CHICKEN SOUP FOR THE BUSY COORDINATOR

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Biological Specimen Management

Scenario

A Principal Investigator (PI) is conducting an Investigator Initiated pre-eclampsia clinical trial in which the Clinical Research Coordinator (CRC) is required to collect blood specimens from pregnant women in the clinic. Once the blood specimens are collected, the CRC will transfer the specimens to the PI's laboratory for processing.

Prior to the blood collection, study site should ensure the following:

- The PI should assign the task of biological specimen management to the CRC and ensure that training of biological specimen collection and handling is provided.
- Informed consent must be taken prior to any research activities by the PI or a qualified member of the study team who is listed in the DSRB Application Form as the designated person / study role for conducting the informed consent discussion. For clinical trials that are regulated by HSA, only an investigator who is a qualified practitioner is allowed to obtain informed consent from the subjects.

For blood samples collection, the PI and/or designated staff should:

- Ensure that the logistic arrangement of biological specimen collection, transportation and storage is made prior to any biological specimen collection.
- Label test tubes or other containers and study required forms appropriately (e.g. with subject identification code, date, time, and any other required information).
- It is recommended to handle only **1** subject's blood specimen at any one point of time to avoid getting mixed up; and to label each blood specimen immediately after collection to avoid making errors.
- Record the date and time of the collection as well as any relevant information pertaining to the subject's status at the time of the procedure in the source documents and the biological specimen log.

For processing, the PI and/or designated staff should:

- Verify the accuracy of patient information and ensure that it corresponds with the information on labels on collection tubes.
- Processing the specimens in accordance to IRB/HSA approved study protocol (e.g. centrifuge speed, duration, and temperature requirements).
- Ensure that the laboratory requisition/order forms are completed if applicable.

Documentation required:

- Relevant written laboratory procedures (e.g. study laboratory manual/work flow) are accessible.
- Documentation on the competency of the facility to perform required tests and support reliability of results (e.g. lab certification/accreditation, external quality assessment, appropriate storage conditions) are maintained in the investigator file, where required
- Normal reference range for study specific tests should be accessible where applicable.
- All test results are filed appropriately as per sponsor/institution's requirements.

REFERENCES

1. 501-A02 Responsibilities of the Research Team
2. 501-C01 Informed Consent Form and Process
3. 501 –C04 Biological Specimen Collection and Handling
4. NHG Investigator's Manual

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