Memorandum

To: All Faculty and Staff subscribed to the irb-updates listserv
From: Nanda Gudderra, Ph.D., Senior Director of Research Compliance
Subject: IRB Updates
Date: December 3, 2015

Dear Colleagues,

The Institutional Review Board (IRB) and associated IRB administrative staff members of the Office of the Vice President for Research Administration aim to provide faculty members, staff and students with the guidance and support to conduct research with human subjects in an ethical manner and under the appropriate requirements with respect to federal guidelines.

Recently, the IRB has received an increase in the number of inquiries concerning what types of activities are governed by IRB review and how to determine which types of research activities require an investigator to prepare a full protocol for review.

The attached checklist is designed to help investigators determine if their work is subject to IRB review and therefore requires the development of a protocol. If, after reviewing the checklist, you are unsure if your research is human subject research, please send a short synopsis of your proposed work to the IRB staff (irb@temple.edu) and you will be provided with a written determination as to whether or not you need to provide more information or you need to complete a full protocol with respect to your planned activities.

Activities that are not “Human Research” under the guidelines (see HRP-421: Human Worksheet) do not require IRB review. Activities that comprise human subjects research are reviewed via three methods: a) a convened IRB; b) an expedited review conducted by an IRB designated reviewer; or c) a determination by the IRB designated reviewer that research that is exempt from further IRB review. Note that the determination for exemption is made by the IRB not the investigator.
Following these steps will help ensure the timely review of your questions and protocols. Investigators should anticipate a response to an initial inquiry about whether or not research activities constitute research that requires IRB approval within three business days. Once that is determined, investigators will either be able to move forward with activities that do not require a review or receive further instruction on information needed to obtain approval to conduct expedited or exempt research. Investigators need to plan their activities to reflect that the expedited and exempt review processes normally take two weeks to complete. Protocols that go to the IRB board require a between 30 – 60 days to review depending on the timing of the receipt of the protocol and the timing of board meetings. Every effort will be made to conduct the review within 30 days.

Please contact the IRB Office if you have any questions or concerns. The contact information for the office is: irb@temple.edu or (215) 707-3390 (2-3390).