

Deadline: Tuesday at 5:00 P.M. the week prior to the meeting.

Meeting: The IRB meets every Tuesday at 5:30 P.M.

Exceptions occur on holidays or with an unanticipated lack of quorum.

PREPARATION

Make sure you are ready for a business relationship with IRC. (see section 2.1)

Has an indemnification form been signed that covers the current study?

If Yes - obtain copy for your IRB file

If No - talk with the IRC business office and your Institutional Officer

REVIEW SCHEDULE FOR A "TYPICAL" FULL BOARD SUBMISSION

(without the usual "We are the speediest" hype)

M	T	W	TH	F	Sa	Su
	Submit to IRC by 5pm → Process & Send to IRB Members	Reviewed by Members	Reviewed by Members	Reviewed by Members		
Reviewed by Members	Full Board Meeting (Approved Contingent)	Draft Letter to Client	Draft Letter to Client	Send Letter to Client		
Wait for Client Response	Wait for Client Response	Wait for Client Response	Receive Response. Quality Control & Send to Reviewer.	Review needs clarification. Communication with client, & Approval!		

*Client response time may vary.

SUGGESTIONS

- Ideal critical path planning for an initial review would allow time for two appearances on the agenda. (better safe than sorry)
- Use the IRC checklist to make sure all pieces are submitted.
- In preparing a submission, think with your IRB member hat on.
- Find someone who has a critical eye, a sharp red pencil from outside the team. Have that person review the submission and the consent form.
- We hate to say it (it is certainly not PC) but, "A lack of planning on someone else's part does not constitute an emergency on our part." We will certainly try our hardest to meet your needs.

APPLICATION STEPS FOR "TYPICAL" CLINICAL INVESTIGATION

<p>Determine if study is full board or expedited See explanation of eligibility for expedited review</p>		
<p>EXPEDITED PROTOCOL Obtain forms 4.1.x Checklist 4.2.x Expedited claim</p>	<p>INVESTIGATOR Form 4.3.x Investigator Application form and associated items</p>	<p>FULL BOARD PROTOCOL Obtain forms 4.1.x Checklist 4.2.x Protocol cover</p>
<p>PREPARE SUBMISSION - OBTAIN SIGNATURES</p>		
<p>SUBMIT 2 collated sets Study information Consent documents or waiver request Investigator information</p>		<p>SUBMIT 8 collated sets Study information Test article information Consent forms Investigator information</p>
<p>SUBMISSION</p>		
<p>Submit at any time</p>		<p>Submit by Tuesday 5:00 PM</p>
<p>Wait - Allow sufficient time for circulation and consideration</p>		
<p>Allow 3 business days from IRC receipt before response</p>		<p>Review the following Tuesday, Response within three business days</p>

