

## **Principal Investigator Responsibilities for Reviewing and Relying Sites**

When a reliance agreement is made it is important for investigators at both sites to understand their responsibilities. This document is intended to review the responsibilities for Both PIs and their teams to assure compliance with all applicable regulations and protocol responsibilities.

### **The Reviewing Site's Principal Investigator will:**

- 1) Collect information from the Relying Site PI required for the protocol application, including but not limited to the information listed below and information regarding any special local considerations that must be considered by the Reviewing IRB; and provide such information to the Reviewing IRB.
- 2) Include in the Reviewing site protocol application the following:
  - The list of the Relying Site PI and other research personnel involved in the Study at Relying Site;
  - Evidence of training for the Relying Site PI and research personnel at the Relying Site;
  - Any financial interest disclosure for Relying Site PI and each research personnel involved in the Study at the Reviewing Site and any associated management plans, if applicable.
- 3) Promptly provide the Relying Site PI with:
  - Current approved protocol and consent documents;
  - Approved modifications, amendments or changes to the protocol;
  - Approval of continuing reviews, reviews of unanticipated problems;
  - Any other information required by the Reviewing IRB to be provided to the Relying Site.
- 4) Notify the Relying Site PI of the standards and guidelines of the Reviewing IRB for the reporting of any post-approval events, such as (i) proposed amendments or changes in Study activities, (ii) injuries, adverse events or unanticipated problems involving risks to subjects or others, and (iii) protocol violations.
- 5) Collect required information from the Relying Site PI in order to complete the continuing review submission form. The Reviewing site continuing review must cover information from all Relying Sites.
- 6) Collect reports from the Relying Site PI of any unanticipated problems deviations, suspensions and terminations, noncompliance, subject complaints, and submit such reports to the Reviewing IRB.

- 7) Notify the Relying Site PI about any lapses of approval. Forward to the Reviewing IRB, any request from the Relying Site PI for continuation of a specific patient on a research protocol during a lapsed period of approval.

### **The Relying Site PI**

The Relying Site PI understands that the Relying Site has ceded IRB review to Reviewing site and, therefore, all IRB responsibilities for the Study will be assumed by the Reviewing IRB. The Relying Site PI has direct responsibilities to the Reviewing IRB, as described below.

The Relying Site PI will:

- 1) Notify the Reviewing site PI about any special local considerations that must be considered by the Reviewing IRB for the Relying Site.
- 2) Provide the Reviewing PI:
  - The list of all research personnel involved in the Study at the Relying Site;
  - Evidence of training for the Relying Site PI and all research personnel involved in the Study at the Relying Site;
  - Any other information required by the Reviewing IRB regarding the Relying Site PI and/or research personnel involved in the Study.
- 3) Assure that any additional local requirements for ancillary human research protection reviews (pharmacy, nursing, radiation safety, etc.) are obtained and followed at the Relying Site.
- 4) Assure that research activities at the Relying Site are not initiated until all Reviewing and Relying Site requirements for the Study regarding funding and clinical trial agreements are finalized.
- 5) Conduct the protocol and obtain informed consent as approved by the Reviewing IRB.
- 6) As requested on a continuing basis, provide the Reviewing site PI with any information necessary for the continuing review process. This may include information regarding subject recruitment, summary of all enrolled subjects, screen failures, minor violations and all other information needed for continuing review.
- 7) If at any time Study approval lapses, cease all human subject research work related to the protocol at the Relying Site. If the Relying Site determines that subjects who are already enrolled on the trial may be harmed if research ceases, notify the Reviewing site PI about the individual subject(s) and the justification for remaining on the trial.

- 8) Consistent with the Reviewing site policies, report all post-approval events such as proposed amendments, deviations, subject injuries, unanticipated problems involving risks to subjects or protocol violations to the Reviewing site PI.
- 9) Promptly cooperate with any Reviewing or Relying Site investigation regarding serious or continuing noncompliance or an unanticipated problem upon request.
- 10) Promptly cooperate with any Reviewing or Relying Site quality assurance /quality improvement or monitoring of the Study protocol upon request.
- 11) In the event of the need for an audit, allow the Reviewing site PI and institutional officials access to research related records.
- 12) Maintain records of all research and related activities conducted under this Agreement for at least seven years, and longer if required by law, after completion of any Study.
- 13) Promptly respond to all requests for information from the Reviewing site PI or Reviewing IRB, including but not limited to the information set forth in this Agreement.
- 14) Cooperate with the Reviewing site in reporting and resolving any conflicts of interest reported by the Relying Site PI and/or research personnel at the Relying Site, including but not limited to entering into management plans, as required by the Reviewing IRB.