1 PURPOSE
   1.1 This procedure establishes the process to update the InfoEd System.
   1.2 The process begins when an SOP requires the InfoEd System to be updated.
   1.3 The process ends when the InfoEd System has been updated.

2 REVISIONS FROM PREVIOUS VERSION
   2.1 None

3 POLICY
   3.1 None

4 RESPONSIBILITIES
   4.1 IRB staff members are responsible for carrying out this procedure.

5 PROCEDURE
   5.1 For new entries not related to training, enter the following fields in a new entry:
      5.1.1 Name: Enter the name of the investigator.
      5.1.2 Date Entered: Enter the date the letter was sent that included the request.
      5.1.3 Items Awaiting Receipt: Enter one of:
         5.1.3.1 Modifications Required to Secure Approval.
         5.1.3.2 Protocol for Emergency Use.
         5.1.3.3 Five-Day Report of Emergency Use.
         5.1.3.4 FORM: Continuing Review Progress Report.
      5.1.4 IRB ID.
      5.1.5 Protocol Title.
      5.1.6 Deadline:
         5.1.6.1 Enter a deadline of 5 days for “Five-Day Report of Emergency Use.”
         5.1.6.2 Enter a deadline of 90 days for “Modifications Required to Secure Approval.”
         5.1.6.3 Enter a deadline of 30 days for “Protocol for Emergency Use.”
         5.1.6.4 Enter a deadline of 30 days before the Expiration Date for “FORM: Continuing Review Progress Report.”
      5.1.7 Date of Response: Leave blank.
      5.1.8 Type of Response: Leave blank.
      5.1.9 Restricted: “FALSE.”
   5.2 For training notifications, enter the following fields:
      5.2.1 If there is a previous entry, update the following fields:
         5.2.1.1 Date of Response: Date the IRB was notified that training was completed.
         5.2.1.2 Items requested: “Items Requested.”
         5.2.1.3 Restricted: “FALSE.”
      5.2.2 Enter the following fields in a new entry:
         5.2.2.1 Name: Name of individual.
         5.2.2.2 Date Entered: The date the IRB was notified that training was completed.
         5.2.2.3 Items Awaiting Receipt: “Training Notification.”
         5.2.2.4 IRB ID: Leave blank.
         5.2.2.5 Protocol Title: Leave blank.
         5.2.2.6 Deadline: Enter a one year deadline from the date of training
         5.2.2.7 Date of Response: Leave blank.
5.2.2.8 Type of Response: Leave blank.

5.2.2.9 Restricted: “FALSE.”

5.3 For withdrawal from consideration of a new protocol or modifications to an approved protocol with a status of “Submitted” or “Modifications Required to Secure Approval update the following fields in the appropriate row:

- 5.3.1 Date of Response: Date of response.
- 5.3.2 Type of Response: “Withdrawn by Investigator” or “Withdrawn by IRB.”

5.4 For all other items submitted update the following fields in the appropriate row:

- 5.4.1 Date of Response: Date of response.
- 5.4.2 Type of Response: “Items Requested.”
- 5.4.3 Restricted: “FALSE.”

5.5 To place an individual on the Restricted list change Restricted to “TRUE.”

6 MATERIALS

6.1 InfoEd System

7 REFERENCES

7.1 None