

## IRB PROCEDURE STATEMENT

**Procedure:** Approval and Expiration Dates for Informed Consent Documents

**Procedure ID:** 2022-17

**Effective:** January 1, 2004

**Revised:** July 1, 2021; May 2022

### A. Background

The Office for Human Subjects Research Protections (OHRP; <https://www.hhs.gov/ohrp/>) recommends that IRBs affix the approval and expiration dates to all approved informed consent documents for Full Board and Expedited review projects. OHRP also stipulates that copies of these dated documents must be used in obtaining consent. This procedure helps ensure that only the current, IRB approved informed consent documents are presented to subjects and serves as a reminder to some investigators of the need for continuing review.

### B. Procedure

1. Informed consent documents for **Exempt projects** are not stamped because there is no annual continuing review report required. For an **Exempt review**, minor changes may be made to the study without IRB approval. However, amendments or modifications to Exempt studies that **substantively change or alter** the criteria or details used to make the initial Exempt determination must be submitted to the IRB for approval.

For **Full Board or Expedited reviews**, after notification of final approval of a new Full Board or Expedited IRB application, a **Continuation request**, or an **Amendment Request** resulting in new or revised consent documents, the IRB office will date all relevant consent documents with the date on which approval became effective and the date on which the approval expires. The approval period will never be for more than 12 months, and may be less than 12 months (e.g., for consent documents changed as the result of a Modification Required).

2. A master copy of the dated documents will be provided to the PI and copies of these dated documents must be used in obtaining consent. These forms can be found by the PI for the project at [IRBNet](#).

**Note:** This procedure of **assigning dates to consent forms** applies to Full Board projects, and Expedited projects. For Exempt projects, no expiration date is affixed to consent forms.