Category: Training and Quality Assurance – Work In Progress

"Who Cares? It's Just a Minimal Risk Study": The Case for Research Compliance Oversight of Cancer Population Sciences (CPS) Research

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1. Background

Cancer Center Support Grant eligibility for NCI-designated Cancer Centers lists "Prevention, Control, and Population Science Research" amongst the three major research areas to be found at qualifying centers[1]. While many centers are working to grow this area of research at their facility, there is minimal guidance surrounding the research compliance oversight of cancer population sciences (CPS) research. Although these studies are required to adhere to 45 CFR 46, which contains regulations for IRB oversight and informed consent, the Food and Drug Administration (FDA) and the International Council on Harmonisation (ICH) Good Clinical Practice (GCP) E6(R2) have little to say about CPS non-pharmaceutical research. At Huntsman Cancer Institute (HCI) at the University of Utah (U of U), we discovered that this lack of GCP guidance resulted in inconsistent and minimal to non-existent research compliance oversight.

As an NCI Comprehensive Designated Cancer Center, HCI is committed to cancer research including but not limited to laboratory research; clinical research; and prevention control and population-based research. While the Data and Safety Monitoring Committee (DSMC) at HCI is tasked with oversight of primarily interventional treatment clinical trials, there remains a need to ensure patient safety and data quality for CPS research which may not be subject to this rigorous monitoring oversight.

[1] Cancer Center Support Grants (CCSGs) for NCI-designated Cancer Centers (P30 Clinical Trial Optional): https://grants.nih.gov/grants/guide/pa-files/PAR-20-043.html

2. Goals

Our goal at HCI was to create a method of oversight for CPS studies in order to ensure research compliance to higher institutional standard.

3. Solutions and Methods

Standard Operating Procedures (SOPs) with a reasonable set of expectations based on ICH GCP were developed in collaboration with the U of U for all trial types. The HCI's Research Compliance Office (RCO) developed a role specific for CPS based auditing. The auditor has been conducting audits of CPS studies for 5 years and ensures adherence to these SOPs.

Audit prioritization is given to studies which are:

- Greater than minimal risk
- Grant funded, and/or
- Interventional

The audit process closely mirrors that of our treatment clinical trial auditing, with specific focus on:

- Informed consent form process and consent process (including version check)
- Eligibility documentation
- Protocol and SOP compliance
- Source documentation
- Safety reporting requirements (as applicable)
- Data completion and accuracy
- Regulatory binder/essential documents

Audit findings are reviewed and discussed with study teams. When all queries are resolved, an abbreviated audit report is provided to the study team and filed with the U of U IRB.

4. Outcomes

The process has provided the following benefits:

- Overall improvement in compliance and data quality.
    - Over a three-year period we saw a 30% increase in "Outstanding" audits.
- Increased communication between the RCO and CPS study teams.
    - More teams are reaching out for guidance and preventative trainings.
- Direction for development of SOPs to support future compliance.

5. Lessons Learned

- How can we increase Principal Investigator (PI) and study team support for compliance oversight of CPS studies?
- How can we create a standard which is rigorous, but not preventative of institutional research projects?
- What metrics can we develop to gauge efficacy of CPS auditing?