

Office of Research
Integrity and Compliance

2300 Children's Plaza, Box 205
Chicago, Illinois 60614-3394 **December 20, 2007**
773.755.6306
Fax 773.755.6304
www.childrensmrc.org

*Affiliated with
Northwestern University's
Feinberg School of Medicine*

TO: Investigators and Research Staff
Children's Memorial Research Center

FROM: Institutional Animal Care and Use Committee (IACUC)

Re: New Submission Requirements and Review Process for IACUC Protocols

Dear Investigators:

Attached is a summary of the new submission requirements and review processes that have been developed by the Institutional Animal Care and Use Committee. So as to ensure continued compliance, the Committee and the Office of Research Integrity and Compliance have devoted significant time and effort in researching the applicable regulations, and in developing the new forms.

Listed below are some of the more significant changes:

- **An annual certification Form 300 is no longer required unless you are using USDA covered species.** Only investigators whose protocols involve the use of USDA species need to submit the new "CMRC Annual Certification Form 300 for USDA Species".
- **Rodent Breeding Protocols:** For protocols involving rodent breeding investigators need to submit the **Rodent Breeding Form 400** annually in between *de novo* reviews for purposes of annual renewal/certification.
- **All other protocols:** Protocols not involved in rodent breeding or not using USDA covered species, are only required to undergo *de novo* review every three years.
- **For modifications, we will now require a Form 200** – This is a checklist form where the investigator checks off the type of modification, and then submits it **along with an updated ASP Form 100 highlighting the modification.**
 1. This will ensure that the protocol Form 100 is always complete and up to date instead of a protocol Form 100 that is a couple of years old with a series of addenda attached to it.
 2. This will allow for an improved review by the committee and also, when the time comes for *de novo* review, the preparation of the Form 100 for *de novo* should be easier and less time consuming.

******The IACUC, and IACUC office, is implementing the new forms starting in January 2008 and will provide educational outreach sessions and sample protocols for the website so that the investigators and research staff will be able to learn about the new processes and forms as we make the transition. IACUC committee members and staff are also available to meet one on one with PIs or research staff to assist in preparing submissions******

We look forward to providing our investigators and research personnel with an improved and more meaningful submission review process while maintaining our high standards of research ethics and compliance.

Sincerely,

A handwritten signature in black ink, appearing to read 'Xiao-Di Tan', with a stylized flourish at the end.

Xiao-Di Tan, MD
Chair, Institutional Animal Care and Use Committee
Children's Memorial Research Center

Summary of the Revised IACUC Protocol Submission Guidelines and Requirements

The following is a summary of the changes to the submission requirements and review processes that the CMRC IACUC is implementing as of January 1, 2008. Please do not hesitate to contact the IACUC office (755-6302) if you have any questions or concerns regarding your protocols, their submission requirements, including questions concerning protocol modification, expiration dates and approval letters. The new forms are being posted this week on the IACUC website. *Sample forms to assist PIs in completing these forms are being prepared and will be posted shortly.*

NEW Protocols:

- Complete an Animal Study Protocol “ASP” Form 100
- Requires full committee review

DE NOVO protocols are reviewed *de novo* every three years:

- Complete an ASP Form 100
- Requires full committee review.
- Submission deadline is two meeting cycles prior to expiration date.

EXISTING Protocols – Annual Renewals:

1. USDA Covered Species – Annual Renewals:

- *CMRC Annual Certification Form 300 – USDA Species:* Required annually in between the *de novo* reviews for protocols involving the use of USDA covered species.
- This form will be processed, reviewed and approved by the IACUC using the designated reviewer method.
- Submit only one original, signed form.

2. Rodent Breeding Protocols – Annual Renewals:

- *CMRC Annual Rodent Breeding Certification Form 400:* Required annually, in between *de novo* reviews, for protocols involving rodent breeding.
- IACUC office reviews in collaboration with RSF Director and IACUC Chair.
- Submit only one original, signed form.

3. ALL OTHERS - Non-USDA Species and/or No Rodent Breeding:

- ***Do not submit any annual renewal forms*** - from now on an annual Form 300 is no longer required.
- Accounting of animals is tracked by the RSF Director and IACUC office - as PIs request animal purchases, the IACUC and RSF will verify IACUC approval of the additional animals prior to signing off on the purchase.
- Only requires *de novo* review (ASP Form 100) every three years by the full committee.

Addendum to Approved Protocols – FORM 200
To request protocol Changes/Modifications:

Submit the new *CMRC Addendum to an Approved ASP Form 200* **with** an updated ASP Form 100 that incorporates the modification(s) requested. The updated ASP Form 100 must have the changes **highlighted**.

The Form 200 is a checklist form where the PI simply checks off the box or boxes that describe the type of modification(s) he/she is requesting. The modification(s) are to be incorporated into an updated version of the currently approved ASP Form 100 as described above.

Examples of protocol changes/modifications are:

- Personnel – Add or delete
- Title change or funding source
- Animal care, animal numbers, changes in species
- Change in procedures
- Other

Depending on the nature and scope of the modification(s) requested these may be handled administratively by the IACUC office (example –deletion of personnel), by the designated reviewer method, or by full committee review if either requested by an IACUC member or at the discretion of the Chair.

******NOTE: The IACUC requests that when submitting a Form 200 with the highlighted Form 100, that you use the new ASP Form 100 and incorporate both the new modification requested and all previously approved addenda since the last Form 100. However, please only highlight the new modification that is being requested as per the Form 200. This will ensure that both the PI and the IACUC have the most up-to-date protocol on file******

PROTOCOL INACTIVATION REQUESTS- *Form 500* – under development.

- If you wish to close-out/inactivate a protocol, please contact the IACUC office at (773) 755-6302 for information. You will be required to provide the reason for inactivation, the disposition of any animals still under the protocol and a brief progress report.
- The IACUC office will administratively review and a letter of acknowledgement of the inactivation is sent to the PI.

QUESTIONS??? Please call the IACUC office at 755-6302

AVIAN EMBRYO Protocols: The IACUC is working to create an improved method to monitor these protocols as they do not fall under the purview of the IACUC unless there is hatching. For further information, please contact the IACUC.