

UNIVERSITY OF SANTO TOMAS HOSPITAL RESEARCH ETHICS COMMITTEE



INITIAL PROTOCOL REVIEW PROCESS FLOWCHART

PRINCIPAL INVESTIGATOR

Submits a Research Protocol Package and other required requirements



REC STAFF

Returns documents to Principal Investigator and requests submission once documents are complete

REC STAFF

Assigns a PROTOCOL REFERENCE NUMBER and encodes protocol in the logbook, tracking form, and REC electronic database

REC OFFICER

Classifies research protocols according to type of review and assigns PRIMARY REVIEWERS

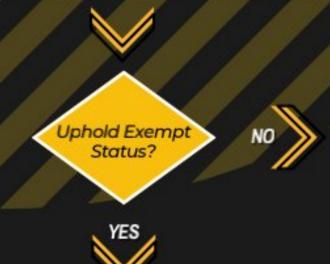
Type of

Review?

EXEMPT FROM REVIEW

REC HEAD

Consolidates and finalizes results. Decides to uphold EXEMPTION status or reclassify as EXPEDITED



REC STAFF

Prepares the Action or Approval Letter of Exemption from Review for signature of the REC Head and includes the protocol in the Agenda of the Meeting for reportorial and documentation purposes



REC HEAD

Signs the Action or Approval Letter of Exemption from Review addressed to the Principal Investigator



REC VICE HEAD

Reports the assessment findings, recommendations, and decision during the REC Meeting



PRINCIPAL INVESTIGATOR

Acts on the Action or Approval Letter accordingly

EXPEDITED REVIEW



REC STAFF

Distributes protocol package with the PROTOCOL and INFORMED CONSENT ASSESSMENT FORMS to the assigned PRIMARY REVIEWERS



PRIMARY REVIEWERS

Review and submit findings and recommendations to the REC Staff. Recommends if for APPROVAL, MINOR MODIFICATIONS, MAJOR MODIFICATIONS, DISAPPROVAL, or CLARIFICATORY INTERVIEW. May also recommend if protocol needs FULL REVIEW which will be decided by REC Head



REC STAFF

Prepares the Action or Approval Letter for signature of the REC Head and includes the protocol in the Agenda of the Meeting for reportorial and documentation purposes



REC HEAD

Signs the Action or Approval Letter addressed to the Principal Investigator



REC VICE HEAD Reports the assessment findings,

recommendations, and decision during the REC Meeting



PRINCIPAL INVESTIGATOR

Approval Letter accordingly

Acts on the Action or

"Let us keep the tradition of caring and healing which the University of Santo Tomas Hospital is known for."

FULL REVIEW



REC STAFF

Distributes the protocol package with the PROTOCOL and INFORMED CONSENT ASSESSMENT FORMS to the assigned PRIMARY REVIEWERS



PRIMARY REVIEWERS

Review and submit assessment findings and recommendations to the REC Staff.

Recommends if the protocol is for APPROVAL, MINOR MODIFICATIONS, MAJOR MODIFICATIONS, DISAPPROVAL, or FOR CLARIFICATORY INTERVIEW.



REC STAFF

Includes protocol in the AGENDA OF THE MEETING for the committee's discussion. deliberation, and decision



PRIMARY REVIEWERS

Present the protocol synopsis, findings, and recommendations during the REC Meeting



REC MEMBERS

Deliberate, decide, and vote a decision: APPROVAL, MINOR MODIFICATIONS, MAJOR MODIFACTIONS, or DISAPPROVAL



REC STAFF

Prepares the Action or Approval Letter for signature of the REC Head



Signs the Action or Approval Letter addressed to the Principal

Investigator

PRINCIPAL INVESTIGATOR Acts on the Action or

Approval Letter accordingly