UNIVERSITY OF WISCONSIN IRB EFFICIENCY PROJECT

PROJECT CHARTER

At the request of the University of Wisconsin Associate Vice Chancellor for Research Policy and Compliance, within the Office of the Vice Chancellor for Research and Graduate Education, UW Human Research Protections Program (HRPP) stakeholders are collaborating with Huron to plan, manage, and deliver improvements to the HRPP and IRB operations under the umbrella of this project. UW and Huron have developed this charter to outline the project purpose, objectives, and other important project considerations that will guide the project team as they work toward those improvements.

CONTENTS

Project Overview/Purpose

The purpose of this project is to implement key changes to improve the efficiency and effectiveness of the UW Institutional Review Boards (IRBs) with the primary aims of reducing administrative burden and IRB approval times, while also improving UW investigator and study team member satisfaction with the IRB experience. These aims are aligned with UW's 2020-2025 Strategic Framework, particularly with the Strategic Priorities of Excellence in Research and Scholarship[1] and Living the Wisconsin Idea,[2] in that they will contribute to improving and modernizing the UW human subjects research infrastructure. These aims are also consistent with UW's strong commitment to the protection of human subjects through regulatory compliance and the application of best practices for the review of human subjects research. This project will leverage Huron's HRPP Toolkit, a set of standard operating procedures for the IRB, to meet and/or exceed currently recognized IRB, HRPP, and AAHRPP standards, along with changes to the ARROW application to support the execution of these changes to business processes.

Objectives

Within the broader framework of improving the efficiency and effectiveness of the UW IRBs, UW and Huron have identified multiple project objectives, which are outlined below:

1. Substantially altering the IRB intake and pre-review processes to reduce time-to-review, which is an important component of time-to-approval for IRB submissions;
2. Re-aligning IRB staff roles and responsibilities to improve customer service, to support a more efficient workflow, to enhance IRB staff member skillsets, and to position IRB operations to more readily adapt to institutional needs;
3. Removing duplicative information in ARROW application and IRB protocols so that submission materials are maximally streamlined while also providing IRB members with sufficient information for review.
4. Coordinating with the UW research community, including UWHC, to define research initiation processes outside of the IRB functions;
5. Implementing changes to the UW IRB committees to maximize flexibility and improve turnaround times.
6. Unifying the IRB offices under one administrative structure to align HRPP-related business processes and accountability.

The associated project plan will include more detailed steps, milestones, and deliverables for achieving these objectives. In addition, the Project Success Criteria outlines how achieving objectives will be measured.

Guiding Principles

As UW continues to promote discovery and build its capacity for achieving its Strategic Priorities in the service of the Wisconsin Idea. Areas supporting research, like the HRPP and IRBs, must evolve to meet to the institution's needs. To ensure that our project work remains aligned with those priorities while also making the protection of UW's human subject populations of paramount concern, we have established guiding principles for this project. The principles underlying our project work and informing our decision-making throughout the life of the project will include the following:

- Efficiency: Streamlined administrative processes and services that minimize response times and unnecessary administrative requirements.

- Organizational Effectiveness: Accountability assigned to the most appropriate owners and responsible parties to strike an appropriate balance between investigator, study team, and IRB responsibilities.

- Compliance: In keeping with UW's strong commitment to both innovation and human subjects protection, policies, procedures and systems developed or modified as part of this project will not only be efficient and effective, but also will maintain compliance with federal and state regulations related to human subjects research.

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[1] https://strategicframework.wisc.edu/excellence-in-research-scholarship/
[2] https://strategicframework.wisc.edu/living-the-wisconsin-idea/

- High Service Levels: The UW HRPP will operate with a service orientation that emphasizes listening, understanding, and responding to the needs of the UW research community.

- Data Access: Clear and transparent performance metrics and measurable outcomes for research administration and management processes.

Project Success Criteria

Success criteria include:

1. Improved investigator and study team satisfaction: Investigator and study team frustration with some aspects of the IRB experience is currently high, while there is great satisfaction with other aspects. This criterion for success will be met if investigator and study team satisfaction with IRB processes is enhanced where already high, and improves where currently low, as measured by satisfaction surveys.

2. Improved IRB member experience: IRB members dedicate their time, energy, and expertise to the ethical review of human subjects research. As necessary changes are made to more closely align the IRB review process with UW's Strategic Priorities, successful education regarding these changes and adoption by IRB members will be measured with a combination of self-evaluation and HRPP management evaluation tools. In addition, IRB members must feel that their contributions are valued and that their service is appreciated. This will also be measured by satisfaction surveys.

3. Improved IRB staff experience: IRB staff serve as the backbone of the ethical review process. They are responsible for coordinating with investigators, research staff, other research administration and compliance functions across UW, and IRB members, all while ensuring that ethical and regulatory requirements have been met. As expectations for IRB staff evolve, newly developed competencies will be measured with a combination of self-evaluation and HRPP management evaluation tools. Satisfaction with operational changes that impact IRB staff duties will also be taken into account as the project progresses.

4. Improved IRB turnaround times: Current turnaround times significantly exceed median turnaround times for AAHRPP-accredited institutions. This criterion for success will be met if turnaround times are as good as or better than AAHRPP turnaround times within six (6) months of the completion of this project.

5. Maintained high level of customer service: Although there will be many changes to IRB operations throughout this project, a crucial component to project success will be the HRPP's ability to continue providing a high level of customer service as IRB staff collaborate with those across the UW community impacted by those changes.

6. Minimized disruption: UW and Huron will aim to achieve the project objectives while minimizing disruption to ongoing IRB operations throughout the duration of the project. To this end, when changes to business processes are introduced, UW and Huron will incorporate transition plans for the implementation of those changes and review turnaround times to understand the immediate impact to IRB operations.

Factors Critical to Success

In addition to adhering to a mutually agreed-upon set of guiding principles, the right factors for the successful completion of the objectives must be in place for project objectives to be met. These include:

1. Support from UW research leadership, including in the Office of the Vice Chancellor for Research and Graduate Education, UW Schools and Centers, and UW Hospital and Clinics. This includes providing engagement as needed throughout the project to enable success.

2. Timely decisions by project leadership around issues that impact project scope, budget, and/or timeline.

3. Effective, non-partisan collaboration among all project team members, stakeholders, and other invested parties. This includes demonstration of respectful, transparent, and honest communications among parties.

4. Delivery of an effective training and mentoring program by the project team that facilitates both initial adoption and sustained proficiency with business processes and practices that align with project objectives.

5. Willing adoption by stakeholders of those business processes and practices that are developed in the project.

UW and Huron acknowledge that this project is launching at a time of uncertainty related to the COVID-19 virus. Federal, state, or institutional recommendations or requirements related to COVID-19 may impact the project scope, budget, and/or timeline. For example, certain project work may need to be conducted remotely rather than in-person. One overarching factor critical to success—and implied by the factors listed above—is that project leadership, team members, and other project stakeholders must be nimble and eager to adapt creatively to achieve project objectives as the impacts of the virus unfold.

Project Organizational Structure

The project organizational chart is included below and includes the following roles and responsibilities:

1. Executive Committee: The Executive Committee resolves issues related to the project Scope of Work and ensures that proposed project outcomes align with broader UW considerations regarding research with human subjects. The Executive Committee may review issues escalated from the Advisory Working Group.

2. Advisory Working Group: The Advisory Working Group includes representatives from across the UW human subjects research community who represent different viewpoints concerning the IRB experience. The Advisory Working Group provides expertise and guidance as needed to the Project Managers (e.g., project tasks and timelines) and the work product of the Project Groups (e.g., implementing draft human subjects research policies and process changes). Project Managers and Project Groups provide regular updates regarding the status of project initiatives to the Advisory Working Group.

3. Project Managers: The Project Managers represent UW and Huron perspectives related to business processes and technology and are in charge of driving the daily aspects of the project plan. This includes coordinating the Project Groups and other team members, managing project scope and budget, allocating project resources, and escalating issues to the Advisory Working Group and the Executive Committee as needed.

4. Project Groups: Project Groups have been established to address key project tasks. These collaborative groups work to translate the project objectives into workable, sustainable proposed solutions to be reviewed by the Advisory Working Group and implemented by UW HRPP leadership following adoption.

The individuals and groups above are empowered to provide project support according to the responsibilities assigned to them. However, the following areas are out of scope for the groups above:

- Revisiting finalized decisions related to UW HRPP organizational design and project deliverables without sufficient justification. Sufficient justification includes changes to institutional policy that would render a project decision unworkable, relevant changes to federal or state regulations that have a bearing on project decisions, or other similarly substantial justification.

- Addressing individual investigator or study team member complaints or concerns unless related to specific project progress or organizational design issues that are more broadly applicable.

Project Organizational Chart

Executive Committee

Nadine Connor Associate Vice Chancellor for Research Policy and Compliance	**Lynn Haynes** Director of Office of Research Compliance

Advisory Working Group

Name(s) TBD Advisory Working Group Chair	**Name(s) TBD** IRB Committee Leadership	**Name(s) TBD** IRB Office Leadership	**Name(s) TBD** Investigator Community	**Name(s) TBD** ICTR/UW Hospital and Clinics	**Name(s) TBD** Legal Affairs	**Name(s) TBD** Research IT Leadership

Project Managers

Carol Pech UW Project Manager	**Jonathan Hunter** Huron Project Manager

Project Groups

Staff Review Names TBD	**IRB Staffing** Names TBD	**IRB Committee Structure** Names TBD	**Toolkit Tools** Names TBD	**Toolkit Templates** Names TBD	**ARROW Re-Design** Names TBD	**Education and Outreach** Names TBD

Project Timeline and Milestones

UW IRB Efficiency Project Timeline — weekly columns from 5/4/2020 through 4/26/2021 (5/4/2020, 5/11/2020, 5/18/2020, 5/25/2020, 6/1/2020, 6/8/2020, 6/15/2020, 6/22/2020, 6/29/2020, 7/6/2020, 7/13/2020, 7/20/2020, 7/27/2020, 8/3/2020, 8/10/2020, 8/17/2020, 8/24/2020, 8/31/2020, 9/7/2020, 9/14/2020, 9/21/2020, 9/28/2020, 10/5/2020, 10/12/2020, 10/19/2020, 10/26/2020, 11/2/2020, 11/9/2020, 11/16/2020, 11/23/2020, 11/30/2020, 12/7/2020, 12/14/2020, 12/21/2020, 12/28/2020, 1/4/2021, 1/11/2021, 1/18/2021, 1/25/2021, 2/1/2021, 2/8/2021, 2/15/2021, 2/22/2021, 3/1/2021, 3/8/2021, 3/15/2021, 3/22/2021, 3/29/2021, 4/5/2021, 4/12/2021, 4/19/2021, 4/26/2021)

Row	Timeline details
Key Dates	IRB Staff Begin Using HRPP Toolkit; IRB Committees Begin Using HRPP Toolkit; Roll-out of HRPP Toolkit and ARROW Updates to Research Community
Project Management	
Staff Review Group (PG1)	
IRB Staffing Group (PG2)	
IRB Committee Structure Group (PG3)	
Toolkit Tools Group (PG4)	
Toolkit Templates Group (PG5)	
ARROW Re-Design Group (PG6)	
Education and Outreach Group (PG7)	