Hire More Staff in ORSP

1. There is exceptional talent in our ORSP office. However, there is not enough staff to cover all the work that needs to be done for a comprehensive research university (e.g., pre-award grant development and submission; post-award grant reporting; post-award grant financial management; IRB; IACUC; effort reporting; faculty R&PD and internal awards; faculty scholarship activities; undergraduate/graduate student research and travel funds; and identifying external funding opportunities.). The office used to house a staff of eight. Currently, there are three full-time staff.
2. Specific to IRB needs, **the University needs an IRB administrator who can also serve as a compliance officer (CO).**
   a. An IRB administrator oversees and manages the IRB system and its operations, including working in collaboration with the Board in the development and maintenance of appropriate policy, procedures, processes, and records.
   b. A CO should be experienced in monitoring research projects to ensure compliance, reviewing laws to identify changes and incorporate at the local level, developing institutional policies, and providing support regarding compliance to the university community.
3. ORSP is currently conducting a second PSS4 whose job description includes some IRB-related work. While IRB work may be split across multiple staff members, having one central person who is responsible for these duties allows for the development of expertise in IRB administration and human research protections.
4. An IRB administrator who also serves as a CO would help ensure compliance with several federal regulations (see 3 and 5 here) and the local MOA that requires the equivalent of one (1) full-time staff person in ORSP dedicated to IRB duties, including recording keeping (see here).

Support the Development of an IRB Policy and Procedure Manual

1. "To ensure the consistent and unbiased application of the requirements for human research protection, the IRB must be allowed to function independently…, but in coordination with other institutional regulatory committees." (see guidance here). Policies and procedures used to govern the IRB should be developed by the IRB, with input from other institutional entities.

2. The Office of Human Research Protections (OHRP) indicates that IRBs should provide written policies and procedures for over 105 regulatory items (see <u>here</u>). The current eight-page document is not sufficient nor comprehensive (see <u>here</u>).
3. **The University needs to support the development of a policy and procedure manual (PPM) authored primarily by the IRB to ensure the autonomy and independence required by federal law.** This will require working collaboratively with ORSP, Legal, ITS, etc.
4. Per the Union, the expectation that the IRB Chair oversee the creation of an entirely new PPM is beyond the scope of the duties specified in the <u>MOA</u>.
5. A PPM would help ensure compliance with several federal regulations (see 4 <u>here</u>; see <u>here</u>) and ensure the IRB Chair is able to complete the duties listed within the MOA.

Update the IRB System

1. The current IRB Chair, former CTLD Technology and Pedagogy Fellow, and ITS are working on developing an updated, comprehensive IRB system that includes an initial application, modification form, adverse/unanticipated event form, renewal form, and final report form to be used by investigators. The new system will also include a FWA review form for the IRB Chair and IRB committee members.
2. The current IRB Chair <u>MOA</u> does not include this task assurance nor the responsibility of ensuring compliance.
3. **No additional resources (i.e., time, compensation, support staff) are needed**. The current Chair and former CTLD fellow have agreed to continue this project without compensation. ITS has continued to prioritize this project. We anticipate roll out in Fall 2023.
4. Updating the IRB system will help meet several compliance regulations (see 4 <u>here</u>; see <u>here</u>, <u>here</u>, and <u>here</u>) and ensure the IRB Chair is able to complete the duties listed within the MOA.