATION REMINDER

A user who forgets his/her password may now receive the password by email directly from the system. Click on the "Forgot your password?" link on the Login page of AdvantageEDC.   The user must have a valid email address, security question and response saved in User Administration to be able to use this function. To add or change a security question, the user must click on the 'Maintain User IDs' link under the Utilities and Reports Subheading on the Main Menu of AdvantageEDC. The user will be redirected to the User Administration: User Profile screen in which the user can select a security question from a drop-down list and enter a corresponding answer.

AdvantageEDC^{SM} Login Screen

User ID:	
Password:	
	Forgot your password? ←

Log In	Cancel

The next screen will allow the user to enter his/her User ID and then the answer to his/her security question.

Enter your User ID:		Verify

After entering the User ID:

NOTE: In order to retrieve your password via email, you MUST have a valid email, security question, and response saved in the User Administration module.
All security responses are case-sensitive.

Enter your User ID: snikles2

The User ID is valid and has a security question and response.

Security question: What was the name of your elementary / primary school? [   ] Verify

After submitting a valid User ID and response to the Security question, the user will receive a confirmation that his/her password has been sent to the email address displayed.

NOTE: In order to retrieve your password via email, you MUST have a valid email, security question, and response saved in the User Administration module.
All security responses are case-sensitive.

Enter your User ID: snikles2

The User ID is valid and has a security question and response.

Security question: What was the name of your elementary / primary school? *not displayed*

The password has been mailed to snikles@emmes.com.

The email appears as below. Please do not attempt to reply to the email. To ensure the confidentiality of the password, no staff at Emmes receives any replies to the email address that is included for the password email, it is not a valid email address.

Password request

noreply@emmes.com
Sent: Wed 11/25/2015 11:19 AM
To: Sarah Nikles

This is an automatically generated email. Do not respond to this email.

Password request for Duke Stem Cell Application
User ID: snikles2
password: sniklesdkutest
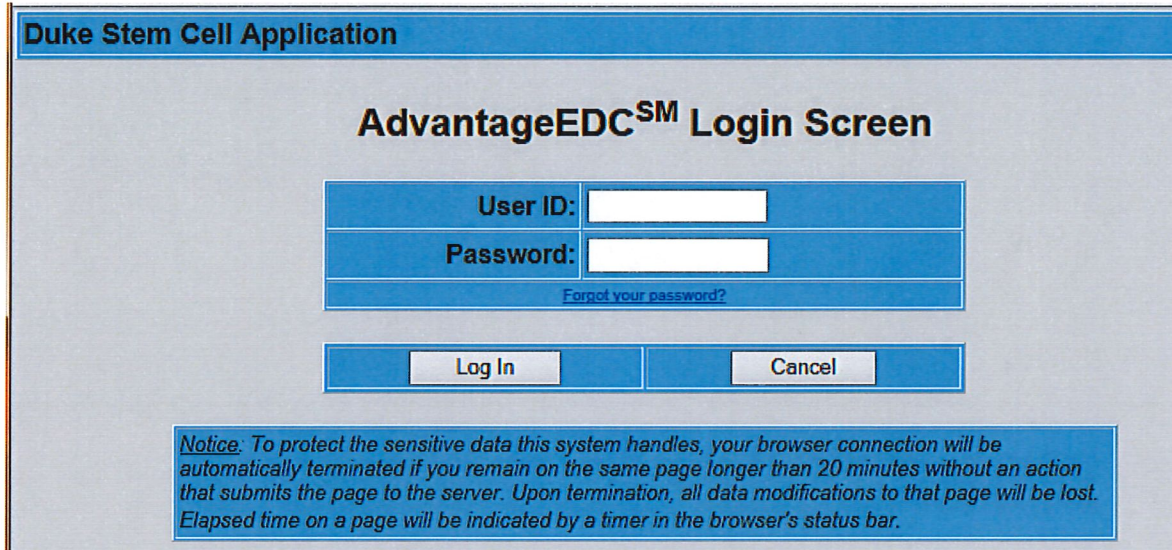
7.   LOGIN AND MAIN MENU

7.1.   Login to AdvantageEDC^{SM}

To access AdvantageEDC^{SM}, establish an Internet connection and start Internet Explorer. In the **Address/Location** box of the web browser, type https://secure.emmes.com/duke/jsp/login.jsp

The AdvantageEDC^{SM} Login Screen will be displayed (see below).

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

Duke Stem Cell Application

AdvantageEDC^{SM} Login Screen

User ID: _____

Password: _____

Forgot your password?

| Log In | 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. Elapsed time on a page will be indicated by a timer in the browser's status bar.

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 AdvantageEDC^{SM} 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. The first time you log in, your password will be CHANGEME.
- 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.

The following screen will appear if you are logging in for the first time. Click on **Maintain User IDs**. When prompted change your password from CHANGEME to a password that is at least 5 characters long.

Password Expired

To use this application please proceed to change your password by clicking on the "Maintain User IDs" link below.

Maintain User IDs

7.2. Main Menu

Once you are logged into AdvantageEDC^{SM}, the first screen to display is the **Main Menu**, which is the gateway to enrollment/randomization in Duke Stem Cell Application protocols, data entry of forms and access to system utilities. Use the computer mouse and click to select the activity you wish to perform.

Wed Nov 25 2015 11:25:38 AM EST	Duke Stem Cell Application V. 1.05	Sarah Nikles
	Site/Center: Duke Clinical	

• **Extend Session** • **Preferences** • **Logout**

Main Menu

Data Entry	Utilities and Reports	Other Materials
• Registration • Data Entry System • Change Site	• Maintain User IDs • Download Data • Missing Values Report • Missing Forms Report • Review Missing Forms Exceptions • Grant/Deny Missing Value/Range • View Deleted Records	• User Guide TBD

From the **Main Menu** you may choose the following functions:

Data Entry

Registration: The Enrollment/Randomization module is used to enter demographic data, enroll a patient onto a protocol and when applicable, receive a randomization assignment.

Data Entry System: The Data Entry module is used to access and enter data in forms for a patient.

Utilities and Reports

Maintain User IDs: This is an administrative management feature that gives the administrator capability to provide and maintain access rights for Duke Stem Cell Application protocol staff.

Download Data: This option enables transplant centers to download patient data in two formats: a version of XML and a version of comma-delimited text.

Missing Values Report: This report enables transplant centers to view missing data fields, data exception requests, and out of range exception requests. This report is updated in real time to

reflect the current status of the data. Centers should review and resolve queries on this report at least monthly. Queries can be resolved by either entering the data or requesting exceptions.

Missing Forms Report: Includes a summary of all missing forms for the center. This report is updated in real time to reflect the current status of the data. Centers should review and resolve queries on this report at least monthly. Queries can be resolved by either entering the data or requesting exceptions.

View Deleted Records: This report enables transplant centers to view deleted records for a specific data range, form, or patient ID.

Other Materials

This area contains information and materials needed to operate studies at the participating centers. The items it includes are:
- Protocols;
- AdvantageEDC^{SM} User's Guide;
- Data Management Handbook;
- Case Report Forms; and
- Protocol specific documents.

8.   ENROLLMENT SYSTEM

8.1.   Demographic Data, Protocol Selection, and Enrollment Segments

The Enrollment System consists of two parts – collection of demographic data and confirmation of eligibility. The process must be completed:

- After the patient has been screened, determined to be eligible for a protocol, and signed the informed consent document, and
- By an individual who has been granted specific user rights to the Enrollment module (see Section 3.2.3).

Points to Remember:
- Once patient information is entered into the system, found to meet eligibility requirements and randomized, if applicable, the patient is considered 'enrolled' and cannot be removed from the system without the specific intervention of the Emmes Corporation.
- For sites needing enrollment and/or randomization when AdvantageEDC^{SM} is temporarily unavailable (e.g., loss of power at the clinical site), please notify The Emmes Corporation or the site Protocol Monitor for assistance in the process.

8.2.   Enrolling a New Patient

8.2.1. Accessing the Enrollment System
At the Main Menu, click on **Enroll Patient**. The following screen will appear:

8.2.2. Begin Enrollment for a New Participant
Enter a participant ID in the Recipient Registration box and click on **Begin Enrollment**. A pop-up will appear requesting the new participant ID be entered again to confirm the ID. Enter the participant ID again and click OK. The two IDs must match or the system will not allow you to enroll the new participant.

An example of the pop-up may be seen in the screenshot below.

New Registration

Recipient Registration

SCP007

Select an existing Recipient

[⌄]

Begin Registration

emmes.com needs some information   ☒

Script Prompt: OK

Please confirm the Participant ID by entering the ID in the space below:

Cancel

SCP007

An example of the demographics data entry screen for a new patient is shown below:

Demographics

Recipient:
SCP007

Continue

Web Version: 1.0; 2.01; 10-08-15

Enrollment is for: ☐ Duke Stem Cell Lab   ☑ UCB for Cerebral Palsy Protocol

⬤ Date of Birth: [   ] *(mm/dd/yyyy)*

⬤ Gender: ☐ 1-Male   ☐ 2-Female

⬤ Race: [⌄]

⬤ Ethnicity: [⌄]

Continue

- **Race:** Select the patient's predominant race (that he/she considers himself/herself) from the dropdown list of **Race**.

After completing the demographics screen, click on **[Continue]** and you will move to the Select Protocol screen.

8.2.3. Demographics that Match a Previously Enrolled Patient
If the patient you are currently attempting to enroll has the same demographic information as a patient previously enrolled, the system will ask you to verify the patient as either a new patient or a previously enrolled patient.

There may be a time when there is more than one match. Choose the correct patient match by selecting the corresponding **[Pick and Continue]** button to continue the enrollment process.

If it is a new patient (demographics are the same but it is NOT the same patient) then select **[This is a New Patient]**.

8.2.4. Enrollment Process
After completing the Demographics form, the protocol in which the participant will be enrolled must be selected. Choose the appropriate protocol/segment and click **[Continue]** to navigate to the enrollment form.

8.2.4.1. Inclusion criteria
The participant must meet all of the inclusion criteria to be eligible for participation in the study. Any ineligible responses will result in a warning message displayed at the top of the screen and response will be highlighted in red.

> Patient is ineligible. Questions with errors are highlighted (in this color) below.

In some cases, date and laboratory values must also meet criteria for inclusion. Additional warning messages may activate ineligibility because of the date or value entered.

8.2.4.2. Exclusion criteria
Patients will not be enrolled in the study if they meet any of the exclusion criteria. Any ineligible responses will result in a warning message displayed at the top of the screen and response will be highlighted in red.
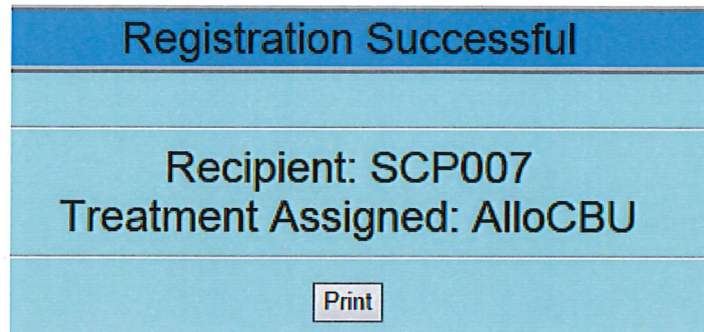
> Patient is ineligible. Questions with errors are highlighted (in this color) below.

In some cases, date and laboratory values must also meet criteria for exclusion. Additional warning messages may activate ineligibility because of the date or value entered.

8.2.5. Enrollment Completed

After completing the enrollment form criteria, click **[Continue]** to continue enrollment. When a patient is enrolled successfully, the Enrollment Successful screen is displayed.

Registration Successful
Recipient: SCP007 Treatment Assigned: AlloCBU
Print

8.2.6. Multiple Enrollment Segments

The Duke Stem Cell Application protocols may have multiple segments for which a patient must be enrolled. The protocol specific Data Management Handbook will outline the segment enrollment procedures for each protocol.

8.2.7. Updating and Printing Demographics and Enrollment Forms

After the enrollment process is completed, the user has the option of updating and/or printing the demographics and enrollment forms for their records, i.e., patient-specific binders. The forms can be updated and/or printed by performing the following:

Step 1: Select **Data Entry System** from the main menu screen.

Step 2: On the Data Entry Main Menu screen select the appropriate **Protocol** and **Patient ID**.

Step 3: From the Data Entry Main Menu screen select the **Demographics Review** form within the forms box and select **Data Entry**. The Demographics form will appear with the information entered at the beginning of the enrollment process. Use your internet browser print button to print the screen.

Step 4: From the Data Entry Main screen select the **Enrollment Review** form within the forms box and select **Data Entry**. If there is more than one segment required to be completed for the enrollment process the **Segment Selection** screen will appear. If there is NOT more than one segment completed or required for the enrollment process, the Enrollment Form will appear with the information entered during the enrollment process. User your internet browser print button to print the screen.

Segment Selection	
Protocol: Autologous UCB for Cerebral Palsy	**Recipient:** CP001

Segment	Action
Autologous UCB for Cerebral Palsy	Update
Demographics	Update

Step 5: From the Segment Selection screen, click on the **Update** button for the segment you would like to update and/or print. The selected segment will appear with the information entered during the enrollment process. Use your internet browser print button to print the screen.

Return to the Segment Selection screen if you would like to print other Enrollment Form segments.

9.   FORMS STATUS/REQUEST FORM AND FIELD EXCEPTIONS

9.1.   Forms Status

All data for patients enrolled in studies will be reviewed for completeness, accuracy and timeliness. Based on a certain trigger date (i.e., transplant date), all protocol-specific scheduled assessments will be tracked.

9.2.   Scheduled Form Status

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

Sibling UCB Transplant Segment

Form Visit # Target Date	D00 Day 0 11/22/2015	D02 Day 2 11/24/2015	D07 Day 7 11/29/2015	M03 Month 3 02/20/2016	M06 Month 6 05/20/2016	M12 Month 12 11/21/2016	M24 Month 24 11/21/2017
Safety Assessment Form		⚠	⚠	⚠	⚠	⚠	⚠
Key Data Elements					⚠		
Current Medications and Active Problem List	⚠				⚠		
Medical History	⚠				⚠		
Pregnancy and Birth History	⚠				⚠		
Growth Measurements	⚠				⚠		
Laboratory Results	⚠				⚠		
Motor Function Assessments	⚠				⚠		
Neurological Assessments	⚠				⚠		
Social History	⚠				⚠		
Therapies/Special Services	⚠				⚠		

9.2.1. Form Schedule Status Table

The table represents the form's visit schedule to indicate at which visit and date a particular form required data to be entered and sent to the EMMES Corporation. The column headers show the visit that data is required and the expected visit date. Symbols within the table indicate the current status of a form for each visit. The meaning of each symbol is found in the table labeled **Key**.

Key:

⚠ Scheduled	⚠ Scheduled and Overdue	☑ Received	✔ Received and Not Scheduled
EXI Exception Requested OK Exception Granted		✖ Requirement Removed ♀ Reviewed	

9.2.2. Key Symbols

⚠

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

Scheduled and Overdue: The form due date has passed 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 (a request by the site to not submit a form) has been submitted.

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

9.3.   Form Data Entry

You may access a form from the form status table to complete or modify an existing form by performing the following steps:

Step 1: Select Data Entry function in the box in the upper left corner of the page.
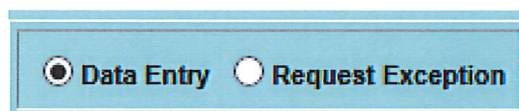
Step 2: Click on the key symbol corresponding to the desired form and visit number.

9.4.   Requesting a Form Exception

In the event that data collected on a particular form cannot be obtained (e.g., a missed visit), the user may request a form 'exception'.

- This feature is to be used only when the entire form cannot be completed. Data entry for a form should be completed for all available data, and except requests can be submitted for any missing data

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.

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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:

Step 3: Select a reason for the exception from the **Select Reason** pull down list. If none of the reasons in the list apply, type in a new reason in the textbox next to or **Enter a New Reason**.

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

Return to the Forms Grid by selecting Forms Grid on the toolbar or request another exception for the same form by selecting Key Selection and repeat Steps 3 and 4.

If the Emmes Corporation is not able to grant the requested exception (e.g., 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.

9.5.   Requesting a Field Exception

In the event that data collection on a particular data item within a form cannot be obtained (e.g., lab sample was not obtained), the user may request a field exception. All field exceptions are executed by performing the following:

Step 1: Click the ⬤ icon next to the data field. The following screen will appear:
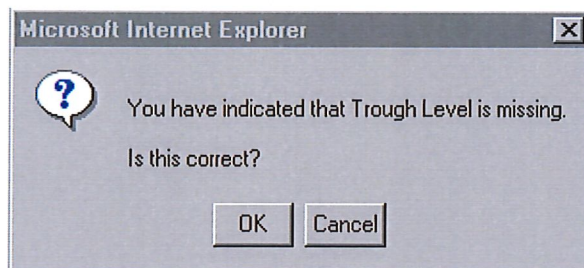
Step 2: Click on the **[OK]** button. The following screen will appear:
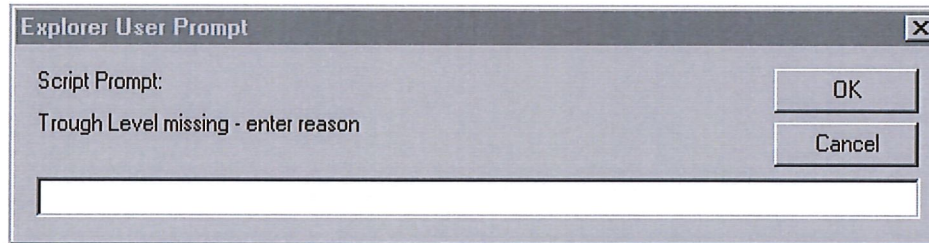
Enter the reason the field is missing. Click on the **[OK]** button. The ⬤ icon will change to the 🔷 icon, indicating that a missing value data exception has been requested and review by the Emmes data manager is pending. You can continue entering data on the form.

At any time, an Emmes data manager can review the missing value requests and either grant or deny the requests. When the Emmes data manager approves a missing value exception request, the icon will change to the **EX** icon. When a missing value exception request is denied, the icon will change to the **EX** icon. Fields with denied missing value exception requests will appear in the "Missing Value/Range Request Report".

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10.   MISSING FORMS AND MISSING VALUES REPORTS

The missing forms and missing values reports are useful tools to quickly display unresolved information for a particular site or Patient ID.

The reports can be accessed two ways:

1. From the AdvantageEDC^{SM} Main Menu, Reports Tab, click on the requested report from the Reports section to display

2. From the forms grid display, the missing forms and missing values link are located below the links to select the patient or forms to view.

10.1. Missing Forms

The Missing Forms report will list all missing and overdue forms for the patient, to include those forms triggered by answers to questions within other forms. This form may be generated from the Main Menu or the Forms Grid as mentioned previously. The user may navigate to the form by clicking on the form hyperlink in the list.

When generated from the Main Menu link, the report will automatically list all the missing forms for all participants on a specific protocol unless the filters are enabled. The report will also display pending form exceptions, and if enable all expected forms.

When generated from the Forms Grid, the report only displays missing forms for a specific participant. Also, the report does not display pending form exceptions or expected forms.

Missing Forms Report when generated from the link on the <u>Main Menu</u>

Recipient	Form	Status	Visit #	Trigger Date	Target Date	Protocol	Reason	Triggering Form
SCP001	Current Medications and Active Problem List	⚠	D00	11/22/2015	11/22/2015	SCP01A	Enrollment	Sibling UCB Transplant Segment Checklist
SCP001	Current Medications and Active Problem List	⚠	M06	11/22/2015	05/20/2016	SCP01A	Enrollment	Sibling UCB Transplant Segment Checklist
SCP001	Growth Measurements	⚠	D00	11/22/2015	11/22/2015	SCP01A	Enrollment	Sibling UCB Transplant Segment Checklist

Missing Forms Report when generated from the link on the <u>Forms Grid</u>

- The report lists the Patient ID and Form.
- The Status is indicated via the same icons used on the Forms Grid to indicate the form status.
- The Visit # column will list the applicable Visit Number of the overdue form for scheduled / visit-based forms. Non-scheduled forms, e.g. Injection / Infusion Form, Adverse Event Form, Death Form, will not have a Visit # displayed.
- The Trigger Date will be the date the patient was enrolled for the visit-based forms. For unscheduled forms, the Trigger Date will be the date prompting the form request, e.g., the Death Form Trigger Date is the date entered on the Follow-Up Form in the *'If yes, record the date of death'* field.
- The Target Date is the date by which the form is expected to be submitted. For visit-based forms, the Target Date is the target date of that visit number. For many non-visit based forms, the Trigger Date and the Target Date will be the same, e.g., the date of death as reported on the Follow-Up Form. .

Non-visit based form expectations are satisfied by the submission of the record within the expected window. Centers should review and resolve queries on this report at least monthly. Queries can be resolved by either entering the data or requesting exceptions.

10.2. Missing Values

The functionality of the Missing Values report is the same. It may be generated from the Main Menu or the Forms Grid. Centers should review and resolve queries on this report at least monthly. Queries can be resolved by either entering the data or requesting exceptions.

When generated from the Main Menu link, the report will automatically list all the missing values for all participants on a specific protocol unless the filters are enabled. The report will also display pending field exceptions, out-of-range fields, and if enabled all expected forms.

When generated from the Forms Grid, the report only displays missing values, pending field exceptions, out-of-range exceptions, denied field exceptions, and denied out-of-range exceptions for a specific participant.

Missing Values Report when generated from link on the <u>Forms Grid</u>

Missing Values Report when generated from link on the <u>Main Menu</u>

• <u>Extend Session</u> • <u>Preferences</u> • <u>Logout</u>

Missing Value/Range Request Report

Sort Order

Sort #1	Sort #2	Sort #3
Recipient ∨	Form ∨	Protocol ∨

Filter

Select Protocol: Sibling Allogeneic UCB for Children with Cerebral Palsy ∨

Select Recipient: SCP001 ∨ or enter Recipient ID: SCP001

☐ Select to filter on Protocol   ☐ Select to filter on Recipient

Please select Sort Order, Filter Options and click Generate Report

| Generate Report | Download Report |

Report Settings
Sort #1:   Recipient
Sort #2:   Form
Sort #3:   Protocol
Protocol: ALL
Recipient: ALL

Key:
◯ Active
[EX] Exception request denied
(EX) Exception request pending
(OR) OR request pending
[OR] OR request denied

Protocol	Recipient	Status	Form	Extra Keys	Field	Ex. code
SCP01A		◯	Serious Adverse Event Form	A11/09/201501	Site awareness date	
SCP01A		◯	Serious Adverse Event Form	A11/09/201501	Expected	
SCP01A		◯	Serious Adverse Event Form	A11/09/201501	Severity of event	
SCP01A		◯	Serious Adverse Event Form	A11/09/201501	Relationship to study pro	

11.   DATA ENTRY PROCEDURES

11.1.   Key fields

Main points to remember about key fields:

- Keyfields are the fields (data items) that make an individual data record (form) unique from all others.
- For forms that are based on protocol-specific assessments (visit-based), the key fields usually consist of Patient ID, Name Code, Protocol Segment and Visit Date.
- For forms that are not based on protocol-specific scheduled assessments (non-visit-based), key fields typically consist of Patient ID, Name Code, Protocol Segment and Start Date for the Event.
- Once entered, key fields are displayed at the top of the form and cannot be modified. If you make a mistake, the record must be deleted (Section 8.4) and the key fields re-entered with the correct information. Following deletion, you must also re-enter the data for the form.

11.2.   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 patient ID number for any patient enrolled in a protocol at the center. To select a patient ID, either click on the down arrow and choose a listed patient ID number or enter a valid ID in the adjacent box at the right. You will be required to enter a valid patient ID and name code before access to data entry on any form is allowed.

Instructions:
1. **Select Patient and Name Code**: For data entry of forms for a particular patient, select the patient ID from the pull down menu or enter the patient ID in the textbox provided.
2. **Forms:** Click on the form type you wish to enter.

3. **[Data Entry]**: Click on **[Data Entry]** and if applicable, the Key Selection menu for the form selected will display as shown below:

Key Selection

Protocol:	Recipient:	Form:
Sibling Allogeneic UCB for Children with Cerebral Palsy	SCP001	Laboratory Results

Select Visit Number from the list   [⌄] or enter : [   ]

[Add Record]

Existing Records

Visit Number	Action
D00 Day 0	[Update]
M06 Month 6	[Update]

All data on the Key Selection page are key fields and are required prior to entering the form. If the form did not have any key fields, then the form would display after selecting it from Data Entry Main.

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

11.3. Existing Records

The bottom of the **Key Selection** screen lists records that have previously been accessed and saved. These records are arranged in rows with columns representing the key field values.

- To modify an existing record, locate the row in the **Existing Records** section that has key field values identical to the ones of the record to be modified.
- Click on **[Update]** and the form with all saved information will be displayed. This form can be modified in the same manner as new forms are added.
- To save new information, click on the **[Save]** button. If you do not wish to save all changes made, click on one of the links in the toolbar at the top of the screen. The system will display a message stating that changes were made and asking if you are sure you want to leave without saving. Click on **[OK]** and the form will remain unmodified.
-

11.4. Form Deletion

Once a form has been saved, it is available for deletion. Forms should only be deleted if a key field has been entered incorrectly or a form was added in error.
To delete a form click on the **[Delete]** button. The system will display a message asking if you are sure that you would like to delete the record. Select **[OK]** if you want to delete the record. Select **[Cancel]** if you have made an error and do NOT want to delete the record.

Message from webpage

? Are you sure you wish to delete this record?

OK   Cancel
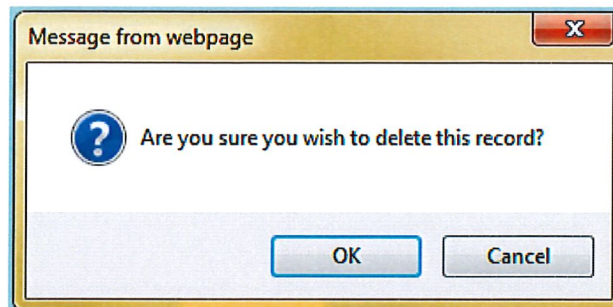
Once the form has been deleted the screen will be cleared and the following notification will appear at the top of the screen:

Main Menu > Data Entry Main > Forms Grid   • Extend Session • Preferences • Logout

Pre-Thaw CBU Characteristics (Adding)
Record was deleted.

11.5. Data Entry Notes

- To choose data entry for the same type of form for the same patient, click on the Key Selection on the top toolbar in the form.
- Unless otherwise specified, all data items on each form are required each time the form is due.
- 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 and will not be read immediately by the Data Manager. All relevant comments and messages to the Data Manager should be emailed or communicated separately.

12. VIEW DELETED RECORDS

The user now has the capability to view records that have been deleted. Note that this feature applies only to records deleted after 07JUL2010. Records deleted prior to this date will be listed, but cannot be viewed. Select View Deleted Records from the Utilities section of the Main Menu.
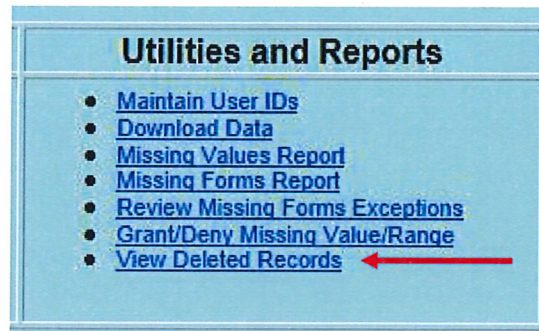
The user can define filtering criteria that include a certain time frame, a particular form or a particular Patient ID. The form, identified by the Patient ID, form name and form keys, is listed with the user who deleted the record and the date and time the form was deleted.

To view the deleted record, click on the form name highlighted in blue. The deleted record will be shown in the panel on the right. Scroll down to the bottom of the form to see the audit history for the record prior to its deletion.

View Deleted Records

Main Menu   • Extend Session • Preferences • Logout

Filter deleted records by:

Print deleted record

☐ Date from [_____] to [_____]
☐ Form [CBU Infusion Form ▼]
☐ Recipient [SCP001 ▼]

Generate List of Records

Choose deleted record
(Only records deleted on-line since 04/29/2010 may be viewed)

Recipient	Screen Name	Extra keys	User	Date	Time
SCP001	Pre-Thaw CBU Characteristics	A	Sarah Nikles	11/25/2015	12:29:52

Pre-Thaw CBU Characteristics

Protocol:	Recipient:	Form:
Sibling Allogeneic UCB for Children with Cerebral Palsy	SCP001	Pre-Thaw CBU Characteristics

Web Version: 1.0; 1.00; 11-20-15

1. ✔ Date completed: [11/12/2015] (mm/dd/yyyy)
2. ○ UCB ID: [_____]

A. Pre-cryopreservation Characteristics

1. ○ Collection date: [_____] (mm/dd/yyyy)
2. ○ Cord blood bank (Select one): [_____ ▼]
   Specify private bank: [_____]
   Specify public bank: [_____]
3. ○ Collection volume (not including anticoagulant): [____] (xxx.x) mL
4. ○ Processing [_____ ▼]

Clinical Audit History

The date and time of listed records are represented in U.S. Eastern Time Zone.

FIELDNAME	OLDVALUE	NEWVALUE	REASON	USERID	DATE	TIME
Date completed	Missing	11/12/2015		Sarah Nikles	11/25/2015	11:02:05

The above grid contains 1 records.

13.   BLANK FORM SAVE

In an effort to prevent the submission of blank forms, a message will be displayed if the user clicks 'Save' on a form for which no fields have been completed. Clicking OK will allow the save action to proceed. Clicking Cancel will restore the user to the blank form unsaved.
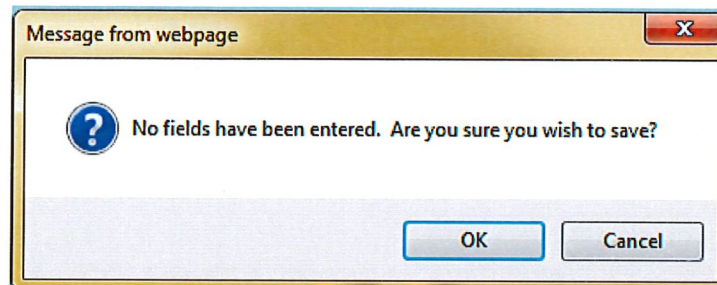
14.   DATA MANAGEMENT INSTRUCTIONS

14.1.   Special Data Entry Instructions – Estimating Dates

Estimated dates: Dates entered into AdvantageEDC^{SM} 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 AdvantageEDC^{SM}:

> If the **month of the year** is estimated: Enter "06."
> If the **date of the month** is estimated: Enter the 15th ("15").
> 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 patient remembered that he started taking a particular medication "sometime in the year 2002." Efforts by the clinic staff to elicit a more precise response were unsuccessful. The date would be estimated as "06/15/2002" and a note of the estimated date should be added to the progress notes in the patient's chart and in the **Comment** section of the form.

Signature Manifest

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All dates and times are in Eastern Time.

STCL-GEN-015 JA2 Duke Stem Cell Laboratory System Advantage EDC-SM User's Guide

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