

DEPARTMENT: INSTITUTIONAL REVIEW BOARD
POLICY NUMBER: 019
SECTION: IRB REVIEW PROCEDURES
REVIEW RESPONSIBILITY: IRB
EFFECTIVE DATE: AUGUST 13, 2003
REVISION DATE:
LAW IMPLEMENTED: 45 CFR 46.103

SUBJECT: Procedure for Human Subject Database Information

1. The IRB support staff shall have access to the database information for human subjects.
2. The database utilizes FileMaker Pro Version 6, and the file located server is named "Humansubjects".
3. To start the server, the following procedures are utilized:
 - a) Turn on log in locally username hserver.
 - b) Give password.
 - c) Once logged in, go to start – Programs – Filemaker Pro.
 - d) File – open file 10-16-02 Human Subject.fp5 or current database file.
 - e) Click open.
 - f) Type in user password.
 - g) Minimize Filemaker Pro.
 - h) Turn off monitor.
 - i) A backup is performed everyday to a tape drive at 4:35 pm
 - j) Shut down Database and computer every Friday PM, and reboot every Monday AM.
4. To open the database, the following steps should be performed:
 - a) Go to start – Programs – FileMaker Pro.
 - b) Once in FileMaker Pro, go to File – open remote (to open remote the server must be on with Filemaker up and the file open).
 - c) Choose HumanSubjects Host.
 - d) File 10-16-02 Human Subject.fp5 or current database file.
 - e) Click open.
 - f) Type in user password.
 - g) Begin work in the database.
5. The procedure for generating renewal (continuing review) notices is as follows:
 - a) Renewals are generated at the beginning or end of each month for the next prospective month in the year.
 - b) Go to the find screen in list view (ctrl +f).

- c) In the expiration date field, type the beginning date then from the symbols list choose the range symbol (...) then the ending date. Example: 5/1/2003...5/31/2003.
- d) Press Enter.
- e) A list of all projects that expire between those dates will show on screen.
- f) Print the list and place in the renewal folder.
- g) To print list, go to file-print. In the print screen, change the print pull down menu from current record to records being browsed and print range to all instead of 1 to 1.
- h) Go back and repeat steps b and c.
- i) Review all to insure the listing has a proper mailing address, zip code, and City names spelled out in full.
- j) In the oppr cat field choose exempt.
- k) Press enter.
- l) Now just a list of the exempt/expedited projects that expire will show on screen.
- m) Change screen to the renewal exempt and print letters.
- n) Use step g.
- o) Perform steps j through m for Full Committee renewals. Change screen to full committee.
- p) Make three copies – one for office file, the researcher, and the cc.
- q) Mail out together with the renewal form.
- r) Sign off process renewal letter with the date and initials on the first page of the month and date mailed out in same manner.

6. Procedures for generating termination notices are as described below.

- a) Termination notices should be generated approximately two months after the expiration date during the course of the month.
- b) Staff should go to the renewal folder, and pull out the list of renewals for the month that you must send termination notices.
- c) Check to see if the project has been renewed in the database by searching by title or researcher name.
- d) If project has not been renewed and/or researcher has not responded to the renewal letter indicating that no renewal is necessary, then a termination notice letter must be prepared.
- e) Review to insure the file has a proper mailing address, with zip code and City spelled out.
- f) Change view to termination.
- g) To print, go to file – print, in the print screen change the print pull down menu from to current record and the print range to 1 of 1.
- h) Perform for all listed that have not renewed and write on the office sheet log, next to the project, that you have sent out the termination letter.
- i) Make three copies, one for the office file, one for the researcher, and one for the cc.
- j) Mail out termination letter.

- k) Then, sign off process termination letter with date and initials on the first page of the month and the date mailed out in same manner.

DEPARTMENT: INSTITUTIONAL REVIEW BOARD
POLICY NUMBER: 020
SECTION: GENERAL IRB POLICIES
REVIEW RESPONSIBILITY: IRB
EFFECTIVE DATE: AUGUST 13, 2003
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LAW IMPLEMENTED: 45 CFR 46.113

SUBJECT: Prompt Reporting of Serious or Continuing Noncompliance

1. All credible reports of inappropriate involvement of human subjects in research must be investigated by the IRB Office and Associate Vice President of Research. Such reports of noncompliance may come from any source including IRB Committee members, investigators, subjects, institutional personnel, the media, anonymous sources or the public. The results of the investigation will be reported to the Vice President of Research. Thereupon, the Vice President shall notify the Department head, Dean of the Investigator's School, and the Chair of the IRB. When applicable, notification will also be forwarded to the Faculty Advisor. Regulatory authorities such as OHRP, FDA, NIH, or other federal sponsoring departments or agencies will also be promptly notified by the Associate Vice President of Research of any serious or continuous noncompliance.
2. Between IRB continuing reviews of a protocol and at the time of continuing review of a protocol, it is the Investigator's responsibility to keep the IRB Office informed of any unanticipated problems involving risks to subjects or adverse events that were serious, unanticipated, and resulted in a change to the risk/benefit ratio, even if the event occurred at a location for which the FSU IRB is not the IRB of record. An investigator is responsible for the accurate documentation, investigation and follow-up of all possible study related adverse events. Investigators are also responsible for informing government and other sponsors of any unanticipated events, as appropriate.
3. The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB policies, is not in compliance with federal regulations, or has been associated with unexpected serious harm to subjects.