Final Report Executive Summary:
Office for the Protection of Research Subjects Protocol Application Process Improvement Project [UIUC]

Business Case

The Office for the Protection of Research Subjects (OPRS) is responsible for ensuring ethical and compliant oversight for research engaging human subjects and is part of the Office of the Vice Chancellor for Research (OVCR). OPRS provides administrative support to the Institutional Review Boards (IRBs), which are the committees that review and approve research engaging human subjects. Each university within the University of Illinois system has human research protection offices that run independent of one another. OPRS at the University of Illinois at Urbana-Champaign supports two IRBs, comprising 30+ committee members, who review both bio-medical and social and behavioral science research. In FY 2015, OPRS received over 3,000 submissions, 1,000 of which included new protocol review submissions. The remaining 2,000 protocols include the required annual review of active studies, modifications to existing protocols, and unanticipated events (e.g., adverse events, participant complaints, etc.). Delayed turnaround time due to inefficient procedures, business practices, and inconsistent reviews could result in a loss of external funding and low customer satisfaction by researchers.

Goal

Standardize business practices and reduce cycle time of processing protocols by increasing efficiency of staff roles and responsibilities.

Approach

Mapped the protocol application process. Discussed issues and causes with OPRS staff. Identified opportunities for improvement and brainstormed potential solutions. Developed transition action plan to prioritize potential solutions, assign owners to tasks, and establish a timeline.

Outcome

Identified 6 recommendations, expected to result in faster turnaround time for reviewing protocol applications by eliminating waste in the process and distribution of tasks to administrative staff. This will provide the staff reviewers with more time to focus on the Faculty and Researcher requests. Recommended the hiring of new administrative staff to assist with application tasks. Recommended a pilot program with two units from the department of Psychology to implement an electronic application process by March 2017.

Key Findings

- **Lack of staff resources to handle incoming submissions in timely manner**
- **Lack of policy on business practice implementation and customer expectations**
- **Incomplete submissions; several different formats for applications**
- **Large number of clerical tasks on each application that is time consuming**
- **Tracker (online database system) is lacking in functionality and cannot be updated, which causes duplication of work and incomplete data for metrics**
- **Inadequate space: lack of file space, no conference room for meeting with researchers, no WIFI capabilities**
- **Only school in Big Ten Alliance that does not have an electronic system for protocol applications**

Short-term Improvement Recommendations

1. **Hire full time staff person to perform front- and back-end protocol application duties**
   Provides staff reviewers with assistance on clerical tasks for each application submission, which will allow for faster turnaround time on reviews.

2. **Move to new space to provide wireless internet, file space, and conference space to meet with researchers**
   Allow staff reviewers the capability to meet with researchers about protocol applications and provide adequate storage for all paper file protocols.

3. **Develop pilot submission process for two units in Psychology Department**
   Reduce the inconsistent application submissions from researchers; allow staff reviewers a more efficient way to review each protocol and track all changes made to protocol; and eliminate paper waste from the process.

4. **Develop and publish standard operating procedures**
   Reduce the inconsistency of steps taken in the protocol application review process and standardize each procedure.

5. **Analyze electronic systems for protocol application submission**
   Allow OPRS to keep in line with peer institutions by providing a faster, more efficient way for researchers to submit protocol applications.

Implementation of Recommended Improvements

Short term recommendations are currently being implemented with most activities scheduled for completion in March 2017. Implementation and communication of new policy and procedures for electronic application submission for all units supported by OPRS is scheduled for completion by September 2017.