

 <b>CAMPBELL</b> UNIVERSITY	<b>IRB SOP: IRB Project Records Retention</b>		
	NUMBER	APPROVED BY	EFFECTIVE DATE
	HSR-110	IRB Chair, IRB Office Campbell University	10/08/2019

## **1 PURPOSE**

- 1.1 This procedure established the process to retain IRB records.
- 1.2 The process begins at the creation of a record.
- 1.3 The process ends when records that no longer need to be retained are destroyed.

## **2 REVISIONS FROM PREVIOUS VERSION**

- 2.1 None.

## **3 POLICY**

- 3.1 Project (protocol) records are to be retained for a minimum of 3 years following project closure or as long as required by University Policy and law, then destroyed.
- 3.2 Records may be maintained in paper form or electronically.
- 3.3 Protocols in which there was no subject enrollment or no research was conducted are to be retained according to the same standards as protocols where research was conducted.
- 3.4 All records for research conducted or funded by a Common Rule department or agency are to be accessible for inspection and copying by authorized representatives of that agency at reasonable times and in a reasonable manner.
- 3.5 Records maintained that document compliance or non-compliance with Department of Defense (USDOD) regulations shall be made accessible for inspection and copying by representatives of the DOD at reasonable times and in a reasonable manner as determined by the supporting DOD component.
- 3.6 All records for research subject to USFDA regulations are to be accessible for inspection and copying by authorized representatives of USFDA at reasonable times and in a reasonable manner.

## **4 RESPONSIBILITIES**

- 4.1 IRB Office staff members follow these procedures.

## **5 PROCEDURE**

- 5.1 Destroy project (protocol) records for US Department of Defense (USDOD) research when approved by the US Department of Defense. The agency may require submitting records to the US Department of Defense for archiving.

## **6 MATERIALS**

- 6.1 None

## **7 REFERENCES**

- 7.1 45 CFR 46.115(b)