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Welcome to the New Social/Behavioral IRB Chair

Effective July 1, 2013, Michael Burke, PhD resigned as Social/Behavioral IRB Chair due to other University responsibilities, but remains on the Board. Dr. Burke has served very effectively as chair for almost 2 years. We are grateful for his distinguished service and wish him well.

We are pleased to announce that Fred Buttell PhD, Professor of Social Work, assumed the role as Social/Behavioral IRB Chair effective July 1. Dr. Buttell completed his graduate work at the University of Alabama and was an Assistant Professor at the University of South Carolina, where he served on the IRB, before joining the Tulane faculty in 2002. He currently serves as the Program Director of the City, Culture & Community Ph.D. program and as the Director of the Wisner Center for Research on Children & Families in the School of Social Work. Dr. Buttell currently teaches courses on social policy, clinical practice and theory. His research interests are in the field of intimate partner violence. Please join us in welcoming Dr. Buttell to his new role.

AAHRPP RE-ACCREDITATION

Tulane University is currently seeking re-accreditation from the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP).

The site visitors were on campus May 29 through May 31, 2013 and viewed a selected number of our active research protocols, conducted interviews with the Human Research Protection Programs (HRPP) Members, and some individuals in the research community.

The Human Research Protection Office (HRPO) would like to thank all of those who participated in the process. The visit went well, thanks in large part to the dedication of the Tulane research community in adhering to high quality research standards.

The HRPO will keep the research community informed of the status of our re-accreditation application.

WHAT’S NEW

The HRPO has created a variety of new forms. We have strived to make these new forms more user-friendly for all types of research. We will be releasing these new forms for use in the near future.
What is a Human Research Protection Program (HRPP)?

An HRPP is an integrated process where all of the various components of our organization involved in the conduct of human research work together to protect the rights and welfare of study participants.

The HRPP is not an office; it is a collective effort of all who participate in the conduct, review, approval, and facilitation of human subjects research at Tulane University.

TULANE UNIVERSITY HRPP’S MISSION IS TO:

- Safeguard and promote health and welfare of human subjects engaged in research by ensuring that the rights, safety, and well-being are protected
- Facilitate excellence in human subjects research
- Provide initial and on-going training and quality education
- Provide timely review and monitoring of projects
- Cultivate a culture of awareness in researcher

MECHANISMS TO IMPLEMENT THE HRPP’S MISSION INCLUDE:

- Overseeing research protection
- Monitoring, evaluating and continually improving protection of subjects
- Dedicating sufficient resources
- Educating IRB members and support staff, PIs, investigators and research staff on ethical responsibility to protect subjects
- Intervening as appropriate in research and responding directly to concern of subjects
- Educating subjects and community

Research at Tulane University

The Tulane University Human Research Protection Office (HRPO) manages two Institutional Review Boards (IRBs):

A Biomedical IRB and a Social/Behavioral IRB

Currently, the following types of research protocols are active under the Biomedical IRB:

- Exempt: 133
- Expedited: 403
- Convened (Full Board): 275
- Administrative (CIRB or Other): 56
- Total: 867

Currently, the following types of research protocols are active under the Social/Behavioral IRB:

- Exempt: 59
- Expedited: 191
- Convened (Full Board): 17

The total number of Active Research Protocols Involving Human Subjects at Tulane University is: 1,134.

Tulane University HRPO:
Website: http://tulane.edu/avpr/irb
Email: irbmain@tulane.edu

*Please email us if you have any questions, concerns, or suggestions

STAFF:
Roxanne Johnson, HRPO Director
James Outland, HRPO Assistant Director/Biomedical IRB Vice-Chair
Ellen Dauchy, IRB Analyst/Social-Behavioral IRB Vice-Chair
Carla Siconeaux, Sr. Program Coordinator
Judy Taplin, Sr. Program Coordinator
Tanisha Banks-Favorite, Program Coordinator
Andrea Foreman, Program Coordinator
Lucia La Salle, Program Coordinator
Shammeia Crisler, Records Coordinator
### Feature Story

**RESEARCH INVOLVING CHILDREN**

**GUIDANCE FOR INVOLVING CHILDREN IN RESEARCH**

The HHS regulations at 45 CFR Part 46, subpart D permit IRBs to approve three categories of research involving children as subjects:

<table>
<thead>
<tr>
<th>Regulation</th>
<th>Description</th>
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<tbody>
<tr>
<td>45 CFR 46.404</td>
<td>Research not involving greater than minimal risk to the children.</td>
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<tr>
<td>45 CFR 46.405</td>
<td>Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual child subjects involved in the research.</td>
</tr>
<tr>
<td>45 CFR 46.406</td>
<td>Research involving greater than minimal risk and no prospect of direct benefit to the individual child subjects involved in the research, but likely to yield generalizable knowledge about the subject's disorder or condition.</td>
</tr>
<tr>
<td>45 CFR 46.407</td>
<td>Research that the IRB believes does not meet the conditions of 45 CFR 46.404, 46.405, or 46.406, but finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children.</td>
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- **45 CFR 46.404** - Research not involving greater than minimal risk to the children.

To approve this category of research, the IRB must make the following determinations:
- the research presents no greater than minimal risk to the children; and
- adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in HHS regulations at 45 CFR 46.408.

- **45 CFR 46.405** - Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual child subjects involved in the research.

To approve research in this category, the IRB must make the following determinations:
- the risk is justified by the anticipated benefits to the subjects;
- the relation of the anticipated benefit to the risk presented by the study is at least as favorable to the subjects as that provided by available alternative approaches; and
- adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in HHS regulations at 45 CFR 46.408.

- **45 CFR 46.406** - Research involving greater than minimal risk and no prospect of direct benefit to the individual child subjects involved in the research, but likely to yield generalizable knowledge about the subject's disorder or condition.

In order to approve research in this category, the IRB must make the following determinations:
- the risk of the research represents a minor increase over minimal risk;
- the intervention or procedure presents experiences to the child subjects that are reasonably commensurate with those inherent in their actual, or expected medical, dental, psychological, social, or educational situations;
- the intervention or procedure is likely to yield generalizable knowledge about the subject's disorder or condition which is of vital importance for the understanding or amelioration of the disorder or condition; and
- adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in HHS regulations at 45 CFR 46.408.

- **45 CFR 46.407** - Research that the IRB believes does not meet the conditions of 45 CFR 46.404, 46.405, or 46.406, but finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children.

If the IRB believes that the research does not meet the requirements of 45 CFR 46.404, 46.405, or 46.406, but finds that it presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children, it may refer the protocol to HHS for review. The research may proceed only if the Secretary, HHS, or his or her designee, after consulting with a panel of experts in pertinent disciplines (e.g., science, medicine, education, ethics, law) and following an opportunity for public review and comment, determines either: (1) that the research in fact satisfies the conditions of 45 CFR 46.404, 46.405, or 46.406, or (2) the following:
- the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
- the research will be conducted in accordance with sound ethical principles; and
- adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in HHS regulations at 45 CFR 46.408.
The Tulane University Human Research Protection Office (HRPO) would like to recognize the following Biomedical and Social/Behavioral Institutional Review Board members and thank them for their service, time, and efforts.