ALTERNATIVE SITE MODEL

INTEGRATED RESEARCH ORGANIZATION

WHAT IS AN INTEGRATED RESEARCH ORGANIZATION?

A CLINICAL RESEARCH INFRASTRUCTURE THAT INTEGRATES CLINICAL TRIALS WITH THE PATIENT CARE CONTINUUM

WHAT PROBLEMS DOES THIS MODEL AIM TO SOLVE IN TRIALS?

Patient
...recruitment
...retention
...accessibility

Access
...to rare disease patients
...to diverse patients
...to underserved/ underrepresented patients
...new geographic reach for sites
...to de novo/new investigators

Cost
...may decrease with hub and spoke network

HOW CAN THIS SITE MODEL BE USED IN TRIALS?

- ✓ As an HCP location
- ✓ As an additional location for a traditional site
- ✓ Integrated/satellite site for PI
- ✓ Stand-alone site
- ○

WHERE ARE THESE SITE MODELS AVAILABLE FOR USE IN TRIALS?

SPECIAL CONSIDERATIONS/LIMITATIONS

INVESTIGATIONAL PRODUCT PREPARATION

Consider IP safety profile and complexity
- Research experienced vendor meta-site, if sponsor allows, could receive/store/prep IP by qualified IRO staff
- IRO site(s) trained on protocol with appropriate storage capabilities

INVESTIGATIONAL PRODUCT ADMINISTRATION

IP route of admin & safety profile define needs:
- Ensure proper licensure for IRO staff re IP ordering/ administration
- Ensure complete training on IP administration/ safety procedures
- Proper supplies to handle severe reactions, ie., crash cart supplies as appropriate for IP

PRIVACY

- Minimal considerations: Medical practices accustomed to privacy needs
- If in-home visits, clarify patient preferences

PI OVERSIGHT

- Ensure clear expectations between Central / coordinating center PI and any local IRO sub-investigators
- Create a risk management/ mitigation plan including all significant risks
- Clear set of accountabilities for the central PI and the local sub-investigators (RACI)
- Consider sponsor approval of Risk plan / RACI

BIOSPECIMEN COLLECTION

- Ensure overarching IRO SOP on biospecimen collection, documentation, and storage/ shipment.
- Ensure protocol training on biospecimen collection / processing needs
- Consider all supplies and shipping processes needed to enable sample acquisition, prep and storage / shipment to local or central lab.

TRIAL SPECIFIC ASSESSMENTS

- Ensure overarching SOPs for clinical trial conduct are in place and agreed upon with any local IRO location
- Plan, execute and document any protocol specific training for all IRO-location staff, including central PI and IRO coordinating center staff.

MEDICAL WASTE MANAGEMENT

Minimal considerations - lots of options in US
- Assume local IRO site is already acting as point of care for patients

ACCESS

- If IRO locations are at clinics, assume basic services are in place. e.g. Water, washrooms, electricity will be essential to conduct study visits
- WiFi / Cellular and Technology needed for eDiaries, telehealth, eConsent, etc.