



# UNIVERSITY OF SANTO TOMAS HOSPITAL RESEARCH ETHICS COMMITTEE



## INITIAL PROTOCOL REVIEW PROCESS FLOWCHART

### PRINCIPAL INVESTIGATOR

Submits a Research Protocol Package and other required requirements

Complete Protocol Package?

NO

### REC STAFF

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

YES

### 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

### EXEMPT FROM REVIEW

Type of Review?

### FULL REVIEW

### REC HEAD

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

### EXPEDITED REVIEW

### REC STAFF

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

### REC STAFF

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

Uphold Exempt Status?

NO

YES

### 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

### 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

### 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.

Continue Expedited Review?

NO

YES

### REC HEAD

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

### REC STAFF

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

### REC VICE HEAD

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

### 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

### 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 MODIFICATIONS, or DISAPPROVAL

### PRINCIPAL INVESTIGATOR

Acts on the Action or Approval Letter accordingly

### REC HEAD

Signs the Action or Approval Letter addressed to the Principal Investigator

### REC STAFF

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

### REC VICE HEAD

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

### REC HEAD

Signs the Action or Approval Letter addressed to the Principal Investigator

### PRINCIPAL INVESTIGATOR

Acts on the Action or Approval Letter accordingly

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Acts on the Action or Approval Letter accordingly

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