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CONTRACTS & GRANTS OFFICE SANTA BARBARA, CALIFORNIA 93106-9490

August 29,2017

Re: Changing Policies Impacting NIH-funded studies involving Human Subjects

To: All – Faculty Listserv

This email is to notify you of two upcoming changes to NIH's policies regarding human subjects research. These changes will apply to all competing grant applications for due dates on or after January 25, 2018. Please share this information with researchers who plan to submit proposals to NIH in 2018 or beyond for research projects involving human subjects.

The first policy change pertains to NIH's definition of clinical trials. Please see the attached announcement from NIH. NIH is in the process of updating its policies and procedures regarding applying for and administering NIH-funded clinical trials – see here for more details: https://grants.nih.gov/policy/clinical-trials.htm. A key part of these revisions includes the implementation of the NIH's broader definition of "clinical trial," as first announced in 2014 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html). Although NIH might continue to narrow the applicability of this new definition, the broader definition of "clinical trial" could mean that research projects that would not formerly have been classified as clinical trials would now fall under that definition and be subject to all the NIH's clinical trial requirements, including but not limited to reporting and registration. Also, "clinical trials" under the new definition would need to be submitted using additional clinical trial application forms and could not be submitted using the generic "parent" NIH funding announcements. UCSB's Research Integrity team will continue to provide updates and guidance as we get further clarification from NIH. However, principal investigators should begin now to familiarize themselves with this new definition and the increased regulatory requirements for proposals to be submitted in 2018 or later.

The second policy change pertains to NIH's new single IRB rule. The NIH Policy on the Use of a Single Institutional Review Board for Multi-site Research, effective January 25, 2018, will require all NIH funded multi-site studies, in which each site is conducting the same non-exempt human subjects research, to use a single IRB for review and approval of human subjects research at all participating sites. Please see UCSB's Research Integrity website for more details.