



DON Human Research Protection Program

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# Department of the Navy Human Research Protection Program

**Issues to Consider When  
Transferring Principal Investigator (PI)**



# PI Responsibilities



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When a study is transferred to a new PI, the new PI is responsible for all aspects of the conduct of the study: past, present, and future.



# PI Responsibilities: SECNAVINST 3900.39D



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PIs are responsible for:

- compliance with all human protection regulations, directives, and instructions;
- completing and documenting initial and continuing research ethics and human subject protections training;
- obtaining written determination of whether the proposed activity is research with human subjects or the research meets criteria for exemption;



# PI Responsibilities: SECNAVINST 3900.39D



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PIs are responsible for:

- obtaining institutional approval prior to conducting or continuing research;
- obtaining institutional approval prior to implementing proposed amendments to approved research;
- notifying the IRB in writing of unanticipated problems involving risks to subjects or others (UPIRTSO); serious adverse events; serious or continuing noncompliance with the human subject protection regulations and IRB requirements; and protocol deviations;



# PI Responsibilities: SECNAVINST 3900.39D



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PIs are responsible for:

- obtaining informed consent from research subjects or their legally authorized representatives and provide them with a copy of the completed informed consent document prior to the start of research, unless a waiver of the documentation is approved by the institution.



# Additional PI Responsibilities: FDA-Regulated Studies



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Per 21 CFR 312 and 812, PIs are Responsible for:

- ensuring that an investigation is conducted according to the investigational plan;
- protecting the rights, safety, and welfare of subjects under the investigator's care;
- control of drugs or devices under investigation;



# Additional PI Responsibilities: FDA-Regulated Studies



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Per 21 CFR 312 and 812, PIs are Responsible for:

- assuring that an IRB complies with the requirements set forth in 21 CFR 56 that will be responsible for the initial and continuing review and approval of the proposed clinical study
- maintaining accurate, complete and current records relating to the investigator's participation in an investigation.



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# PI Transfer: Questions to Ask BEFORE Taking Over a Research Study



# Questions: Data



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- Where is the data collected to date?
  - How is the data protected?
  - Where are the data stored?
  - Who has access to the data?
- Who is collecting data?
  - Are personnel trained in data protection?
  - Are personnel compliant with HIPAA and PII policies and regulations?
- Are the data being transferred?
  - Who is responsible for the transfer?
  - How is the transfer protected?



# Questions: Informed Consent



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- Where are the signed consent forms?
  - How are the signed consent forms protected?
  - Who has access to the consent forms?
- Who obtains consent from participants?
  - Are personnel trained on the ethical considerations of obtaining consent?



# Questions: Other



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- Are there any CRADAs or MOUs associated with the investigation?
  - What commitments are made in the CRADA or MOU?
  - Does the CRADA or MOU need to be amended based on the change in PI?
- Is the investigation being conducted under an IND or IDE?
  - Who is the sponsor of the IND or IDE?
  - How does this impact the PI?



# Questions: Other



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- Were commitments made by the previous PI that are transferable to the new PI?
- What problems have occurred during the conduct of the study?
  - Any SAEs, if yes, what are they?
  - Any UPIRTSOs, if yes, what are they?
- Have any other challenges arisen?



# For Discussion



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### SITUATION:

Shortly after a PI took over a study, a previously enrolled participant in the study had questions and contacted the investigator listed on the informed consent document. The participant was upset at not having the correct contact information and having to contact the IRB office listed on the consent form to receive the correct information.

### QUESTION:

What could the PI have done when taking over the study that might have prevented this situation?



# For Discussion



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### IDEAS:

- The new PI could create, and have the IRB approve, an announcement with new contact information to all previously enrolled participants
- For new participants in the study, ensure most up-to-date, IRB approved, consent document is used

What other steps might have been taken to prevent a situation like this?



# Questions

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Please contact DON HRPP with any follow-up questions or concerns.

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