How to Effectively Engage the PI
- I know, It’s Embarrassing that We Have to Talk About This

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Objectives

- Describe why the PI is required to have direct oversight of study activities.
- Describe how to have a conversation with the PI to determine and then develop structure for PI’s engagement in study oversight.
- Give examples of specific scenarios that require immediate PI input.
Adequate PI Engagement, What’s at Stake?

- Subject safety
- Data integrity
- Future Funding
- Institution’s, PI’s and Your Reputations
Let’s Start at the Very Beginning – the Necessity for Adequate PI Oversight -

PI Oversight Plan

- Training
- Check-Ins & Communications
- Safety Checks
- Quality Checks

Compliance with Ethical Standards & Regulations

- Nuremberg Code, Declaration of Helsinki & Belmont Report
- HHS (45 CFR 46)
- FDA 1572 Investigator Agreement
- Univ. of Rochester’s Study Summary Sheets for Responsibilities for Investigators: FDA, Non-FDA & Exempt
- State laws
- Institutional Policies (Ex. Univ. of Rochester Policy 901)
Signing of the 1572 - the PI agrees to:

- Conduct the study in accordance with the current protocol
- Personally conduct or supervise the investigation
- Inform subjects that the product is investigational
- Obtain informed consent
- Report adverse experiences/events to the sponsor and/or IRB accordingly
- Ensure all team members are informed of their obligations
- Understands the risks/side effects of the investigational product
- Supervise use and control of the investigational product
- Maintain adequate and accurate records
- Submit protocol revisions for IRB review prior to implementation
PI Engagement - Have the Conversation Before Study Begins

**Purpose:** Develop strategy to engage PI to review trial progress, events of concern and general required processes (safety, regulatory, protocol compliance, personnel).

**Discuss and develop** methods for communicating between PI and

- Sub-Investigators?
- Research Coordinator?
- Research Administrator?
- Lab Personnel?
- Research Nurse?
- IRB?
- Sponsor?
- Others?

**Create systems** that help in the engagement and communication and that limit opportunities for errors. Use standardized processes when possible. (SOPs, guidance, and reports)

**Identify** who will manage and document these communications and train staff to the plan?
What methods might be used?

**Engagement Options**
- Email
- Walk and Talk
- Phone call
- In-Person
- Presentation
- Webinar

**Considerations**
- Block time on PI’s & staff calendars (check both clinical and research calendars)
- Comply with requirements in protocol
- Take into account Holiday & Vacations
- Identify specific methods to communicate *Emergency* issues
- What reports could be used to help with engagement?

Again, **regroup** with PI on occasion to discuss if engagement plan is working well for PI & team.

*My Experiences – the good, bad and the ugly. What needs PI immediate input?*
Develop a strategy to engage PI for oversight.

Create systems that limit opportunities for errors, use standardized processes when possible.

Train study staff to the engagement and communication plan and systems to be used.

Regroup on occasion to discuss if engagement plan is working well for PI & team.
References

Nuremberg Code, Declaration of Helsinki & Belmont Report
HHS (45 CFR 46)
FDA 1572 Investigator Agreement
FDA Guidance on Investigator Responsibilities, 2009;
Univ. of Rochester, OHSP, Core Module for PI Oversight 2017
Univ. of Rochester OHSP, Policy 901