

**SYRACUSE UNIVERSITY
HUMAN RESEARCH PROTECTION PROGRAM
STANDARD OPERATING PROCEDURES**

TITLE: APPROVAL AND EXPIRATION DATES ON INFORMED CONSENT DOCUMENTS		DOCUMENT NUMBER: 020	
REVISION NUMBER	REVISION DATE (SUPERSEDES PRIOR VERSION)	EFFECTIVE DATE	PAGE NUMBER
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Title: APPROVAL AND EXPIRATION DATES ON INFORMED CONSENT DOCUMENTS

1.0 Purpose:

The purpose of this Standard Operating Procedure (SOP) is to provide guidance on stamping Institutional Review Board (IRB) approval and expiration dates on informed consent documents (ICDs) and calculating IRB expiration dates.

2.0 Policy:

It is the policy of the Syracuse University (SU) Office of Research Integrity and Protections (ORIP) to stamp all IRB-approved informed consent documents with the Date of IRB Expiration. The Office for Human Research Protections (OHRP) recommends that IRBs require expiration dates on all approved informed consent documents and that only those documents bearing expiration dates be used when obtaining informed consent from human participants.

ORIP must affix the expiration dates to all approved informed consent documents. Copies of the current, date-stamped approved documents are the only versions that may be used by Investigators in obtaining consent for research activities. This procedure helps assure that only the current IRB-approved informed consent documents are presented to participants and serves as a reminder to the Investigators of the need for continuing review.

- 2.1 Date of IRB Approval.** The approval date is the date that the IRB application and informed consent documents were granted final approval by the IRB, unless one of the following apply:
 - 2.1.1** If the Application has received a continuing review and approval of the research activities and informed consent documents, the date of the last continuing review approval is used;
 - 2.1.2** If the IRB has approved a modification to the informed consent documents, the date of the IRB's approval of the modification is used; or

- 2.2 Date of IRB Expiration.** The expiration date is the last date that the protocol is approved (i.e., if the approval period is January 1, 2010-December 31, 2010, December 31, 2010 will be the last day that the protocol is approved).The Federal regulations make no provision for any grace period extending the conduct of research beyond the expiration date of IRB approval. Therefore, continuing review and re-approval of research must occur on or before the date when IRB approval expires.

3.0 References and Reference Documents:

OHRP Guidance Document

4.0 Procedure:

4.1 Investigator Responsibilities.

- 4.1.1** Investigators are to submit all ICDs as a part of a new study submission for review and approval. It is recommended that the Investigator use the informed consent template located on the IRB website in the column under "Other Forms."

- 4.1.2 Investigators are required to submit a clean (unstamped) copy of the most recent ICDs with all continuing review applications amendments, when appropriate. Following review and approval, the consent forms will be returned including the IRB expiration date stamp. All original IRB date stamped versions of the consent forms are to be retained by the Investigator as a master for copying and distribution to participants
- 4.1.3 Continuing reviews with no intent to enroll additional participants do not require the forwarding of a clean (unstamped) copy of the ICDs to the IRB for re-approval and stamping. However, the research study cannot be re-opened to enrollment without an amendment including the submission of a current ICD for IRB approval and date stamping.
- 4.1.4 It is the Investigator's responsibility to use only those ICDs bearing expiration dates when obtaining informed consent from research participants.

4.2 IRB Committee Responsibilities.

- 4.2.1 The IRB Committee is to determine the appropriate review interval based on the Federal regulations and IRB policies and procedures regarding review and approval.
- 4.2.2 For continuing renewal reviews t, the IRB Committee is to verify that the currently approved and correctly date-stamped ICDs have been submitted for review.

4.3 ORIP/IRB Administrator Responsibilities.

4.3.1 Calculating the "Date of IRB Approval" on the ICDs.

- 4.3.1.1 **Approval at a convened meeting.** When the convened IRB Committee approves the IRB application, the date of the convened IRB Committee meeting is the "Date of IRB Approval" stamped on the ICDs.
- 4.3.1.2 **Approval pending changes at a convened IRB Committee meeting.** When the IRB application is approved with specific changes requested, pending review and approval by the Chair, the date that the changes are verified by the Chairperson or his/her designee is the "Date of IRB Approval" stamped on the ICDs.
- 4.3.1.3 **Expedited Review.** When the IRB application is approved through an expedited review process, the date that final approval is extended by the Chairperson or his/her designee is the "Date of IRB Approval" stamped on the ICDs.
- 4.3.1.4 **Continuing Review.** OHRP recognizes the logistical advantages of keeping the IRB approval period constant from year to year throughout the life of each project. When continuing review occurs annually and the IRB performs continuing review within 30 days before the IRB approval period expires, the IRB may retain the anniversary date as the date by which the continuing review must occur.
- 4.3.1.5 **Amendments.** The "Date of IRB Approval" for amended ICDs is based on the type of review or determination as described above. For example, when an amendment is approved pending changes, the date that the changes are verified by the Chairperson or his/her designee is the date of IRB approval stamped on the informed consent documents.

4.3.2 Calculating the "Date of IRB Expiration" on the ICDs.

- 4.3.2.1 **Approval at a convened IRB Committee meeting.** Based on the approval period granted, the date of expiration is calculated 365 days from the date of the convened IRB Committee meeting minus one day. For example, if the committee meeting date is 2/01/2010, then the "Date of IRB Expiration" is 1/31/2011 for a 12 month review interval.
- 4.3.2.2 **Approval pending changes at a convened IRB Committee meeting.** Based on the approval period granted, the date of expiration is calculated 365 days from the date of the convened IRB Committee meeting minus one day. It is not calculated from the date the Chairperson or his/her designee verifies and grants final approval. For example, if the committee approves pending changes on

2/01/2010 and provisions are verified by the Chair on 3/1/2010, then the “Date of IRB Expiration” is 1/31/2011 for a 12 month review interval and 7/31/2010 for a 6 month review interval.

4.3.2.3 Expedited review. Since there is no convened meeting in an expedited review, the “Date of IRB Expiration” will be calculated based on the review interval determined by the Chair or his/her designee using the date that the initial IRB application was approved or most recent Continuing Review Application was approved by the Chair or his/her designee. Based on the approval period granted, the date of expiration is calculated 365 days from the date of approval minus one day. For example if an initial application was approved or the most recent Continuing Review application was approved on 2/01/2010, then the “Date of IRB Expiration” is 1/31/2011 for a 12 month review interval.

4.3.2.4 Amendments. The approval date of an amendment does not affect the calculation of the expiration date unless the IRB increases or decreases the review interval.

4.3.3 How to Date Stamp ICDs.

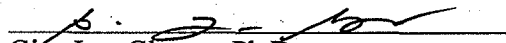
4.3.3.1 Once approval is granted, the ORIP/IRB Administrator or designee will stamp the date of IRB expiration in the bottom margin in the ICD using the official IRB stamp. The date of IRB expiration will match the date indicated in the approval letter.

4.3.3.2 The ORIP/IRB Administrator or designee will stamp amended ICDs, when approved, retaining the original expiration date, unless the review period was changed.

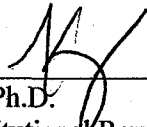
4.3.3.3 The ORIP/IRB Administrator or designee will copy the date-stamped ICDs and the approval letter and verify the copies are reproducible. The Administrator will forward the original date-stamped ICDs and the original approval letter to the Investigator. A copy of the date-stamped ICDs will be maintained in the IRB file.

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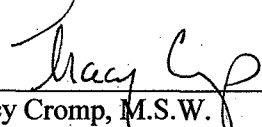
Approved by:


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6-14-2010
Date


Kathleen King, Ph.D.
Chair of the Institutional Review Board
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11 June 2010
Date


Tracy Crompton, M.S.W.
Director of Office of Research and Integrity Protections
Syracuse University

6-11-10
Date