GUIDELINE FOR RSRB AUDITS

According to OHSP Policy 401 Functions of the RSRB Office, one of the responsibilities is that the office will conduct internal audits of study files. Audits will take place at least annually, but generally will be conducted twice a year in January and June. The following steps should be followed to complete this process.

1. Obtain a list from the IT administrator, sorted by department, of full board studies and expedited studies that need to be audited. The list should also include the Investigator and date of last audit (if applicable).

2. Studies that need to be audited will be generated based on the following criteria:
   - 10% for each department of expedited studies
   - 25% for each department of full board studies
   - 50% for each department of FDA regulated studies

3. Select a study that hasn’t been audited, or hasn’t been audited in the last year and go to the appropriate study in ROSS to verify whether there was a previous audit.

4. Using the Webridge Audit Form (see page 2 and 3 or shared drive RSRB Auditing folder), complete review of the following items in ROSS:
   - Print Application
     - Section 3.1, Type of Funding
     - Section 75.1, check for vulnerable populations
   - Front Page
     - View “Initial Approval Letter” (refer to Audit Form)
   - Checklists
     - New Studies: Specialist and Chair checklists are located under the history log
     - Continuing Reviews: Specialist checklist is located under the “RSRB Only” tab, Chair’s checklist is located under the history log
     - Amendments: Specialist and Chair checklists are located in the “RSRB Only” tab
   - Amendment tab
     - View recent amendments
   - Documents tab
     - View protocol (there should only be one protocol; however, there could be a tracked and clean protocol with same version date)
     - View measures and grant sections
   - Continuing Review tab
     - View most recent continuing review (printer friendly version)
   - Study File (study home page)
     - View for last signed consent(s) and other study documents, if applicable

5. If information is required, the Audit Form is given to the Specialist for clarification or correction as applicable.

6. Once the Audit Form is complete, click on “Record Study Audit” to complete the process and proceed to the next study.
WEBIDGE AUDIT FORM

RSRB # __________________
PI __________________ Board: ______

PREVIOUS AUDIT
- Date of last audit (if applicable): ____________________________
  - Check here if there were any findings? □ Yes □ No □ N/A
  - If so, were findings addressed? □ Yes □ No □ N/A

APPLICATION
- Section 3.1
  - Type of funding: ____________________________
  - Check here if prisoners are involved. □ Yes □ No
  - If yes, was the study assigned to Board P? □ Yes □ No
  - Check here if vulnerable populations are involved.
    (children/minors, pregnant women & prisoners)

FRONT PAGE
- View Initial Approval Letter
  - Approval period dates are correct □ Yes □ No
  - Is the Length of Review on the letter? □ Yes □ No
  - Approval letter is signed and dated □ Yes □ No
  - If expedited, is the expedited category listed? □ Yes □ No □ N/A
  - If no, is the initial approval was done □ before or □ after 1/1/06?
    □ Yes □ No □ N/A
  - Does “Date Expire” on the front page match the expiration date on
    approval letter? □ Yes □ No

RSRB ONLY TAB - HISTORY TAB (INITIAL APPROVAL)
- Specialist Checklist
  - Is specialist checklist uploaded/filled out? (can also be located under “History” tab) □ Yes □ No
  - If study is expedited, what is the category selected? □ Yes □ No □ N/A
  - If study is expedited and 75.1 is checked (look above), are protocol
    and consent forms findings sections filled out? □ Yes □ No □ N/A

Chair’s Checklist
- Is the chair’s checklist filled out? (under “History” tab) □ Yes □ No
- Is the Length of Review mentioned on the checklist? □ Yes □ No
- If study is expedited, does the category selected
  match the category that was selected by the specialist? □ Yes □ No □ N/A
- Check here if study is full board and the chair indicated that the study
  should be expedited at next review (Category 9). □ Yes □ No
- Are there vulnerable populations listed on the checklist? □ Yes □ No □ N/A
  - If yes, are those noted on the approval letter? □ Yes □ No

Notes: __________________________________________

AMENDMENT TAB
- There have been no amendments. □ Yes □ No
  View amendment approval letters for each amendment
  - The expiration date is correct □ Yes □ No
  - Approval letter signed and dated □ Yes □ No
  - Is specialist checklist uploaded under RSRB only tab? □ Yes □ No
  - If the chair checklist filled out under RSRB only tab? □ Yes □ No
  - If there is a problem, please note the specific amendment number(s):__________

Notes: __________________________________________
DOCUMENTS TAB

Study Protocol
- Is there one version of the protocol uploaded? □ Yes □ No □ NA
  □ (When revised, protocols should be replaced not added. OK to have tracked & clean version)

Study Materials:
- Are these only materials uploaded in this area? □ Yes □ No □ NA

Foundation Grants:
- If funded by a Gov. Agency or Foundation, does one of the following apply?□ Yes □ No □ NA
  □ Complete grant including the face page uploaded.
  □ Foundation letter uploaded.
  □ Funded by Core Grant / Umbrella study (RSRB# referenced in section 73.4) *
  □ The UR is a subcontractor for study (section 6.1) *
  *(No grant needed)

Notes:

CONTINUING REVIEW TAB

- There have been no continuing reviews □ Yes □ No
  □ If a continuing review has been done, are the dates on the letter correct? □ Yes □ No
  □ Approval letter is signed and dated □ Yes □ No
  □ Is the length of review and the study status listed on the letter? □ Yes □ No
  □ If expedited study, is the expedited category listed on the letter? □ Yes □ No □ NA
  □ If the study was initially reviewed by the full board and is now expedited, is Category 8 or 9 listed on the re-approval letter? □ Yes □ No □ NA
  □ Is specialist checklist uploaded under RSRB only tab? □ Yes □ No
  □ Is the expedited category consistent with the initial approval? □ Yes □ No □ NA
  □ Is the class checklist filled out under History tab? □ Yes □ No
  □ Is the length of Review mentioned on the Chair’s checklist? (should be on the re-approval letter too) □ Yes □ No
  □ Does the category match the category that was selected by the specialist? □ Yes □ No □ NA
  □ Are vulnerable populations* listed on the Chair’s checklist? □ Yes □ No □ NA
  *(children/minors, pregnant women & prisoners)
  □ If yes, are they noted on the re-approval letter? □ Yes □ No

Notes:

STUDY FILE BUTTON

- If a continuing review was done, have the last signed consent(s) been uploaded? (Can also be located in the Progress Report section 7.2)
  □ Yes □ No □ NA
  *(last signed consent should be uploaded, if in progress report # 1.2C shows enrollment and # 7.1 shows they have a consent form.)

- Do all documents uploaded under the Study File belong to this study? □ Yes □ No □ NA
  □ If no, indicate the name of the document:

Notes:

Actions necessary:
□ File in order.
□ No changes required.
□ Information required. Audit form forwarded to:

Audit performed by:

Revised: 08/2010