

Policy Number: 34

Title: Approval Dates on Informed Consent Documents

Date of Last Revision: 08/10/05, 09/27/10, 06/05/13, 09/01/15

Policy:

It is the policy of the UC Irvine (UCI) Institutional Review Board (IRB) to stamp all IRB-approved informed consent documents with the Date of IRB Approval.

- I. Neither the Food and Drug Administration (FDA) or the Office for Human Research Protections (OHRP) mandate that the IRB stamp the final IRB- approved copy of the consent document. As part of UCI HRP policy, HRP staff affix the IRB approval date to all approved informed consent documents and recruitment materials. Copies of the current, date-stamped as approved documents are the only versions that may be used by Investigators in recruiting and obtaining consent for research activities.
- II. **Date of IRB Approval** - The approval date is the date that the IRB application and informed consent documents were reviewed and granted approval by the IRB, either at initial review, modification or continuing review. The date of IRB approval which appears on the informed consent documents is the date of approval for the latest version of the informed consent documents.
- III. **Date of IRB Expiration** - The expiration date is the date that signifies the end of the current IRB approval period. 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. In a measure to reduce administrative burden, HRP Staff do not include the expiration date on the final, IRB-approved copy of the consent document(s), as part of the IRB stamp.

Procedure Number: 34.A

Title: Procedure for Stamping IRB Approval Dates on Informed Consent Documents

Procedure:

The purpose of this procedure is to provide guidance on stamping IRB approval dates on informed consent documents.

I. Lead Researcher (LR) Responsibilities

- A. LRs are to electronically submit all informed consent documents as a part of a new study submission for review and approval. It is recommended that the LR use the informed consent template located on the IRB website at <http://www.research.uci.edu/ora/forms/> under the heading "IRB Consent Forms."
- B. Investigators are required to submit an electronic copy of the most recent informed consent documents with modification requests. For continuing reviews, Investigators need to indicate on the continuing review application which informed consent documents need to be kept active. When reviewed and approved by the IRB, if changes have been made, a new approval date will be date-stamped on the active informed consent documents.
- C. Informed consent documents do not need to be reviewed in continuing reviews with no intent to enroll additional participants. However, the research study cannot be re-opened to enrollment without a modification request to reactivate the consent form.
- D. It is the LR's responsibility to only use the most current version of the informed consent documents bearing the approval date when obtaining informed consent from research participants. All current approved informed consent documents are available to the study team at the IRB Document Depot.

II. IRB Committee Responsibilities

- A. The IRB Committee is to determine the appropriate review interval based on the Federal regulations and IRB policies and procedures regarding review and approval.

III. IRB Analyst or Higher Responsibilities

- A. Calculating the "Date of IRB Approval" on the Informed Consent Documents
 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 informed consent documents.
 2. Minor revisions required 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 or her designee is the "Date of IRB Approval" stamped on the informed consent documents.
 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 or her designee is the "Date of IRB Approval" stamped on the informed consent documents.
 4. Continuing Review

The "Date of IRB Approval" for the Continuing Protocol application is based on the type of review or determination as described above. For example, when an Expedited continuing application is approved pending changes at a subcommittee meeting; the date that the changes are verified by the Chairperson or his or her designee is the

date of IRB approval stamped on the informed consent documents.

5. Modifications - The "Date of IRB Approval" for amended informed consent documents and for re-consent cover memos, if applicable, is based on the type of review or determination as described above. For example, when an amendment is approved pending changes at a convened IRB Committee meeting, the date that the changes are verified by the Chairperson or his or her designee is the date of IRB approval stamped on the informed consent documents.

IV. **IRB Analyst or Higher Responsibilities**

A. How to Date Stamp Informed Consent Documents

1. Once approval is granted, the Analyst will electronically affix the official stamp in the footer of each page.
2. The date of IRB Approval and the assigned Human Subjects Number (HS#) will be entered in the official stamp. The date of IRB approval will match the date indicated in the IRB Approval Letter. The date of IRB expiration will be noted in the IRB Approval Letter only.
3. The Analyst will electronically affix the IRB approval stamp upon initial approval to the informed consent documents and upon modification (and IRB approval) to the informed consent documents.

B. The Analyst will notify the Lead Researcher and administrative contact when the approval is available for downloading at the IRB Document Depot.

C. A copy of the date-stamped informed consent documents will be maintained in the IRB file.