Simplifying and Improving Training and Delegation Documentation

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BACKGROUND

Training and delegation are a primary focus of the Code of Federal Regulations and Good Clinical Practice guidelines. The Huntsman Cancer Institute (HCI) Clinical Trials Office (CTO) identified several areas for improvement in the current training and delegation documentation process:

- Multiple signatures required by the Principal Investigator (PI).
- Frequent changes due to staff turnover.
- Quality control issues.
- No defined process for collecting electronic signatures.
- Sponsor overreach due to too much flexibility in Standard Operating Procedure (SOP).

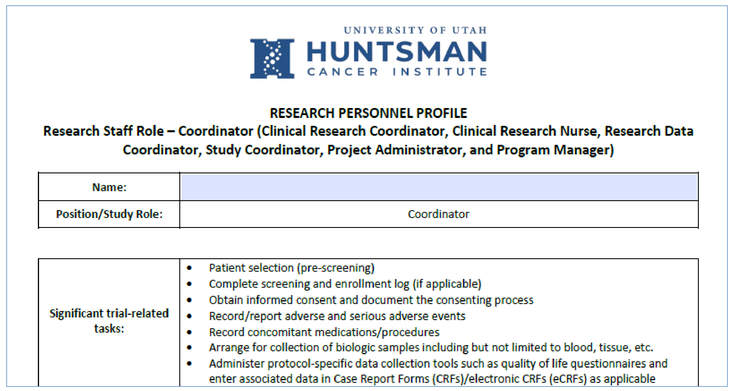
METRICS/GOALS

- Decrease the signature burden on PIs.
- Increase compliance.
- Move from wet ink to an electronic platform.
- Decrease ambiguity for sponsors.

METHODS

- HCI CTO leadership reviewed posts from the American Association of Cancer Institutes Listserv.
- Three primary components were developed:
  1. Research Personnel Profile Page for each research role (Figure 1)
  2. Protocol Assignment and Training Log (Figure 2)
  3. PI Statement of Oversight and Delegation (Figure 3)

Figure 1



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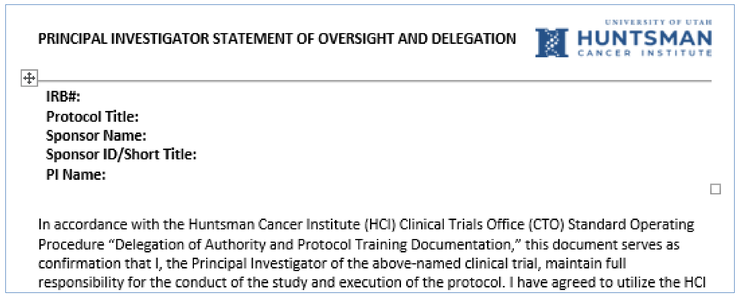
RESEARCH PERSONNEL PROFILE
Research Staff Role – Coordinator (Clinical Research Coordinator, Clinical Research Nurse, Research Data Coordinator, Study Coordinator, Project Administrator, and Program Manager)

Name:	
Position/Study Role:	Coordinator
Significant trial-related tasks:	• Patient selection (pre-screening) • Complete screening and enrollment log (if applicable) • Obtain informed consent and document the consenting process • Record/report adverse and serious adverse events • Record concomitant medications/procedures • Arrange for collection of biologic samples including but not limited to blood, tissue, etc. • Administer protocol-specific data collection tools such as quality of life questionnaires and enter associated data in Case Report Forms (CRFs)/electronic CRFs (eCRFs) as applicable

Figure 2

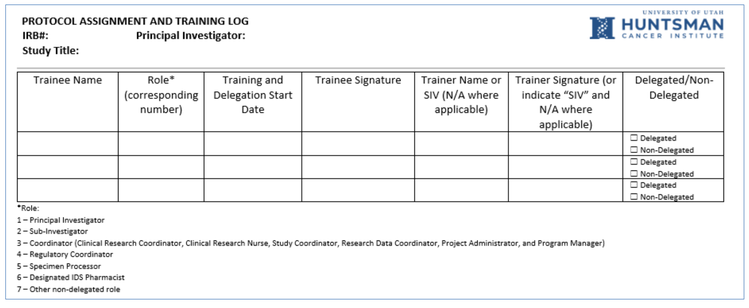


PRINCIPAL INVESTIGATOR STATEMENT OF OVERSIGHT AND DELEGATION UNIVERSITY OF UTAH HUNTSMAN CANCER INSTITUTE

IRB#:
Protocol Title:
Sponsor Name:
Sponsor ID/Short Title:
PI Name:

In accordance with the Huntsman Cancer Institute (HCI) Clinical Trials Office (CTO) Standard Operating Procedure "Delegation of Authority and Protocol Training Documentation," this document serves as confirmation that I, the Principal Investigator of the above-named clinical trial, maintain full responsibility for the conduct of the study and execution of the protocol. I have agreed to utilize the HCI

Figure 3



PROTOCOL ASSIGNMENT AND TRAINING LOG UNIVERSITY OF UTAH HUNTSMAN CANCER INSTITUTE
IRB#: **Principal Investigator:**
Study Title:

Trainee Name	Role* (corresponding number)	Training and Delegation Start Date	Trainee Signature	Trainer Name or SIV (N/A where applicable)	Trainer Signature (or indicate "SIV" and N/A where applicable)	Delegated/Non-Delegated
						☐ Delegated ☐ Non-Delegated
						☐ Delegated ☐ Non-Delegated
						☐ Delegated ☐ Non-Delegated

*Role:
1 – Principal Investigator
2 – Sub-Investigator
3 – Coordinator (Clinical Research Coordinator, Clinical Research Nurse, Study Coordinator, Research Data Coordinator, Project Administrator, and Program Manager)
4 – Regulatory Coordinator
5 – Specimen Processor
6 – Designated IDS Pharmacist
7 – Other non-delegated role

OUTCOMES

After the SOP and other related documents were drafted, a pilot was begun in January 2022.

- The pilot team was able to identify and correct multiple issues.
- Staff and investigators have found the new process to be more convenient.
- Monitors have provided positive feedback for the new process.

FUTURE PLANS

- After a successful pilot, we will roll out the new process to the entire department.
- Study teams will begin the process of transitioning selected studies to the new process.
- We look forward to full implementation and process adjustments as we move forward.

Acknowledgements: We appreciate the other cancer centers who contribute to the AACI Listserv.

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