

Changes to Federal Law Affect (Some) Systems Engineering Research

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Do you work in Human-Systems Integration (HSI) or Human Factors (HF)? If so, listen up! Changes to 45 Code of Federal Regulations (CFR) Part 46, which is the regulation governing the protection of human subjects in research, took effect on January 21, 2019. The revised CFR expands the list of activities deemed not to be research to include: scholarly and journalistic work that focuses directly on the specific individuals about whom the information is collected; public health surveillance activities conducted, supported, requested, ordered, required, or authorized by a public health authority; criminal justice investigations; and authorized operational activities in support of intelligence, homeland security, defense, or other national defense missions.

The last item is a big deal for those of us who work in the Intelligence Community (IC), as we have long argued that intelligence activities do not meet the federal definition of research (a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute generalizable knowledge) because they are (a) not shared outside the IC and (b) usually not applicable to other situations (not generalizable).

There are also changes to the exemption categories in the CFR. Notably, the exemption related to surveys, interviews, educational tests, and observation of public behavior was expanded to include the collection of sensitive and identifiable data. The exemption related to secondary research was expanded to allow prospective data review; maintenance of identifiers for public health information, if all study data is protected health information; and research conducted by, or on behalf of, a Federal department/agency or using government-generated or -collected information that was obtained for non-research purposes and to allow secondary use of identifiable data obtained under “broad consent.” Broad consent is a new concept introduced in the revised CFR – it refers to seeking prospective consent to unspecified future research. Finally, the CFR creates a new exemption for “benign behavioral intervention”—which is defined as “one that is brief in duration, harmless, not physically invasive, painless, not embarrassing or offensive, and not likely to have a lasting adverse impact”—with an adult subject. Excluded from this exemption is research involving deception, physiological data collection, or the collection of sensitive or identifiable data.

While the liberalization of the exemption categories is potentially freeing, it’s effect on those of us whose funding comes from the federal government will be negligible because the CFR requires that an Institutional Review Board (IRB), not the Principal Investigator, make the exemption determination. It is possible to use an expedited review process for these determinations. Check with you local IRB to see what’s available at your site.

There are a few additional changes of which HIS/HF researchers should be aware. The revised CFR removes the requirement to conduct continuing review for certain minimal risk studies and for studies that have completed study interventions and are only analyzing study data. This is another area where you should check with your local IRB. At Los

Alamos, we have developed criteria for determining when continuing review will be required.

In addition, the revised CFR creates a requirement for US-based institutions engaged in cooperative research to use a single IRB for that portion of the work that takes place in the US. This requirement will go into effect later this year and I am anticipating major problems for both DoD and DOE/NNSA Labs where there is a requirement that the site IRB or the central federal agency IRB serve as the IRB of record when agency or site employees or their data are used in human subjects in research. Stay tuned for more on this in future newsletters.

Not for Women Only

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March was Women's History Month, so there was a trove of interesting and inspiring articles. Here are just a few:

National Women's History Month Reminds Us We Can All Be Champions For Change

by Naz Beheshti: <https://www.forbes.com/sites/nazbeheshti/2019/03/04/national-womens-history-month-reminds-us-we-can-all-be-champions-for-change/#632f3f8844d0>

Women's History Month: Legacies & Life Stories:

<http://www.legacy.com/news/explore-history/article/womens-history-month-legacies-life-stories>

Women's History Month: Sharing Our Stories:

<https://www.youtube.com/watch?v=6bUFR4FOURA>

There was also a great *60 Minutes* program about the dearth of women in computer science and what some people are trying to do about it (spoiler alert – it's all about early STEM engagement, done in very creative ways). As the American Association of University Women (AAUW) note in their landmark literature review *Solving the Equation, The Variables for Women's Success in Engineering and Computing* (available for download at <https://www.aauw.org/research/solving-the-equation/>) there are parallels between the two fields when it comes to shortages of women both in the classroom and in the workforce. If you watch the 60 Minutes segment and are inspired to try to do something similar for engineering, contact the Empowering Women as Leaders in Systems Engineering (EWLSE) group at ewlse@incose.org and let's talk!