Quick Reference Guide: Consent, Data Safety Monitoring, Confidentiality

Consent Process

- Consent is a process not just a document.
- The Consent process seeks to obtain an individual's authorization of or refusal for enrollment in a study.
- The process should ensure subject anonymity.
- The Investigator/ Study Team must consider and address potential vulnerabilities of prospective participants.
- The Investigator/Study Team must assure that the process is truly informed, using the Teach back method or other processes for evaluating understanding of the research study.
- The Investigator/Study Team must have a process for determining participant capacity to consent to research
- The consent process should include robust two-way communication to ensure adequate comprehension and contemplation. The Investigator/study team are not just telling potential participants about the research they are engaging in a conversation about the research, asking questions, addressing concerns, and take adequate time to allow for understanding of the material.
- There are special requirements for non-English speakers, vulnerable populations, and legally authorized representatives.

Required elements of consent: 45 CFR 46.116 & 21CFR 50.25

- The study involves Research.
- The purpose of the research, expected duration of participation, description of procedures followed, and identification of any experimental procedures.
- Foreseeable risks or discomforts.
- Potential benefits to the subject or others.
- Appropriate alternatives.
- Extent of confidentiality.
- For more than minimal risk studies: will there be compensation, and/or medical treatments if injury occurs?
- Whom to contact to answer questions.
- A statement that participation is voluntary, and they can discontinue at any time without penalty or loss of benefits.

Additional elements of informed consent

- Risks to the participant, embryo, or fetus if the participant is or may become pregnant.
- How/when a person's participation may be terminated without their consent.
- Additional costs.
- How participation can be terminated by the participant and possible consequences of early termination.
- How significant new findings will be shared.
- Number of subjects involved in the study.

Investigator guidance for the informed consent process can be found here:
https://www.carilionclinic.org/irb/policies#hrpp-toolkit

Templates for consent forms can be found here: Please use Carilion templates when submitting to the Carilion IRB:

https://www.carilionclinic.org/irb/forms?_ga=2.81389207.1263976504.1621877018-205906172.1615832643#consent-templates

Data Safety Monitoring and Confidentiality

What to know

- All research involving human subjects requires data and safety monitoring aligned with the anticipated risks associated with the research.
- The IRB team needs to understand how patient safety will be monitored, how data safety will be assured, whether the study is viable, and how data will be handled, including a data analysis plan (statistical analysis), and who will have access to both identified and deidentified data.

45 CFR 46.111(1)(6)(7)

For IRB approval the following must be addressed:

- (1)(2)Risks to subjects are minimized and are reasonable in relation to anticipated benefits
- (6)The research plan makes adequate provisions for monitoring the data collected to ensure safety of subjects
- (7) when appropriate there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data

What to include in your data safety monitoring plan:

- The entity or Person(s) who will perform the monitoring and the independence or affiliation that the entity or person(s) has with the sponsor or investigator.
- The safety information that will be collected and monitored, including serious adverse events and unanticipated problems.
- The frequency or periodicity of review of safety data.
- The procedures for analysis and interpretation of the data.
- The procedures for review of scientific literature and data from other sources that may inform the safety or conduct of the study.
- The conditions that will trigger a suspension or termination of the research (stopping rules) if applicable.
- Procedures for reporting to the IRB, including a summary description of what information, or the types of information that will be provided.
- The Study team must address the following:
    - Subject risks and safety
    - Data integrity: What data will be reviewed, how often it will be reviewed and who will review it.
    - Monitoring activities to ensure subject privacy: How will subjects be screened, recruited, consented, interviewed, and/or contacted.
    - How data confidentiality will be protected
    - If you need a Certificate of Confidentiality because you will be collecting data that may put participants at risk for civil or criminal liability or be damaging to their financial standing, employability, educational advancements, or reputation.
    - Study documentation process/procedures

Additional guidance can be found in HRP-465 Worksheet: Data and safety monitoring:
https://www.carilionclinic.org/irb/policies#hrpp-toolkit