1. PURPOSE

The purpose of this document is to define the process of obtaining and maintaining informed consent and HIPAA authorization with participants prior to and throughout their participation in human subject research. This SOP describes the informed consent and HIPAA authorization process for each participant in a research study approved by the IRB.

2. REVISIONS FROM PREVIOUS VERSION

2.1 Version 3.0, 09/Mar/2020, updated the date and version number

3. POLICY

DOR Policy 10.3.10 Informed Consent Policy: https://www.fau.edu/research-admin/docs/policies/research-integrity/10.3.10-informedconsent-march2018.pdf

4. RESPONSIBILITIES

4.1 Principal Investigators (PIs)

- 4.1.1 Designate and authorize study staff qualified by education and training to obtain informed consent and HIPAA authorization from participants prior to enrollment in clinical research; ensure that delegation of consent duties complies with any sponsor- or protocol-specific requirements (i.e. person obtaining consent must be MD, RN, etc.).
- 4.1.2 Ensure required ICF and HIPAA authorizations are properly obtained, documented, and maintained for all participants.
- 4.1.3 Ensure that PI and study team follow good clinical practices (i.e. explain all items on ICF, ensure comprehension, etc.) throughout the IC process (before and during participation).
- 4.1.4 Provide potential participant/authorized representative sufficient time and opportunity to consider whether or not to participate in the research study, acknowledging his/her right to withdraw at any time during the study.
- 4.1.5 Minimize the possibility of coercion or undue influence on the potential participant to participate or continue participating in the research study (ICH4.8.3).
- 4.1.6 Ensure ICF and HIPAA authorizations are translated and available in other culturally appropriate forms, including appropriate language, based on study population.
- 4.1.7 If providing ICFs in languages other than English, provide trained staff that can communicate in specific language and has knowledge of the population's culture; or use culturally competent approved translator.
- 4.1.8 Ensure IRB approval of all study ICFs (i.e. main, HIV, genetic, etc.) and HIPAA authorization forms. Revise ICF whenever important new information that may be relevant to the research participants' consent (i.e. new risks, change in emergency contact information, new procedures, etc.) becomes available.

4.1.9 Ensure IRB approval of all revised study ICFs and HIPAA authorization forms.

4.1.10 Ensure process is in place to reconsent study participants using IRB-approved amended study ICFs and HIPAA authorization forms, when applicable.

4.2 Clinical Research Professional (CRP):

4.2.1 In collaboration with the PI and other study team members (as appropriate), obtain, document, and maintain ICF and HIPAA authorization forms for all study participants.

4.2.2 Provide potential participant/authorized representative sufficient opportunity to consider whether or not to participate in the research study, acknowledging his/her right to withdraw at any time during the study.

4.2.3 Minimize the possibility of coercion or undue influence on potential participants to participate or continue participating in the research study (ICH4.8.3).

4.2.4 Ensure that the informed consent process and HIPAA authorizations are fully documented in progress notes or consent process notes.

4.2.5 Maintain documentation of informed consent process and HIPAA authorizations.

4.2.6 Ensure the use of the most current IRB-approved ICFs and HIPAA authorizations.

5. PROCEDURE

5.1 Confirm the use of the most current IRB-approved ICF and HIPAA authorization form prior to initiating the informed consent process.

5.2 Provide an environment for the consent process that will ensure participant privacy.

5.3 Provide an IRB-approved ICF and HIPAA authorization form in a language that the participant comprehends fluently.

5.4 Provide sufficient time for participant/authorized representative to read, review, and discuss ICF and HIPAA authorization forms.

5.5 Provide witness for ICF process, if required by IRB policies and procedures.

5.6 Ensure the person obtaining consent speaks the participant's language fluently or uses an approved translator and understands the participant's culture to ensure comprehension.

5.7 Discuss each item in the ICF and HIPAA authorization form as a part of the entire informed consent process.

5.8 Discuss ICF and HIPAA authorization form with cultural appropriateness.

5.9 Encourage participant/authorized representative to ask questions throughout the entire consent process, as well as throughout study participation.

5.10 Describe the research in an informative manner without using persuasive techniques.

5.11 Ask participant/authorized representative to print his/her own name and sign and

date the ICF and HIPAA authorization form if he/she agrees to participate in the research.

5.12 If a witness was used, ask him/her to print his/her own name and sign and date the ICF.

5.13 Ensure person obtaining consent prints his/her own name and signs and dates the ICF.

5.14 Ensure ICF and HIPAA are signed and dated prior to performing any protocol-specific activities.

5.15 Provide a copy of the signed ICF and HIPAA authorization form to the participant/authorized representative.

5.16 Document the consent process in a progress note or consent process note (see section 6 of this SOP)

5.17 Store original signed ICF(s), HIPAA authorization forms, and other consent documentation in study binder.

5.18 Revise ICF, obtain IRB approval, and reconsent (if applicable, per IRB instructions) all enrolled participants as soon as possible when changes are made to the consent documents that have the potential to affect future study participation (i.e. new risks) or continued participation.

5.19 Exceptions to the standard informed consenting process

- 5.20.1 Refer to FAU Research Integrity/IRB or central IRB policies and procedures (i.e. waiver or alteration of consent process, waiver of documentation of consent, short form consent).

5.20 Document the informed consent process with the following information:

- 5.20.1 Consent was obtained prior to any study-specific procedures being performed.
- 5.20.2 Who was present for the consent discussion.
- 5.20.3 Consent process was performed in a language that the participant or authorized representative comprehended fluently.
- 5.20.4 Consent was fully explained, including all of the required and additional (as applicable) elements of informed consent, and all questions were answered to the satisfaction of the participant and/or legally authorized representative.
- 5.20.5 Document specific questions asked by the participant or legally authorized representative.
- 5.20.6 Participant or legally authorized representative receive a signed copy of the ICF and HIPAA authorization forms.
- 5.20.7 A copy of all ICFs and HIPAA forms were provided to supporting programs/units/entities.

5.21 Maintenance

- 5.21.1 Store original signed ICF(s) and HIPAA authorization form(s) in study binder.
- 5.21.2 Store revised signed ICF(s) and HIPAA authorization form(s) in study binder.
- 5.21.3 Store documentation of consent process with the ICF in study binder.

5.21.4 Scan and save signed ICF(s) and HIPAA authorization form(s) in CRU shared drive.

6. MATERIALS

6.1 Templates

6.1.1 FAU IRB Consent and HIPAA Authorization Templates – Research Integrity, IRBNet.
http://www.fau.edu/research/research-integrity/how-to-submit-via-irb.php

6.2.1 CRU Consent Process Note

7. REFERENCES

7.1 International Conference on Harmonization (ICH) Guidelines for Good Clinical Practice. E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) Guidance for Industry. March 2018
https://www.fda.gov/downloads/Drugs/Guidances/UCM464506.pdf

7.2 Research Integrity/Institutional Review Board Policies and Procedures. Florida Atlantic University, Division of Research, Research Integrity
http://www.fau.edu/research/research-integrity/irb-policies-and-procedures.php

7.3 Western Institutional Review Board
http://www.wirb.com

7.4 Advarra Center for IRB Intelligence (CIRBI) Platform
https://www.cirbi.net

7.5 U.S. Department for Health & Human Services, Agency for Healthcare Research and Quality. The AHRQ Informed Consent and Authorization Toolkit for Minimal Risk Research
http://www.ahrq.gov/funding/policies/informedconsent/

8. SIGNATURES

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