KEMRI SERU REVIEW PROCESS

Obtain peer/institutional/CSC review/approval

Type A submissions: Initial, amendments, notifications, safety reports, protocol deviations/violations, close-out reports

Type B submissions: Resubmissions, continuing review requests

Type C submissions: Import and export requests

PI submits documents as per relevant checklist

START

A systematic investigation (i.e., the gathering and analysis of information) designed to develop or contribute to generalizable knowledge (*45 CFR 46.102(d)*)

This are Proposals that **Do not** involve systematic investigation of a problem and do not lead to any generalizable knowledge e.g a proposal to upgrade a laboratory

RESEARCH PROTOCOLS

Receive and review submissions

NON RESEARCH PROTOCOLS

REFER TO RELEVANT COMMITTEE

Submission complete? — NO → Return to PI for Revision

YES

Type A submissions require full committee review, type B submissions Secretariat review

Full committee review branch

Full committee review of type A submissions

Prepare submission documents for review

Select and assign reviewers

Receive review comments and print for committee meeting

Committee meeting held

Decision

Preparation of decision letter

Communicate decision to PI

END

Secretariat review branch

Secretariat review of type B submissions

Prepare submission documents for review

Check whether submission requires secretariat or committee reviewer

Select and assign to committee reviewer

Select and assign to Secretariat reviewer

Decision

Preparation of decision letter

Communicate decision to PI

END

Type C branch

Secretariat reviews and assesses type C applications

For non-blood submissions these should be reviewed by Biosafety for initial type C applications All import applications will be reviewed by Biosafety

Decision

Recommend for approval or revision and forward to Director KEMRI

Director KEMRI reviews and approves or recommends revisions

Receive Director KEMRI feedback

Communicate decision to PI

END