“Who Cares? It’s Just a Minimal Risk Study.” THE CASE FOR COMPLIANCE OVERSIGHT OF CANCER POPULATION SCIENCES (CPS) RESEARCH

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BACKGROUND

Cancer population sciences (CPS) research is an expanding area for many cancer centers; however, there is little guidance regarding compliance oversight of these studies.

Huntsman Cancer Institute (HCI), an NCI Comprehensive Designated Cancer Center, houses a Cancer Control and Population Sciences Research Program. Our goal at HCI was to a create a method of oversight for our CPS research in order to ensure research compliance to a higher institutional standard.

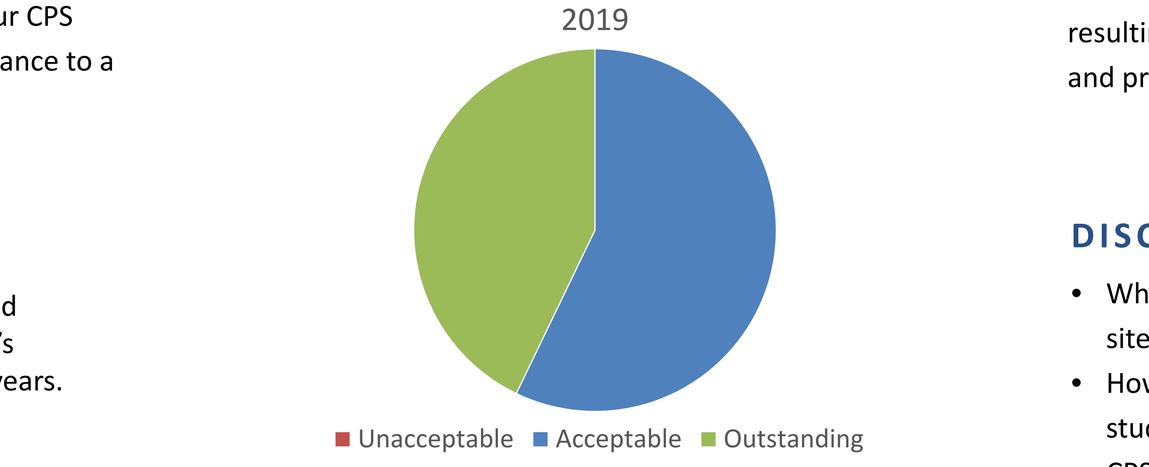
METHOD

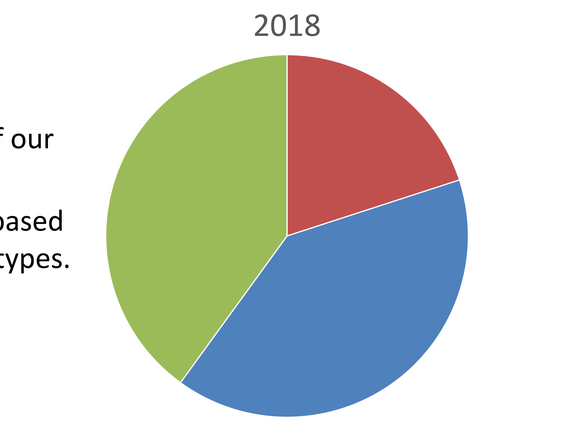
- HCI developed a role specific to CPS based auditing. This role has been a part of HCI’s Research Compliance Office (RCO) for 3 years.
- CPS research is audited annually, with prioritization given to studies which are
    - greater than minimal risk,
    - grant funded,
    - and/or interventional.
- The audit process closely mirrors that of our clinical trial audits.
- Standard Operating Procedures (SOPs) based on ICH GCP were developed for all trial types.

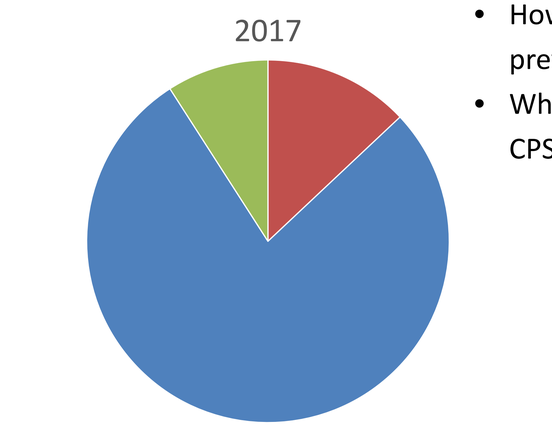
OUTCOME

We have seen the following benefits:

- Overall improvement in compliance and data quality
- 30% increase in “Outstanding” audits over a three year period
- Increased communication between RCO and CPS study teams
- Direction for development of future SOPs to further support research compliance







CONCLUSIONS

The combination of a reasonable standard with routine auditing has greatly improved compliance amongst our CPS research. Repeat annual audits allow study teams to identify areas for improvement, develop tailored trainings, and refine their processes.

The audit process also facilitates increased communication between RCO and CPS study teams, resulting in more requests from teams seeking guidance and preventative trainings.

DISCUSSION POINTS

- What does CPS compliance oversight look like at other sites? What challenges have they seen?
- How can we increase Principal Investigator (PI) and study team support for compliance oversight of CPS studies?
- How can we create a standard that is rigorous but not preventative of institutional research projects?
- What metrics can we develop to gauge efficacy of CPS auditing?

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