STANDARD OPERATING PROCEDURE

IRB Mailing

POLICY:
The Institutional Review Board meets on the second Tuesday of every month and meetings begin promptly at 7:30 a.m. It is imperative that IRB members are given adequate time to review pertinent materials prior to the IRB meetings. The IRB meeting materials are mailed and/or electronically sent to each IRB member two weeks prior to the convened meeting. The list of convened meetings provided to each member may also be found at the IRB page on The Christ Hospital website or the IRB SharePoint site. The list may also be obtained by contacting the IRB Office by email at IRB_Office@thechristhospital.com or by phone at 513-585-2298.

PROCEDURE

INVESTIGATOR:

1. New protocols are to be prepared and submitted by the PI/Study Coordinator as outlined in IRB Reference Manual Section 7.0 “Research Protocol and Consent – Format and Requirements” or SOP 2.01 Guidelines for Protocol Submission.

IRB OFFICE:

1. The meeting materials or “IRB Packets” are mailed and/or electronically sent to all IRB members approximately 2 weeks prior to the scheduled meeting date. This allows for review of materials by the members. Any materials requiring full board consideration must be received in the IRB office three weeks prior to the meeting date.

2. Items to be sent to members include, but are not limited to:
   - Meeting agenda
   - Previous meeting minutes
   - New study protocols
   - Expedited protocol reviews
   - Study closures
   - Amendments/revisions, as necessary
   - Chairman’s report
   - IRB, Ethics and Human Research publication, as available
   - Reviewer Protocol Checklist
Additional correspondence is mailed to the members as indicated by the Chairman, study investigators, study coordinators, Administration, etc.

3. The packet mailed to the Board members must be arranged and sent in the same order as listed on the meeting agenda.

4. Paper copies of the packets are taken to the Mailroom (TCH MOB B-level) and mailed via inter-office mail or by calling 585-0467 and arranging pick up and delivery by courier to off-site members. Electronic materials are sent linked to the monthly agenda.

5. All documents are electronically filed in the appropriate study folder located on a secure IRB drive. Copies of these files are also saved on the IRB SharePoint Page to allow for ease of member review.

REFERENCE:

<table>
<thead>
<tr>
<th>Date Revised</th>
<th>Reason For Change</th>
<th>Revised By</th>
</tr>
</thead>
<tbody>
<tr>
<td>07/01/09</td>
<td>No changes</td>
<td>Becky</td>
</tr>
<tr>
<td>03/16/17</td>
<td>Removed “annual reports” from “Items to be mailed to members”</td>
<td>Emily</td>
</tr>
<tr>
<td>03/12/21</td>
<td>Addition of electronic files and SharePoint. Removed necessity for PI to supply multiple copies of submissions for IRB review. Added Reference section.</td>
<td>Erica</td>
</tr>
</tbody>
</table>