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INSTITUTIONAL REVIEW BOARD

"FLOW CHART OF PROTOCOL SUBMISSIONS"

PROTOCOLS SUBMISSIONS TO SPHI-IRB

Sponsor-Initiated Studies

• CLINICAL TRIALS

Requirements upon submission:

- **Letter of Application & Full protocol**
- **Executive summary that follows research project proposal format**
- **Investigator's Brochure**
- **Data collection form/s**
- **Informed Consent form (English and local dialect)**
- **Budget**
- **CV of the PI and co-investigators and their GCP Certificate**
- **GANTT Chart (as necessary)**
- **Advertisement**
- **Certificate of Technical Review (as necessary)**

Researcher-Initiated Studies

• RESIDENTS • STAFF • STUDENTS
• GOVERNMENT SECTOR • PRIVATE SECTOR

Requirements upon submission:

- **Letter of Application & Full protocol**
- **Executive summary that follows research project proposal format**
- **Data collection form/s**
- **Informed Consent form (English and/or local dialect)**
- **Budget (as necessary)**
- **CV of the PI and co-investigators**
- **GCP Certificate (as necessary)**
- **GANTT Chart (as necessary)**
- **Certificate of Technical Review**

IRB Secretariat receives the complete documents. Issues Acknowledgement Receipt Form. Assigns IRB Protocol Number (Day 1)

IRB Secretariat forwards to the Chair or Member-Secretary the documents to determine if the protocol is for Full Board or Expedited Review (Day 1)

FULL BOARD REVIEW:
Chair/Member-Secretary assigns primary reviewers and independent consultant (as needed) for the full-board review. (Day 2)

The IRB Staff notifies the primary reviewers and sends the complete protocol packages and evaluation forms to all IRB members and Invited Consultant one (1) month prior to IRB monthly meeting. (Day 3)

IRB REGULAR MEETING
(2nd Thursday of the month)
Primary reviewers present the evaluation thoroughly by using the evaluation forms. All members discuss technical and ethical issues.

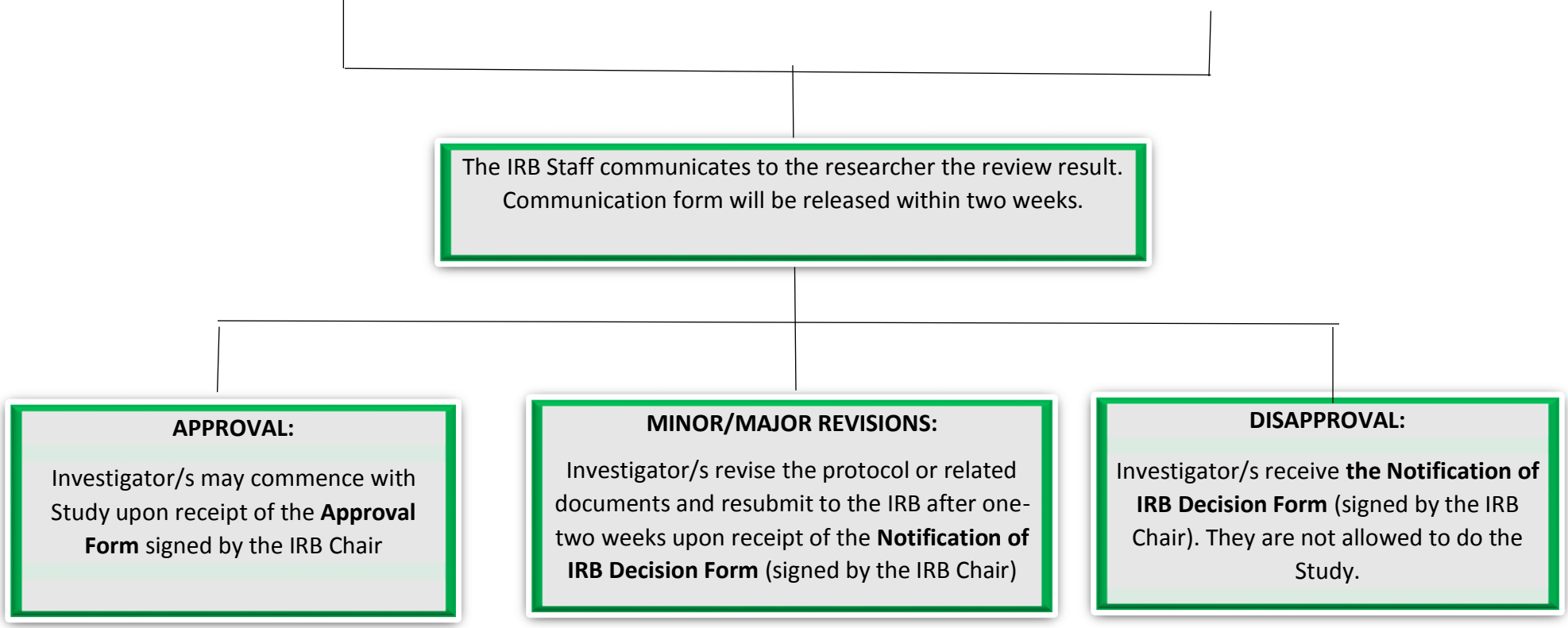
The Chair summarizes the issues. The board decides the result of the full review by consensus. (2nd Thursday of the month)

EXPEDITED REVIEW:
Chair/Member-Secretary assigns one medical member and one lay member to do the expedited review. (Day 2)

IRB Staff notifies the reviewers and sends the complete protocol packages and evaluation forms to their offices two (2) weeks prior to IRB monthly meeting. (Day 3)

Primary Reviewers evaluate thoroughly the documents by completing the evaluation forms. After one (1) week upon receipt, they return it to the IRB Office.
(Day 4-Day 11/Within 1 week)

The Chair consolidates the results of the review and finalizes the decision on the expedited review. (Day 12)
Result is reported by the Member-Secretary in the IRB Meeting.


The IRB Staff communicates to the researcher the review result. Communication form will be released within two weeks.
APPROVAL:
Investigator/s may commence with Study upon receipt of the Approval Form signed by the IRB Chair
MINOR/MAJOR REVISIONS:
Investigator/s revise the protocol or related documents and resubmit to the IRB after one-two weeks upon receipt of the Notification of IRB Decision Form (signed by the IRB Chair)
DISAPPROVAL:
Investigator/s receive the Notification of IRB Decision Form (signed by the IRB Chair). They are not allowed to do the Study.