

IRBNews

Office for the Protection of Human Research Subjects

December 2015

Several IRB policy revisions were approved this month. A summary of those revisions follows on the next pages.

IMPORTANT MESSAGE:

Conflict of Interest thresholds have been revised to be consistent across ETSU.

The threshold for declaring a financial conflict of interest has changed from \$10,000 to \$5,000.

See the next page for details.

Review Policy 17a for details.

If you have questions, please contact Janine Olive at olivef@etsu.edu



EAST TENNESSEE STATE
UNIVERSITY

Several IRB Policies and Procedures were revised to update references to electronic processes, and to correct formatting.

For investigators, the following change is important.

Policy 17 (applies to all studies)

Change Rationale: thresholds for reporting changed to be consistent across ETSU

Change Specifics:

- 1. Lowered the threshold for reporting a financial conflict of interest from \$10,000 to \$5,000**

Specifically, the following definitions were revised (see bold print)

From Section I.E.1.:

- a) **Compensation interest**, meaning salary, consulting fees, wages, retainers, honoraria (including honoraria from a third party, if the original source is a financially interested company), gifts or other emoluments, "in kind" compensation from a financially interested company (or entitlement to the same), or any other thing of economic or monetary value whether for consulting, lecturing, travel, service on an advisory board, or for any other purpose not directly related to the reasonable costs of conducting the research (as specified in the research agreement), that in the aggregate have in the past 12 (twelve) months exceeded **\$5,000**, or are expected to exceed that amount in the next twelve months;
- b) **Equity interest**, meaning i) any equity interest (or entitlement to the same), in a publicly-traded financially interested entity that exceeds **\$ 5,000** in value or represents more than 5% ownership interest in any single entity (see exclusions below), or ii) equity interests, including stock options, warrants, or other convertible securities, of any amount in a non-publicly-traded financially interested entity (or entitlement to the same) whether or not financial value can be determined through reference to public prices;

From Section I.E.2.

- 2) **Exclusions**. Significant financial interest excludes, and therefore is not meant to refer to, the following types or categories of economic or monetary interest:
 - a) **Mutual fund interests**, meaning interests of any amount in publicly traded, diversified mutual funds;

- b) "***De minimis equity interests***," meaning stock or stock options in a publicly traded company that, when aggregated for the covered individual (and/or his or her immediate family members) meets both the following tests: it does not exceed **\$5,000** in value (as measured in reference to public prices or other reasonable measure of fair market value) and does not represent more than a 5% ownership interest in any single entity;
- c) "***Outside payments***," meaning salary, royalties, and other payments from entities other than the University, or via the University to the individual, that when aggregated for the covered individual (and/or his or her immediate family members), over the next 12 months, are not expected to exceed **\$5,000**;

Please note: xforms and handbooks were changed to be consistent with this policy revision.