POLICY:

I. The actual IRB approval date represents the date that the research activities (or change of activities) may begin.

II. The effective approval date refers to the last permissible date that may be used to calculate the expiration date, when applicable.

III. UIC IRB has adopted the fixed anniversary date approach for subsequent continuing reviews.

IV. Research involving any of the following is limited to an approval period of no more than 365 days:
   A. Research is under the oversight of FDA, DoJ, or other agencies that require continuing review at a minimum of once per year (365 days),
   B. Greater than minimal risk,
   C. Review by the Convened IRB, or
   D. As per IRB determination.

V. Research that meets the “no continuing review” provision (refer to the UIC HSPP policy Continuing Review and Administrative Closure of Research) are given an approval date only.

VI. As UIC is not obligated to apply the Common Rule to research that is not federally funded, some research protocols approved between the dates of April 16, 2018 through January 20, 2019 were granted an extended approval period of a maximum of three (3) years (1095 days) rather than the one (1) year (or less) period. Research was excluded from being granted an extended approval period if any of the following applied:
   A. Federal funding (including no cost extension),
   B. Research is under the oversight of FDA, DoJ, ED, or other agencies that require continuing review at a minimum of once per year,
   C. Greater than minimal risk,
   D. Review by the Convened IRB,
   E. Certificate of Confidentiality has been obtained for the research,
   F. Development Only proposal,
   G. Center or Training grant, or
   H. As per IRB determination.

VII. Amendments that change a protocol’s eligibility for the three-year approval period will decrease the expiration date of the research. For instance, if the amendment adds federal funding to the research then the three-year approval period will be
reduced to a one-year approval period. (Refer to the UIC HSPP policy Amendments to Previously Approved Research for additional information.)

VIII. Amendments that change a protocol's eligibility for the “no continuing review” provision will impose an expiration date on the protocol and subsequent continuing review will be required. For instance, if an amendment is determined by the convened IRB to change the overall protocol risk level from minimal risk to greater than minimal risk, then the protocol will be given a one-year approval period from the date of the amendment review.

PROCEDURE:

I. The research review process and range of possible actions (e.g., Approval, Conditions Required to Secure Approval, Deferral) by the IRB are described in the UIC HSPP policies Review of Research by the Convened IRB and Expedited Review Process.

II. Approval Dates:
   A. Actual Date of Approval
      i. The actual date of approval represents the date that the research activities (or change of activities) reviewed and approved by the IRB may begin. For initial reviews, continuing reviews, and amendments to previously approved research, this is the date the convened IRB or the Chair (or designee) determines that all required conditions have been met.
   
   B. Effective Approval Date
      i. Effective approval date refers to the last permissible date that may be used to calculate the expiration date. For examples demonstrating the difference between an actual approval date and effective approval date, please refer to item IV below.
         (a) For initial review, the effective and actual approval dates are the same.
         However, the effective and actual approval dates may differ at continuing review.
      ii. The UIC HSPP has adopted a procedure for maintaining fixed anniversary dates for approval periods (effective approval date and expiration date) at the time of continuing IRB approval.
         (a) As a result, when the IRB performs continuing review and re-approves the research within 30 days before IRB approval expires, the IRB retains the anniversary of the approval and expiration dates of the initial IRB approval as the effective approval date and expiration dates of each subsequent approval period (for approvals less than 1 year, the same process is followed, however changes occur in increments of less than a year).
         (b) For example, if the IRB previously granted an approval period of 7/31/2016 through 7/31/2017, the approval period following re-approval would be 7/31/2017 (effective approval date) through 7/31/2018, provided that the IRB re-approved the research between 7/1/2017 and 7/31/2017 (actual approval date).

III. Approval Periods:
A. Following approval or conditions required to secure approval for the initial or continuing review of a protocol, the IRB determines the continuing review interval appropriate to the degree of risk.
   i. Research that meets the criteria of Policy item IV is limited to an approval period with a maximum of one year.
   ii. Research that does not meet the criteria of Policy item IV may be eligible for “no continuing review” (refer to the UIC HSPP policy Continuing Review and Administrative Closure of Research). Research that no longer requires a continuing review is only granted an approval date.

B. Approval of amendments to previously approved research does not change the “no continuing review” determination unless the amendment affects the criteria of Policy item IV and, therefore, imposes an approval period.
   i. The expiration date will be one year from the date of the approval of the amendment. Approved documents will be stamped with the new approval period.

C. Approval of amendments to previously approved research does not change the currently assigned expiration date for research that was granted an extended approval period of a maximum of three (3) years unless the amendment affects the criteria of Policy item VI and, therefore, decreases the approval period.
   i. The expiration date will be one year from the date of the approval of the amendment. Approved documents will be stamped with the new approval period.

D. The IRB may require continuing review more frequently than required as per federal and/or UIC policy. Studies that the IRB focuses on for imposing review intervals of less than one year include:
   i. studies that pose a very high level of risk to individual participants (very high risk to individuals);
   ii. high risk studies that are expected to have a large number of participants involved (high cumulative risk);
   iii. phase I drug and device studies;
   iv. investigator-initiated studies of investigational drugs or devices; and
   v. studies conducted by PIs who have been non-compliant with the protocol at issue or other protocols, are currently involved in a for-cause compliance investigation, or studies being conducted by new investigators.

IV. Examples of Reviews with Approval Dates and Approval Periods

A. Initial Review
   i. Scenario I. IRB approves the protocol without conditions: effective approval date and actual approval date is date approval occurs OR
   ii. Scenario II. IRB determines conditions are required to secure approval: effective approval date and actual approval date is the date when the IRB Chair (or designee) approves all changes required by the IRB from the investigator.

B. Continuing Review
   i. The effective approval date is based on the current expiration date as described in II.B. above.
(a) If the research is re-approved within 30 days before the expiration date, the effective approval date becomes the current expiration date as a means to maintain the fixed anniversary dates for the approval periods. For example, if the current approval period is 7/31/2016-7/31/2017, and the research is re-approved on 7/15/2017 (actual approval date), due to fixed anniversary dates the new approval period is 7/31/2017 (effective approval date) - 7/31/2018.

(b) The effective approval date is the same as the actual approval date when:

1. The research is re-approved 31 or more days before the expiration date (e.g., actual and effective approval date of 6/15/2017 for approval period of 6/15/2017-6/15/2018), OR
2. The research is re-approved after the expiration date (e.g., actual and effective approval date of 8/2/2017 for approval period of 8/2/2017 - 8/2/2018).

C. Expiration (Continuing Review) Date - Please note that unless specified, the examples are based on a one-year (365 days) approval period.

i. Expiration Date (first continuing review date) for Research Reviewed at a Convened Meeting or by Expedited Procedures at the Time of Initial Review

(a) The expiration date is the last date of the approval period and expires at 11:59 PM. This date is determined by adding the IRB approved continuing review interval to the effective approval date.

Example 1: IRB approves an initial review of a protocol at the 4/1/2016 convened meeting for 1 year. The effective approval date is 4/1/2016. The expiration date is 4/1/2017, and continuing review must be approved before 11:59 PM on this date.

Example 2: IRB determines conditions are required to secure approval for an initial review of a protocol at the 4/1/2016 convened meeting. The IRB sets the continuing review interval at 1 year. The Chair receives and reviews the required conditions on 4/20/2016 and determines the changes made by the investigator are satisfactory. The effective approval date is 4/20/2016. The expiration date is 4/20/2017, and continuing review must be approved before 11:59 PM.

Example 3: IRB defers an initial review of a protocol at the 4/1/2016 convened meeting as substantive changes to the consent form are required. The response to the deferred initial review is reviewed by the IRB at the 5/1/2016 convened meeting, and the response is found to be acceptable with the exception of minor changes to the consent and documentation of training. The IRB determines conditions are required to secure approval and sets an approval interval of 1 year. The response to the required conditions...
is reviewed and approved by the IRB Chair outside a convened meeting on 5/15/2016. The effective approval date is 5/15/2016 and the expiration date is 5/15/2017.

Example 4: A protocol qualifying for initial review by expedited procedures is reviewed by the IRB Chair outside of a convened meeting. The Chair determines conditions are required to secure approval on 4/2/2016. The response to the required conditions is subsequently reviewed by the Chair on 4/26/2016; the response is found to be acceptable, the Chair determined and documented that the research requires a Continuing Review resulting in a 1 year approval period. The effective approval date is 4/26/2016 and the expiration date is 4/26/2017.

Example 5: IRB determines conditions are required to secure approval for an initial review of a protocol at the 4/1/2016 convened meeting. Due to prior compliance issues, the IRB sets the continuing review interval at 6 months. The Chair receives and reviews the response to conditions on 4/20/2016 and determines the changes made by the investigator are satisfactory. The effective approval date is 4/20/2016, and the expiration date is 10/20/2016.

ii. Expiration Date for the Second and Subsequent Continuing Reviews for Research Reviewed at a Convened Meeting or by Expedited Procedures

(a) When re-approval is not obtained by the expiration date (i.e., approval lapses), the approval period when re-approval is finally obtained is calculated based on the date of the convened meeting where the IRB approves the protocol or the date the conditions required to secure approval are approved or, for review by expedited procedures, the date when the IRB Chair (or designee) last reviews and approves the protocol. Thus, if the expiration date is 7/31/2016 but the continuing review submission occurs after this date and re-approval is not obtained until 9/1/2016, the new expiration date is 9/1/2017.

Example 1 (continued): IRB approves an initial review of a protocol at the 4/1/2016 convened meeting for 1 year. The effective approval date is 4/1/2016. The expiration date is 4/1/2017, and continuing review must be approved before 11:59 PM on this date. The IRB conducts the first continuing review of the protocol at a convened IRB meeting on 3/8/2017 (within 30 days prior to expiration) and reapproves the protocol for 1 year. The new continuing review approval period begins on 4/1/2017 (effective approval date), the expiration date for the second approval period is 4/1/2018,
and the next continuing review must be approved by this date.

Example 2 (continued): IRB determines conditions are required to secure approval for an initial review of a protocol at the 4/1/2016 convened meeting. The IRB sets the continuing review interval at 1 year. The Chair receives and reviews the required conditions on 4/20/2016 and determines the changes made by the investigator are satisfactory. The effective approval date is 4/20/2016. The expiration date is 4/20/2017, and continuing review must be approved before 11:59 PM. The IRB conducts the first continuing review on 4/2/2017 and defers the protocol requiring the investigator to explain the higher than expected frequency of skin rash and institute additional protections. Re-approval is not obtained by 4/20/2017, approval lapses and research activities stop. The IRB reviews the clarification and protocol revision from the investigator at a convened meeting on 5/6/2017 (effective and actual approval date) and reapproves the protocol for 1 year. Because re-approval did not occur until after the expiration date, the new expiration date for the second approval period is 5/6/2018, and continuing review must be approved by this date.

Example 3 (continued): IRB defers an initial review of a protocol at the 4/1/2016 convened meeting as substantive changes to the consent form are required. The response to the deferred initial review is reviewed by the IRB at the 5/1/2016 convened meeting, and the response is found to be acceptable with the exception of minor changes to the consent and documentation of training. The IRB determines conditions are required to secure approval and sets an approval interval of 1 year. The response to the required conditions is reviewed and approved by the IRB Chair outside a convened meeting on 5/15/2016. The effective approval date is 5/15/2016 and the expiration date is 5/15/2017. The IRB conducts the first continuing review at a convened meeting on 4/1/2017, and reapproves the protocol for 1 year. Because the re-approval occurs more than 30 days before the expiration date, 4/1/2017 becomes the new effective approval date and the expiration date for the second approval period is 4/1/2018.

Example 4 (continued): A protocol qualifying for initial review by expedited procedures is reviewed by the IRB Chair outside of a convened meeting. The Chair determines conditions
are required to secure approval on 4/2/2016. The response to the required conditions is subsequently reviewed by the Chair on 4/26/2016; the response is found to be acceptable, the Chair determined and documented that the research requires a Continuing Review resulting in a 1 year approval period. The effective approval date is 4/26/2016 and the expiration date is 4/26/2017. The continuing review submission is reviewed by expedited procedures by the Vice Chair on 4/20/2017 (actual approval date), who also determines and documents that the research continues to require a Continuing Review reapproves the research for 1 year. The new continuing review approval period begins on 4/26/2017 (effective approval date), with the expiration date for second approval period is 4/26/2018.

Example 5 (continued): IRB determines conditions are required to secure approval for an initial review of a protocol at the 4/1/2016 convened meeting. Due to prior compliance issues, the IRB sets the continuing review interval at 6 months. The Chair receives and reviews the response to conditions on 4/20/2016 and determines the changes made by the investigator are satisfactory. The effective approval date is 4/20/2016, and the expiration date is 10/20/2016. The continuing review submission is reviewed at a convened meeting on 10/1/2016, conditions are required to secure approval, and the protocol is granted a 1 year approval period. The IRB Chair reviews the response to the required conditions from the investigator outside a convened meeting on 10/10/2016 (actual approval date) and determines that the conditions for approval are met. The new approval period for this research is 10/20/2016 (effective approval date) through 10/20/2017.

V. The approval date/approval period, as applicable, is communicated to the investigator via the approval notice as described in the UIC HSPP policies Review of Research by the Convened IRB and Expedited Review Process.

REFERENCES:
21 CFR 56.109
45 CFR 46.109
OHRP Guidance on Continuing Review of Research, OHRP, DHHS, November 10, 2010
### REVISION LOG:

<table>
<thead>
<tr>
<th>Version (#, date)</th>
<th>Replaces (#, date)</th>
<th>Summary of changes</th>
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</thead>
<tbody>
<tr>
<td>1.0, 1/18/17</td>
<td>N/A</td>
<td>Creation of policy. The information was previously contained within the policy <em>Review of Research by the Convened IRB.</em></td>
</tr>
<tr>
<td>1.1, 04/12/18</td>
<td>1.0, 1/18/17</td>
<td>Revised to include the extended approval period of 3 years for minimal risk research that is not federally funded or under FDA purview.</td>
</tr>
<tr>
<td>1.2, 01/21/19</td>
<td>1.1, 04/12/18</td>
<td>Revised to reflect changes based on 2018 Requirements. Title change to reflect elimination of expiration date for “no continuing review” research.</td>
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