STEM CELL
LABORATORY (STCL)

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EMMES System Advantage EDCSM JA1

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STCL-GEN-015 (JA1)
EMMES System AdvantageEDC^{SM}

1. There shall be a system to limit access to authorized individuals.

2. Individuals making entries shall be identifiable.

3. JavaScript Error Messages

    3.1. If the system suddenly becomes unresponsive and beeps when the mouse is clicked there is a buried JavaScript error.

    3.2. Press Alt+F4 (PC) or Command-W (Macintosh) to close the browser.

    3.3. Then a JavaScript error box should appear

    3.4. 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 and e-mail it as an attachment to the Quality Department.

    3.5. Any unsaved data will be lost, when this error occurs.

    3.6. Then click [OK].

    3.7. Restart the browser to resume data entry.

4. The EMMES Corporation will maintain all Java Script Error reports and the resolution for each error message they received.

5. Assignment and Maintenance of User IDs and Passwords

    5.1. The AdvantageEDC^{SM} database administrator protects patient identity, medical information confidentiality and data entry integrity by requiring users of the online data entry system to enter a unique user ID and password prior to system entry.

    5.2. The AdvantageEDC^{SM} database administrator is responsible for the maintenance and assignment of user IDs and passwords.

        5.2.1. The AdvantageEDC^{SM} database administrator has the ability to limit a user's access to "Read" or "Read/Write".

    5.3. Requirements for Assigning User IDs and Passwords

        5.3.1. Receive request from client to add a new user to system

        5.3.2. Determine level of access to be granted to the new user

    5.3.3. Advantage EDC^{SM} database administrator sends the User ID and password to the client via email (user ID and password are not sent in the same email as the data entry URL)

    5.3.4. Advantage EDC^{SM} database administrator documents the new user's name, user ID and password, access limitations and date.

6. Stem cell laboratory data base

  6.1. Assignment and Maintenance of User IDs and Password

    6.1.1. The STCL database administrator protects patient identity, medical information confidentiality and data entry integrity by requiring users of the online data entry system to enter a unique user ID and password prior system entry.

    6.1.2. The STCL database administrator is responsible for the maintenance and assignment of user IDs and passwords.

    6.1.3. The STCL Advantage EDC^{SM} database administrator has the ability to limit a user's access to "Read" or "Read/Write".

  6.2. Requirements for Assigning User IDs and Passwords

    6.2.1. STCL database administrator determines the level of access to be granted to the new user when utilizing the STCL database.

    6.2.2. Data entry rights are granted based on the employee's job functions/responsibilities.

    6.2.3. User name and password are established for each employee requiring access to the database. This information is communicated to the employee via e-mail.

    6.2.4. STCL database administrator documents the new user's name, user ID and password, access limitations and date.

7. Advantage EDC^{SM} User's Guide

  7.1. This document explains the basic procedures for performing data entry over the Internet using Advantage EDC^{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.

Signature Manifest

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STCL-GEN-015 JA1 EMMES System Advan

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