Principal Investigator Responsibilities for Reviewing and Relying Sites

[*Insert name reviewing institution*] and [I*nsert name relying institution*] are entered into a Reliance Agreement ceding IRB review to [*Insert name reviewing institution*]. When this arrangement 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 to assure compliance with all applicable regulations and protocol responsibilities.

[*Insert name reviewing institution*] 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 [*Insert name reviewing institution*]; and provide such information to [*Insert name reviewing institution*].
2) Include in the [*Insert name reviewing institution*] 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 Relying 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 [Insert name reviewing institution] to be provided to the Relying Site.
4) Notify the Relying Site PI of the standards and guidelines of [*Insert name reviewing institution*] 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 [*Insert name reviewing institution*] 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 [Insert name reviewing institution].
7) Notify the Relying Site PI about any lapses of approval. Forward to [Insert name reviewing institution], any request from the Relying Site PI for continuation of a specific patient on a research protocol during a lapsed period of approval.

<u>The Relying Site PI</u>

The Relying Site PI understands that the Relying Site has ceded IRB review to [*Insert name reviewing institution*] and, therefore, all IRB responsibilities for the Study will be assumed by [Insert name reviewing institution]. The Relying Site PI has direct responsibilities to [Insert name reviewing institution], as described below.

The Relying Site PI will:

1) Notify the [*Insert name reviewing institution*] PI about any special local considerations that must be considered by [Insert name reviewing institution] for the Relying Site.
2) Provide the [*Insert name reviewing institution*] 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 [Insert name reviewing institution] 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 [*Insert name reviewing institution*] 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 [Insert name reviewing institution].

6) As requested on a continuing basis, provide the [*Insert name reviewing institution*] 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 [*Insert name reviewing institution*] PI about the individual subject(s) and the justification for remaining on the trial.
8) Consistent with [*Insert name reviewing institution*] policies, report all post-approval events such as proposed amendments, deviations, subject injuries, unanticipated problems involving risks to subjects or protocol violations to the [*Insert name reviewing institution*] PI.
9) Promptly cooperate with any [*Insert name reviewing institution*] or Relying Site investigation regarding serious or continuing noncompliance or an unanticipated problem upon request.
10) Promptly cooperate with any [*Insert name reviewing institution*] 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 [*Insert name reviewing institution*] PI and reviewing [*Insert name reviewing institution*] 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 [*Insert name reviewing institution*] PI or [*Insert name reviewing institution*] IRB, including but not limited to the information set forth in this Agreement.
14) Cooperate with the [*Insert name reviewing institution*] 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 [Insert name reviewing institution].

*** Responsibilities reflect those outlined in the Master Common Reciprocal Institutional Review Board Authorization Agreement**