Multisite Research Development Checklist

Leadership:

- ☐ **Principal Investigator/Project Director** identified– role to oversee roles/responsibilities of collaborative team partners. Consider also that these roles might be best performed by separate individuals
- ☐ **Determine Study Research Team: Operational Design and Oversight Processes** (scope of work, delineation of deliverables, timelines)
- ☐ **Determine Needed Mentoring Relationships:** role to provide mentoring in protocol design, data gathering, and analysis for principal investigators with less experience.

Initial Multi-site Research Study Organizational Considerations:

- ☐ **Approve a clear conceptualization of the research project**: articulate this *verbally* and in *writing* to ensure consensus and commitment
- ☐ **Establish all team partners roles and responsibilities** for efficiency
- ☐ **Determine policy of transparency and open discourse** for collaborative team partners to address anticipated occurrences (prevent any 'surprises')
- ☐ **Determine source of process/manuscript oversight:** consider the value of a separate committee charged with the objective oversight of the process and resolution of conflict among investigators
- ☐ **Determine contact frequency** [conference calls or face-to-face (F2F)]; Include explicit geographic time zones with consideration to all sites
- ☐ **Address, proactively, any potential political dimensions**
- ☐ **Develop procedures and tracking systems to ensure *standardization of process* and *regulatory (IRB*), governmental compliance*** as well as funding agency requirements are addressed at each site
- ☐ **Determine Fiscal Management: budgeting, tracking and reconciling processes**
- ☐ **Develop processes for data and safety monitoring plan as required**
- ☐ Determine source and availability of **data management/research administrative supports**, clarifying the role, location, and required funding for all necessary support structures or personnel
- ☐ **Determine timeline for project,** setting clear, attainable deadlines for each phase and delineating the expectations for each participant.
- ☐ **Determine process for resolving process-related conflicts** in case deadlines cannot be met
- ☐ **Develop mutually agreed upon guidelines for writing and dissemination process** to proactively address disputes of authorship, including considerations of:
    a) Authorship
    b) Conflict-of-Interest
    c) Publication/Dissemination
    d) Data Sharing/Ownership
    e) Copyrights, Patents, Technology Transfers as required

Ongoing Multi-site Study Considerations:

Operationalizing Multi-site Agreements at Inception of Study:

- ☐ **Re-address any potential conflicts of interest** and logistical issues arising from individual sites on an ongoing basis
- ☐ **Re-visit research methodology** on an ongoing basis: are we maintaining standardization?
- ☐ Continually search for and **systematically eliminate site-to-site variance in implementation strategy** and data collection
- ☐ Engage in **frequent, ongoing communication with co-investigators and oversight committee** to ensure appropriate progress and address nascent conflicts

*IRB – Institutional Review Board

For additional relevant literature, please see Calhoun et al. Empowering the Inexperienced Researcher: A Summary Report and Expert Recommendations; available on the Society for Simulation in Healthcare Research Portal (www.ssih.org).

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