

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

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1. Background

In current clinical research scenario, there is an emerging need for Community Outreach and Engagement. The simplest way is to expand clinical research program to facilities within the same financial and legal entity (satellite sites) and to facilities that are financially and legally independent (affiliate sites). In implementing this process, parent sites often face several logistical challenges. After activating multiple satellite and affiliate sites, HCI has developed a step by step guide for successful site activation.

2. Goals

The main goals of this process are:

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

3. Solutions and Methods

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 current NCI aligned affiliate site activation and was found efficient.

4. Outcomes

Utilizing this process resulted in

- Drastically reduced time to site activation,
- A smoother and streamlined process for parent institution and other sites
- Quality clinical trials in compliance with regulations and requirements

5. Lessons Learned

Future prospects

- 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)