 CAMPBELL UNIVERSITY	**IRB SOP:** IRB Records		
	NUMBER	APPROVED BY	EFFECTIVE DATE
	HSR-270	IRB Chair, IRB Office Campbell University	10/08/2019

1 PURPOSE
    1.1 This procedure establishes the process to maintain IRB records.
    1.2 The process begins when records are received or created.
    1.3 The process ends when records have been filed.

2 REVISIONS FROM PREVIOUS VERSION
    2.1 None

3 POLICY
    3.1 IRB records are to include:
        3.1.1 Electronic project files in the IRB shared Egnyte drive and in the CPHS IRB wufoo account.
        3.1.2 Minutes of IRB meetings.
        3.1.3 Copies of all relevant correspondence between the IRB and the investigators.
        3.1.4 Current and previous IRB member rosters.
        3.1.5 Current and previous IRB member files.
        3.1.6 Current and all previous policies and procedures.
    3.2 Electronic protocol files are to include, as applicable:
        3.2.1 All submitted materials.
        3.2.2 Protocols.
        3.2.3 Investigator brochures.
        3.2.4 Scientific evaluations.
        3.2.5 Recruitment materials.
        3.2.6 Consent documents.
        3.2.7 DHHS-approved sample consent document and protocol, when they exist.
        3.2.8 Progress reports submitted by investigators.
        3.2.9 Reports of injuries to subjects.
        3.2.10 Records of continuing review activities.
        3.2.11 Data and safety monitoring board reports.
        3.2.12 Amendments.
        3.2.13 Reportable Events.
        3.2.14 Documentation of non-compliance.
        3.2.15 Relevant Correspondence between the IRB and investigator related to the protocol.
        3.2.16 Significant new findings and statements about them provided to subjects.
        3.2.17 For initial and continuing review of research by the expedited procedure:
            3.2.17.1 The specific permissible category.
            3.2.17.2 Description of action taken by the reviewer.
            3.2.17.3 Any findings required under the regulations.
        3.2.18 For exemption determinations the specific category of exemption.

3.2.19 Unless documented in the IRB minutes determinations required by the regulations and protocol-specific findings supporting those determinations for:

    3.2.19.1 Waiver or alteration of the consent process.

    3.2.19.2 Waiver of documentation of consent.

    3.2.19.3 Waiver or alternation of HIPPA required authorization.

    3.2.19.4 Research involving children.

    3.2.19.5 Research involving adults unable to consent.

    3.2.19.6 Significant/non-significant device determinations.

3.2.20 For each protocol's initial and continuing review, the frequency for the next continuing review.

3.3 Policies and procedures include:

    3.3.1 Checklists.

    3.3.2 Forms.

    3.3.3 SOPs.

    3.3.4 Template letters.

    3.3.5 Template minutes.

    3.3.6 Worksheets.

3.4 IRB member files include a resume for each IRB member, confidentiality agreement and COI Documentation Form.

4 RESPONSIBILITIES

4.1 IRB Office staff members are responsible to carry out these procedures.

5 PROCEDURE

5.1 Minutes of IRB meetings: Save in the *IRB Meeting Documentation* file on the IRB Egnyte shared drive.

5.2 File correspondence related to a specific protocol in the protocol record located on the IRB Egnyte shared drive.

5.3 File correspondence NOT related to a specific protocol in a file related to that person or topic.

5.4 IRB member rosters: File in *IRB Membership Roster 20XX-20xx* file on the IRB Egnyte shared drive.

5.5 IRB membership records (e.g., curricula vita and resumes): File in *IRB Membership* files located on the IRB Egnyte shared drive.

5.6 Policies and procedures:

    5.6.1 File current policies and procedures in the *IRB SOP* file located on the IRB Egnyte shared drive.

    5.6.2 File outdated versions of policies, procedures, SOPs and forms in the appropriate *Archived* folder on the IRB Egnyte shared drive.

6 MATERIALS

6.1 None.

7 REFERENCES

7.1 None.