

# PPMO-0067 UIC Institutional Research Board (IRB) Protocol Analysis Project [UIC] Executive Summary

## Business Case

The sponsors hope to develop process that is less burdensome and time consuming for active researchers (i.e., research faculty, graduate students, undergraduate students) attempting to get approval for minimal risk research (e.g., surveys, etc.) while ensuring sufficient protections for the human subjects studied. This project will analyze the submission process, including forms, steps, people involved, and performance metrics. It will look at training required and offered to all participants and best practices from peer institutions.

## Goal

Develop a process that is less burdensome and time consuming for researchers (i.e., research faculty, graduate students, undergraduate students) attempting to get IRB approval for Social/Behavioral research at UIC (e.g., surveys, etc.) while ensuring sufficient protections for the human subjects studied.

## Approach

Mapped the Institutional Research Board 2 (IRB2 - the IRB2 Board focuses on protocols for the Social and Behavioral Sciences) process for Social and Behavioral Sciences protocols at UIC, including completion of the IRB Application. Conducted focus groups and discussed issues with the Core Team, the Faculty Focus Group, Students and IRB members, to identify issues. Identified opportunities for improvement and brainstormed potential solutions. Developed transition action plan to prioritize potential solutions, assign owners to tasks, and establish an implementation timeline.

## Outcome

Identified six short-term recommendations, focusing heavily on increased and improved communications and training between the departments and the IRB/OPRS, better understanding of processes by Department Heads, Faculty and Principal Investigators (PIs) and where to direct PIs to find the best and most current information. Implementation is anticipated by May, 2018. Identified two long-term recommendations that will allow review and communication of current IRB submission policies to ensure continued regulatory compliance and adherence and ongoing upgrades to the current IRB application submission system, with implementation on an ongoing basis.

## Key Findings

- Lack of engagement and communication between the Social and Behavioral Science Departments and the IRB
- Need for updated and expanded education and training for the IRB Protocol Process
- Inadequate communication between the IRB Reviewer and the Principal Investigator (PI) to answer outstanding questions and resolve issues
- OPRS assistance is underused, including web-based resources and live support for protocol questions and issues
- Departments do not currently have a pool of targeted IRB Protocol FAQs to help PI's prepare submissions
- Department Heads and Faculty are not informed on the most current or accurate information about the IRB resulting in an inability to cascade this information to PI's
- Negative perceptions currently exist about the UIC IRB which has inhibited communications between the Principal Investigators and the IRB Reviewer for timely protocol approval review
- The IRB Social and Behavioral Sciences Application needs to be updated to remove redundancies, clarify confusing questions and streamline overall
- Website is not being utilized for relevant information regarding IRB submission best practices
- Need for fully automated, electronic IRB application submission system to capture and track more granular IRB submission detail
- Need for increased Faculty Sponsor mentorship and oversight of submission content and accuracy prior to IRB submission

## Short-term Improvement Recommendations

1. **Expand communications between the IRB, OPRS and the Social and Behavioral Sciences Departments.** *This would include increased engagements, increased education and training offerings and the cascade of current, accurate information about the IRB.*
2. **Submission Process requirements and regulations must be better understood and adhered to by Faculty Sponsors and Principal Investigators (PI's).** *Increase Faculty Sponsor oversight of submission content and accuracy prior to IRB review, increase use of OPRS assistance, OPRS website and IRB reviewers to answer questions and revise and streamline the IRB Social and Behavioral Sciences application.*
3. **Increase Staff collaboration between IRB and PI and IRB to validate methodological diversity.** *Encourage increased collaboration with IRB Reviewers on international protocols, issues with IRB Reviewers and other concerns and IRB to better communicate IRB Board diversity, without divulging names, by publishing annual statement validating methodological diversity*
4. **Expand IRB training content and increase training engagements between the IRB and the Social and Behavioral Sciences Departments.** *OPRS/IRB and the Social and Behavioral Science Departments will work together to increase training engagements and expand content in an effort to better prepare PI's for protocol submission.*
5. **Update IRB Social and Behavioral Sciences Application to remove redundancies, clarify confusing questions and streamline.** *IRB re-evaluating the content of the Social and Behavioral Sciences Application and a revised and reduced version will be formally published in June of 2017.*
6. **Encourage increased collaboration between Faculty Sponsors and Student PI's as well as PI's leveraging all current support resources to ensure submission accuracy, completion and efficient processing.** *Student PI's have numerous support resources, including closer collaboration with their Faculty Sponsor, that will help improve the quality of the protocol submission.*

## Long-term Improvement Recommendations

1. **Review current IRB Submission Policies to ensure adherence.** *Also, recognize where updates are necessary to best support the IRB Submission Process overall.*

## Long-term Improvement Recommendations

- 2. Implement an automated, electronic IRB online submission system.** *And in the interim, continue to improve current IRB submission electronic .pdf form.*

## Implementation of Recommended Improvements

Short-term recommendations are currently being implemented with most activities scheduled for completion by December 31, 2017. Of the long-term recommendations, implementation of a fully automated, electronic submission system is being planned, however, a definite date has not yet been identified. All other activities are scheduled for completion by May, 2018.