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
- **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