EHS-417, INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) & RESEARCH HEALTH & SAFETY COMMITTEE (RHSC) REVIEW PROCESS FLOW CHART

PURPOSE
The purpose of this flow chart is to assist investigators in understanding the process for Biosafety Protocol (annual updates, new submissions and amendments) review and approval.

START
1. Go to www.emory.bioraft.com

2. New Submissions:
   - Lab Setup Wizard
   - Bio Wizard

3. Existing registrations:
   - Update members tab & biological summary
     (Annual updates and amendments)

By the 10th of the month.
Protocols received after the 10th of the month will be pushed to the next month’s committee meeting.

Revisions?

4. Notes are added to biological summary
5. Click NOTIFY PI
6. Does the protocol require committee review?
   - No
     Proceed to review administrative requirements
   - Yes
     Change status of BIO registration to “Awaiting IBC review”

7. Proceed to review administrative requirements

8. Change status of BIO registration to “Awaiting RHSC review”

IBC/RHSC COMMITTEE REVIEW

A. Protocol goes to the:
   - IBC
   - RHSC

8. Designate an IBC committee member as the protocol reviewer

9. Designate a RHSC committee member as the protocol reviewer

10. Send link to biological registration to be reviewed (1 wk before meeting)

11. Send reminder (Monday before meeting)

12. Reviewer posts questions and summary under Notes

Was the protocol

Approved?
   - Approved Pending Administrative
   - Not approved, requiring re-submission & re-review?

Typically, the 1st Thursday of the month

If there is time before the meeting, EHSO will contact the PI with any questions from the reviewer

KEY
- Principal Investigator
- Biosafety Officer (BSO)/EHSO
- IBC or RHSC Protocol Reviewer
- IBC or RHSC Members
- IBC or RHSC Chair
ICS/RHSC APPROVED

13 Notify the PI of the protocol review status and specific requirements for final approval
   • training requirements
   • occupational health requirements
   • upload of corrective action plan

ICS/RHSC APPROVED PENDING ADMINISTRATIVE CHANGES

14 Send PI the committee questions for their resubmission
15 Revise biological registration and CERTIFY
16 Send summary of changes to IBC or RHSC reviewer
17 Review revised protocol
Were all questions addressed?
Yes
A1
No
Repeat from Step 14

PROTOCOL NOT APPROVED, REQUIRES RE-SUBMISSION & RE-REVIEW

18 Send PI the committee questions for their resubmission
19 Revise biological registration and CERTIFY
Repeat from Step 10

ADMINISTRATIVE REVIEW & APPROVAL LETTER GENERATION

20 Review all training & occupational health requirements
21 Biological registration status is changed to Approved
22 Create approval letter & addendum
23 Send letter to IBC/RHSC Chair for their signature
24 Sign letter
25 Scan letter & addendum and email to PI

REFERENCES:
- IBC & RHSC Meeting Schedule
- Biosafety Protocol Guidelines
- IBC Standard Operating Procedures
- RHSC Standard Operating Procedures