## IACUC

The Animal Use Protocol (AUP) portion of the Research Management System (RMS) is up and running! All new and three-year renewal protocols must be submitted online via the new system. Full, detailed instructions for use are available online, and we have dedicated help-desk support available during regular office hours (8-5 Monday through Friday). The IACUC no longer accepts paper applications via the old “Web Portal”; there is, however, a Word-document template available on our website to assist users in the conversion to the new online application format.

IACUC and ULAR staff are hard at work on the final configurations of Phase 2 of the software launch, which will allow researchers with approved animal protocols to submit animal orders online. The third and final phase of the project involves automated animal health records and census information, sure to make our already-excellent animal program that much better.

Click [HERE](#) for more information and regular updates about the transition to this new and powerful tool.

## HSCRO

The following documents have recently been revised, and the changes to the documents are briefly described below:

- **Application for review** * (use for a new submission)*
  All new submissions require Full Committee review
- **Protocol Narrative** * (use for a new submission)*
  In Section 2, include the expertise & training for all researchers manipulating cells
- **Continuing Protocol Application**
  Only the lead researcher’s signature would be mandatory
- **Modification Application**
  Describe each research personnel’s role in the study, and include the UCI net ID for personnel to be added to protocols
- **Cell Tracking Table**
  Clarify source of material, and the section on feeder material was removed
- **Flow Chart**
  Converted to a pdf format for ease of printing, and the section for the Working Group was removed
- **Program Policy and Procedures**
  Harmonized with current CDPH guidelines

Note: The [2017 hSCRO Full Committee calendar](#) is now available.
SINGLE IRB (sIRB Review)
Are you looking to collaborate with colleagues at another institution? Is the study sponsor requesting that you use an independent IRB? Are you joining a research consortium that requires single IRB review? UCI can often cede IRB review to another IRB. UCI currently has formal master IRB agreements with Children’s Hospital of Orange County, MemorialCare Health System, National Cancer Institute Central IRB (CIRB), our sister UC campuses, as well as three independent IRBs—Western IRB (WIRB), Quorum IRB, and Schulman IRB. UCI investigators must register their study through UCI’s IRB system by completing an abbreviated application and must secure all required ancillary UCI approvals (e.g., COIOC, Radiation Safety, PRMC), as applicable. For more information, see: http://www.research.uci.edu/compliance/human-research-protections/irb-partners-and-affiliates/index.html or contact Valerie Sanchez, IRB Reliance Administrator, at 949-824-7735 (valerie.ms@uci.edu), or Kirsten McDaniel, IRB Reliance Senior Analyst, at 949-824-6269 (k.mcdaniel@uci.edu).

Stay tuned for more information in early 2017 about NIH’s sIRB review policy which takes effect May 25, 2017. The policy applies to domestic NIH-funded multi-site studies carried out at more than one site “where each site will conduct the same protocol involving non-exempt human subjects research, whether supported through grants, cooperative agreements, contracts, or the NIH Intramural Research Program. For more information on NIH’s sIRB policy, go to their Clinical Research Policy web page.

QUALITY IMPROVEMENT (QI) ACTIVITIES
Distinguishing QI-activities from QI human subjects research activities can be reviewed on a case by case basis. Essential elements of QI-activities include:
• Purpose: designed to implement knowledge; assess a process or program as judged by established/accepted standards
• Starting Point: knowledge-seeking is integral to ongoing management system for delivering health care
• Design: adaptive and iterative
• Benefit: directly benefits a process, system or program
• Risks: does not increase risk to patients (except for the possible breach of confidentiality)
• Participant obligation: responsibility to participate as a component of care
• Endpoint analysis: improve a program, process, or system; or, compare a program/process/system to established standards
• Adoption of results: rapidly adopted into local care delivery
• Publication: encouraged to share systematic reporting of insights
Note: QI activities that meet the definition of Human Subjects Research requires IRB review.

EMPLOYEES AS RESEARCH PARTICIPANTS
In minimal risk research and greater than minimal risk research, it is important to reduce undue influence and the potential for compromised objectivity. Key strategies for protecting employees in employer-based research include:
• Describing measures that will be implemented to protect the rights and welfare of employee participants
• The consent and process should clearly convey that participation in research will have no impact on employee’s status or benefits
• Indirectly recruit participants through the use of recruitment materials
• Supervisor interactions with employees should be restricted during enrollment, consent process, research procedures, and analyses of identifiable data
DECEPTION AND INCOMPLETE DISCLOSURE

Deception or Incomplete Disclosure is used in research when necessary to avoid study bias or to test a hypothesis that requires providing subjects with misinformation or with limited information about the research. Deception or incomplete disclosure is only permitted where the IRB documents that an alteration of informed consent process is justified based on the criteria in the Common Rule. Specifically, the IRB must find and document that all of the following criteria have been satisfied:

- The research presents no more than minimal risk to subjects.
- The alteration shall not adversely affect the rights and welfare of the subjects.
- The research could not practicably be carried out without the alteration.
- Where appropriate, the subjects shall be provided with additional pertinent information after participation.

GENERAL TIPS FOR STUDENT RESEARCH IRB APPLICATION SUBMISSION

To help improve the quality of your IRB Application, keep in mind the following standard recommendations:

- Be clear
- Ensure the consent form includes your contact information
- Describe how confidentiality will be maintained
- Use password-protected websites
- Delete the identifiable data afterwards to protect the subjects from future claims
- Detail your data-security plan; having a secure local storage is important
- If mandatory reporting [UCI HRP Policy 29] laws may apply to your research, please consult with your faculty sponsor for developing a plan on managing incidental findings

EXEMPT VS EXPEDITED RESEARCH

<table>
<thead>
<tr>
<th>EXEMPT RESEARCH</th>
<th>EXPEDITED RESEARCH</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Risk Level</strong></td>
<td>All research activities present no more than minimal risk [45 CFR 46.102(i), 46.303(d)] to human subjects</td>
</tr>
<tr>
<td>The research involves only the procedures or interventions listed in one or more of the Exempt categories</td>
<td>The research involves only the procedures or interventions listed in one or more of the Expedited categories</td>
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</tbody>
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**Required Elements for a Waiver of Informed Consent***

- Research is minimal risk
- Waiver/alteration will not adversely affect the rights/welfare of subjects
- Research could not practicably be carried out without the waiver/alteration
- When appropriate, subjects will be provided with additional pertinent information after participation

**Required Elements for a Waiver of the Requirement to Obtain Documentation of Consent***

- The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality; each subject will be asked whether they want documentation linking them with the research
- The research presents no more than minimal risk and involves no procedures for which written consent is normally required outside of the research context [45 CFR 46.117(c)(2)]
- A Study Information Sheet may be required to provide subjects with a written statement regarding the research

* if the research does not meet all the requirements of a waiver — a written Informed Consent may be required
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