

## “Working with an IRB: A Project Manager’s Guide”

Ask anyone who has managed a clinical trial from start to finish what the key is to a successful and positive experience and they will tell you, “Proper planning and communication.” At Copernicus Group IRB, we consider ourselves to be an extension of your project team as we partner together to protect subjects and offer the following considerations as a guide for working effectively and efficiently with any IRB.

### Initial Study Set-Up

- Who will be the primary contact for the study (ie, person to be copied on all documents and/or person to be contacted for issues with the Principal Investigators and/or questioned regarding the protocol)?
- Who will be a secondary contact in case the primary contact is unavailable? If applicable, inform CGIRB of their contact information.
- Has the sponsor signed an Indemnification Agreement for CGIRB?
- What is the process in place for submitting the investigator documents to CGIRB (ie, will they be coming from sponsor, CRO, institution, or investigator site?)?
- How do you ensure that each investigator is trained in GCP as it relates to Human Subject Protection?
- Will there be any subject recruitment or advertisements submitted with the initial review package?
- Will you need a subject information and consent form or other study information in a language other than English?
- Is this study federally funded or supported? Will the study be conducted under a Federalwide Assurance (FWA)?
- Are you well acquainted with CGIRB and our procedures? If not, call and introduce yourself. Ask any questions regarding how to best communicate with the team.

### Study Maintenance

- Do you anticipate the generation of any IND Safety reports during the study? If so, who will submit these reports? (ie, directly from the sponsor or individually from each investigator?)
- How will the reporting of Unanticipated Problems be handled during this study? Will there be standard reporting forms?

## Study Maintenance (Cont.)

- Does everyone on your team understand the importance of submitting Clinical Investigator Brochure updates and other important safety information to CGIRB in a timely manner?
- Is there a process in place that allows for prompt communication of any changes in the research to CGIRB and/or any unanticipated problems involving risks to subjects or others?
- Will the sites be permitted to submit subject recruitment material on their own behalf after initial review?
- Will the sponsor submit their own HIPAA language?
- Are there any Conflicts of Interest for Principal Investigators involved in the study?
- Do all of your sites and your project team understand that complete submissions ensure timely turn around and incomplete documents that are submitted will delay this process?
- Do you have a firm grasp of what CGIRB needs to review New Principal Investigators?
- Will there be any pediatric subjects or other vulnerable subjects enrolled? If so, are there special protections in place?
- Are you aware of various state laws regarding research?
- Are there any unique qualities about this study that require additional discussion with CGIRB?

## Study Conclusion

- You should maintain all IRB correspondence and approvals.
- Are you familiar with CGIRB's Continuing Review Process and understand the importance of working together to ensure compliance?
- Ensure that all Principal Investigators submit an ***Investigator Site Closure Request and Final Study Status Report*** once the study has been completed at their site.

For more information regarding working with an IRB or to make Copernicus Group IRB your IRB of choice, please call 1-888-303-2224 and ask for Bill Van Nostrand or Rebecca Sipes or email us at [IRB@cgirb.com](mailto:IRB@cgirb.com).