

UNIVERSITY OF ILLINOIS
AT CHICAGO

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TO: Principal Investigators Involved in Research with Human Subjects and/or
Vertebrate Animals

FROM: Eric A. Gislason, PhD
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DATE: September 12, 2007

SUBJECT: Procedure Change Affecting New Grant Applications Involving Human Subjects
and/or Vertebrate Animals

Federal regulations require that all research proposed in a grant application that involves use of human subjects and/or live vertebrate animals be approved prior to the award. Approval requires the Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (ACC) to approve and match the research protocol relating to human subjects and/or animals and the scope of work contained in the grant application.

To better ensure compliance, there will be a change in procedures regarding new grant applications involving human subjects and/or vertebrate animals that will be implemented by the Office of Research Services (ORS), the Office for Protection of Research Subjects (OPRS), and the Office of Animal Care and Institutional Biosafety (OACIB). The new procedure will be effective **November 1, 2007**.

What will be different for investigators?

- 1.) New Proposal Approval Form (PAF) - All new grant applications or competitive renewals must list IRB and/or ACC approval as "pending" at the time of submission to the funding agency.
- 2.) IRB and/or ACC approval dates should not be listed on the grant application.
- 3.) For grant applications submitted to agencies that require verification of approval at the time of submission, investigators must secure IRB or ACC approval prior to submission. Investigators submitting to these agencies must include documentation of OPRS or OACIB approval of both the grant and protocol with the submission of the grant applications to ORS.

How will the procedure work?

- 1.) Following the submission of a grant application involving use of human subjects and/or vertebrate animals to ORS, investigators will receive an email acknowledging the submission and reminding the investigator of their responsibility to ensure appropriate IRB and/or ACC approvals are in place.
- 2.) Once the protocol has been appropriately matched to the grant application and approved by the IRB and/or ACC, the OPRS and/or OACIB will notify ORS that the proper approvals are in place.

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3.) For all funding agencies that require verification of IRB and/or ACC approvals prior to award, such as the NIH "Just in Time" process, ORS will provide verification of IRB and/or ACC approval to the funding agency after the specific grant application has been matched to a protocol and approved by the OPRS and/or OACIB respectively.

4.) For all other awards that involve human subjects and/or vertebrate animals, ORS will process the award for account creation after the specific grant application has been matched to a protocol and approved by the OPRS and/or OACIB respectively.

Exceptions:

1.) For awards whose terms and conditions do not require a specific protocol to be matched, ORS will process the award for account creation without the corresponding IRB and/or ACC approval. Please note that IRB and/or ACC approval is required prior to the initiation of research activities involving human subjects or vertebrate animals.

2.) For awards whose terms and conditions request IRB and/or ACC approval within a specific period of time after an award is made, account set up will be completed on a case-by-case basis, pending review of the requirements and notification of the OPRS and/or OACIB respectively.

3.) Accounts may be created for clinical trials sponsored by pharmaceutical companies prior to final IRB approval. Please note that IRB approval is required prior to the initiation of research activities involving human subjects.

Please remember:

To avoid any delays in ORS's ability to provide verification of the necessary approvals and to process the award, investigators are reminded that it is their responsibility to submit their application to OPRS and/or OACIB for review and approval in a timely manner. Because each research proposal is different, please contact the OPRS and/or OACIB if you have questions regarding the recommended timeframe for the submission of a given proposal to the IRB or ACC.