PURPOSE: The purpose of this document is to provide guidance to all faculty and staff involved in the conduct of research on the best practices related to documentation.

SCOPE: Applies to all study personnel involved in the conduct of research on the best practices related to documentation.

PERSONNEL RESPONSIBLE: Principal Investigator and, when delegated by the Principal Investigator, Sub-investigators, Study Coordinator and/or other pertinent staff.

DEFINITIONS:

- **Email** - A system for sending and receiving messages electronically over a computer network, as between personal computers.
- **Source documents** – Original documents, data and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries of evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, etc.
- **EDC** – electronic data capture using systems to collect clinical trial data in electronic form as opposed to paper form.
- **CRFs** – case report forms is a paper or electronic questionnaire specifically used in clinical trial research. The case report form is the tool used by the sponsor of the clinical trial to collect data from each participating patient.

PROCEDURES:

General Information:

- Maintain records of all data and observations pertinent to the research subject and for the duration in adherence to Dukes ORC instruction. These records should be identifiable to a particular participant.
- Remember that source documents are where the information is first recorded.
- All data must be verifiable.
- Study documentation should be able to recreate the study for any reviewer.
- Apply the ALCOA acronym for proper technique of documentation
  - Attributable-can you tell who wrote and/or did this
  - Legible-Can it be read?
  - Contemporaneous-is the data current, and in the correct time frame? The notation, signature and date should occur at the same time.
  - Original-Has the data been altered?
TITLE: HC SCAP/Research Quality and Data Integrity

Effective Date: January 25, 2017
Revision Date: 2/27/2020

Accuracy
- Are there conflicting data elsewhere? Content should precisely reflect the event.
- Use a signed Note to File to explain any discrepancies, missing or incomplete data.

Standards
- The same standards maintained for medical documentation should be followed for research documentation.
- All documents require 2 identifiers on each page.
- All entries are to be signed and dated in real-time.
- Error corrections are made by drawing a single line through the incorrect entry, initial and date.
- Never obliterate entries that require correction.
- Subject records need to be secure but accessible.
- Do not alter past-dated notes by writing alongside or adding to prior entries. Updates may be made through addenda.
- Use dark ink, do not use pencil.
- Never use whiteout.

Principles

The research data reflects these important principles:
- We foster an environment where scientific integrity is the highest priority.
- We emphasize high-quality, reproducible data and results.
- We value constructive critiques of research.
- We encourage open discussion of any concerns regarding research conduct or integrity.

Addenda

- If the source data is incomplete or deficient, it may be completed or corrected using an addendum. This late entry must be signed and dated at the time it is created.

Note To File

- May be used to correct errors, or as an explanation to a departure from the protocol. Reasons for any departure should be documented and attempts to correct or prevent in the future should be included.
This should not be used as a panacea to correct any error.

Informed Consent
- The process requires documentation and should reflect the process approved by the IRB in a narrative form or through the use of a checklist.
- Signature and date and time must be of the person obtaining the consent, at the time of the process. (Not added later)

Case Report Forms as Source
- Case report forms may be used as source only when this practice is clearly outlined in the protocol, and they represent the data collected for the research are where the data were initially recorded.

Medical Records From Outside Source
- Copies of records from an outside source may be used if they support endpoints, inclusion/exclusion criteria or adverse events.
- Attempts to obtain medical records should be recorded in the research chart

Questionnaires
- Documentation must reflect who completed the questionnaire, in compliance with the protocol
- For questionnaires completed by staff, a note should reflect how the information was obtained ie: direct interview with participant, phone call, chart abstraction

Good study documentation will allow for an individual with basic knowledge of the particular project to recreate the events of the study.

RESOURCES:
- ICH guidelines
- DOM SCAP Science Culture & Accountability Plan to which faculty will attest

TOOLS:
- Study Correspondence
- Study file
- Study Regulatory Binder
- GCP guidelines
- DOSI website

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• LMS training that addresses GCP and research integrity and documentation best practices
• OARC - Duke Office of Audit, Risk and Compliance website
• Responsible Conduct of Research training (RCR)

APPROVALS:

_____________________________    03/08/2020  
W. Schuyler Jones.  
Heart Center CRU Medical Director

_____________________________    2/27/2020  
Jennifer Hamill, RN, MSN  
Heart Center CRU Director of Research Development

Scheduled Review Date:     Removed from Retired status which was put into effect on 1-7-2020
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