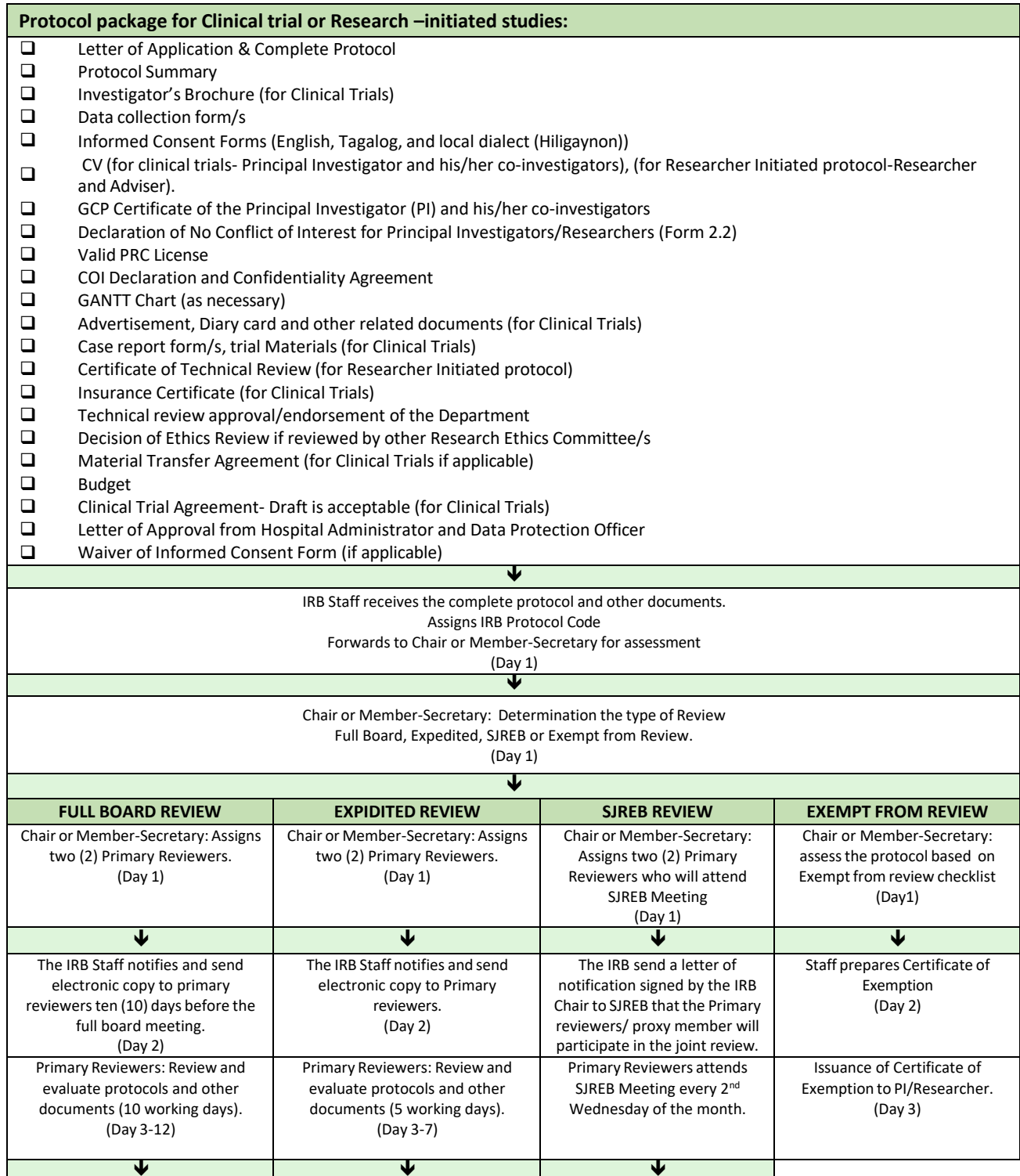




INSTITUTIONAL REVIEW BOARD

II. SPHI IRB: History, Vision, Mission and Organizational Chart

INSTITUTIONAL REVIEW BOARD "FLOW CHART OF PROTOCOLS SUBMISSIONS"





INSTITUTIONAL REVIEW BOARD

II. SPHI IRB: History, Vision, Mission and Organizational Chart

<p>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.</p>	<p>Primary Reviewers returns the evaluation forms five. (Day 8)</p>	<p>The Chair and Member-Secretary consolidates site specific issues and comments, and makes a preliminary decision for reporting to the SJREB during SJREB full board meeting.</p>
↓	↓	↓
<p>The Chair summarizes the issues. The board decides the result of the full review by consensus voting. (2nd Thursday of the month) (Day 19)</p>	<p>The Chair consolidates the results of the review and finalizes the decision on the expedited review. (Day 9-10) Result of expedited review is reported by The Chair in the IRB Meeting (Day 19)</p>	<p>The primary reviewers attend the SJREB full board meeting</p>
↓	↓	↓
<p>The IRB Staff prepares the communication letter of the IRB Decision (Approval, Notification Letter) (Within three- seven (3-7) days after the full board meeting)</p>	<p>The IRB Staff prepares the communication letter of the IRB Decision (Approval, Notification Letter) (Day 11)</p>	<p>The IRB Staff obtains the SJREB meeting minutes and decision notification from the SJREB secretariat seven days after the SJREB full board meeting. The Chair and Member-Secretary conduct an expedited site-specific review within 7 days of receipt And make a local site decision based on SJREB outcomes.</p>
↓	↓	↓
<p>The IRB Staff communicates and released the review result to the PI/Researcher (Within three- seven (3-7) days after the full board meeting) (Day 27)</p>	<p>The IRB Staff communicates and released the review result to the PI/Researcher (Day 12)</p>	
↓		
APPROVAL	MINOR/MAJOR REVISIONS	DISAPPROVAL
<p>PI/Researcher may commence with Study upon receipt of the Approval Form signed by the IRB Chair.</p>	<p>PI/Researcher revise the protocol or related documents and resubmit to the IRB.</p>	<p>PI/Researcher receive the Notification of IRB Decision Form (signed by the IRB Chair). They are not allowed to do the Study.</p>
↓	↓	↓
SUBMISSION OF POST-APPROVAL REPORTS	RESUBMISSION	APPEAL
<p>PI/Researcher required to submit post-approval reports up to final reports.</p>	<p>Revised study Protocol, ICF, and or other study materials: For Major Revision: twenty (20) working days For Minor revision: ten (10) working days after the receipt of the Decision letter</p>	<p>PI/Researcher may appeal the decisions made by IRB by writing a letter to the IRB Chair requesting for re-review and provide the supporting information/material for consideration. (Within 20 days)</p>



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