A Quick Guide to Affiliate and Satellite Site Activation and Oversight Process

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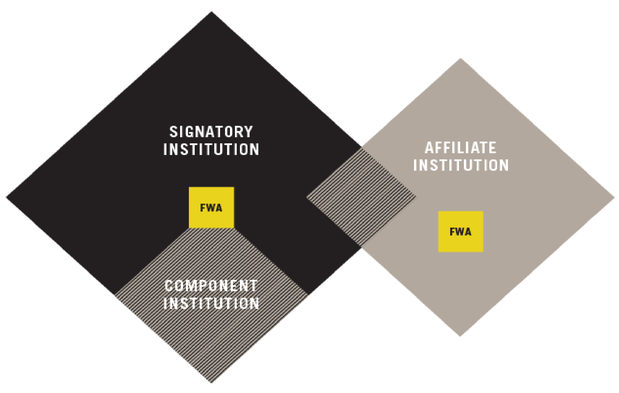
BACKGROUND

In current clinical research scenarios, there is an emerging need for community outreach and engagement. The simplest way for a signatory/parent institution to achieve this would be to expand clinical research programs to satellite sites/component institution (facilities within the same financial and legal entity) and to affiliate sites (facilities that are financially and legally independent). In implementing this process, parent sites often face several logistical challenges. After activating multiple satellite and affiliate sites, HCI has developed a systematic guide for successful site activation.



GOALS

The main goals of this process are

- Time: Faster on boarding time
- Effort: Streamlined process with reduced resource burden
- Process: Defined process development
- Oversight: Ensuring quality, ethics, and compliance

STRATEGY IMPLEMENTED

HCI developed a quick guide as described below and established an Affiliate Site Committee to implement and oversee the process for National Cancer Institute (NCI) trial activation. Steps listed in the guide were followed during HCI's two most recent NCI aligned affiliate site activations and were found efficient.

Approximate Timelines/ Comments	Steps	Approximate Timelines/ Comments
Same legal entity so N/A	Establish **legal agreement** covering responsibilities of parent and affiliate sites relating to conduct of clinical trials	1- 2 months
Gather and assess information on resources and preparedness, provide direction to the site.	**Ensure Adequacy of Key Infrastructure** **Adequate and qualified staff** **Facility and resources** o Specimen processing capabilities o EMR compliance (21 CFR part 11) o Investigational pharmacy services o Radiation facility	Gather and assess information on resources and preparedness, provide direction to the site.
1 month	Help sites fulfil clinical research requirements of **Federalwide Assurance (FWA), Office for Human Research Protections (OHRP), NCI, *Lead Protocol Organization (LPO) Membership*** *(e.g. SWOG, Alliance or NRG)*	3-4 months
Same as parent institute, so no lag phase	**Support fulfilment of Regulatory requirements:** **NCI- CIRB affiliate site membership:** o CIRB authorization agreement o Annual signatory & PI worksheet submission o Boilerplate language addition o Ancillary policies and SOPs submission to CIRB: ▪ HIPAA ▪ Conflict of Interest ▪ Biosafety ▪ Radiation safety	3-4 months
Same as parent institute, so no lag phase	**Provide operational logistics** o Training – Investigator & Research Staff o Policies and SOP development o Regulatory requirements o Finance management o Trial coordination support o Specimen processing	6-9 months initially and ongoing support thereafter

OUTCOME

Utilizing this step by step process resulted in

- Drastically reduced time to site activation
- A smoother and streamlined process for parent institution and other sites
- Establishing quality clinical research in compliance with regulations and requirements

FUTURE DIRECTIONS

Works that are in progress:

- Additional steps to streamline operational logistics
- Develop tools to quantify and assess parent and affiliate institute effort
- Utilize efficiency gained to venture into additional clinical trial opportunities (e.g., IIT and Industry trials at affiliate sites)

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