SOLUTIONS FOR
Integrated Research Compliance

PROJECT SCOPE STATEMENT

Note: Any work not explicitly included in the *Project Scope Statement* is implicitly excluded from the project.

Project Name:	Solutions for Integrated Research Compliance – SIRC
Prepared by:	Garfield A. Bowen
Date (MM/DD/YYYY):	10/20/2010

Version History (insert rows as needed):		
Version	**Date (MM/DD/YYYY)**	**Comments**
1.0	10/20/2010	Based on the Statement of Work

SOLUTIONS FOR
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1. Executive Summary

Provide below a brief overview of this project (e.g., project purpose and justification):

The Office of the Vice President for Research (OVPR) oversees all aspects of research at the University of Minnesota. The OVPR has identified the need for a central research compliance solution. The objective of this Research Compliance Implementation Services (RCIS) is to assist the University project team in the implementation of research compliance management solution**.** The implementation of a research compliance management solution presents an opportunity to significantly improve OVPR research compliance management by establishing a centralized, streamlined, and facilitative process for both researchers and compliance management.

2. Business Objectives

#	Functional Area	Unit Description	Statistics
1	**Institutional Review Board** (IRB)	The University of Minnesota IRB reviews research projects which involve human subjects to confirm that subjects are not placed at unreasonable risk; and they give uncoerced, informed consent to their participation. Functionality desired for submission of research for oversight by IRB will be included in the "Submission" Workflow in the SIRC system.	# Records Managed = Approx. ▪ 8,400 active ▪ 17,200 inactive ▪ 25,600 Total
2	**Institutional Animal Care & Use Committee** (IACUC)	The Institutional Animal Care & Use Committee (IACUC) reviews all projects involving animals to confirm the projects are justified by their benefits and minimize any animal pain or suffering that might occur. This includes research teaching and display of University of Minnesota-owned animals. The IACUC regularly inspects all projects using animals and all projects housing animals along with the University's Research Animal Resources (RAR) staff. Functionality desired for submission of research for oversight by IACUC will be included the "Submission" Workflow in the SIRC system.	# Records Managed = Approx. ▪ 1,300 active ▪ 6,800 inactive ▪ 8,100 Total

2. Business Objectives

#	Functional Area	Unit Description	Statistics
3	**Institutional Biosafety Committee** (IBC)	The Institutional Biosafety Committee (IBC) is charged with the oversight of all teaching and research activities involving: (1) Recombinant DNA, (2) Artificial Gene Transfer, (3) Infectious Agents (bacteria, viruses, protozoans, fungi, etc.), (4) Biologically Derived Toxins. This also includes use of biological materials at sites removed from the University of Minnesota by University faculty, staff, researchers, and non-university staff researchers under grants and contracts to the University. Functionality desired for submission of research for oversight by IBC will be included in the "Submission" Workflow in the SIRC system.	# Records Managed = Approx. ▪ 550 active ▪ 1,000 inactive ▪ 1,550 Total
4	**Human Subjects Research Compliance** (HSRC)	Compliance reviews are performed on any research under the purview of the University Of Minnesota's IRB, which include University of Minnesota, University of Minnesota Medical Center, Fairview Health Systems, and Gillette Children's Specialty Hospital. Functionality desired for oversight of Human Subjects Research Compliance will be included in the "Compliance" Workflow in the SIRC system.	# Records Managed = Approx. 70 reviews/ reports per year
5	**Office of Animal Welfare (OAW) Compliance**	The OAW Compliance division provides support, resources, education, and oversight to enable compliance with all Federal, State and University policies and regulations to support the proper and necessary use of animals in research and teaching. Functionality desired for oversight of OAW Compliance will be included in the "Compliance" Workflow in the SIRC system.	# Records Managed = Approx. ▪ 600-700 reviews per year
7	**Controlled Substances** (CS)	The Controlled Substances group is part of the RIOP Unit responsible for auditing Controlled Substances related to IACUC-approved study locations. Unit and Location Registrant functionality will be included in the "Submission" Workflow as a separate process in the SIRC system. Controlled Substance Compliance functionality will be included in the "Compliance" Workflow in the SIRC system.	# Records Managed = Approx. ▪ 150-200 Reviews per year; ▪ 150-200 Registrant managements per year ▪ 150-200 Reporting reminders

2. Business Objectives

#	Functional Area	Unit Description	Statistics
8	**Unfunded Research Agreements** (UFRA)	The-Unfunded Research Agreement group oversees agreements between the University and other entities that have no associated income and relate (primarily) to materials being obtained for research performed by the University of Minnesota. NOTE: Previously this functional area was called MTA/MTARF. Existing UFRA submission functionality will be included in the "Submission" Workflow in the SIRC system.	# Records Managed = Approx. ▪ 700 - 800 agreement requests per year
9	**FIRST Training Function**	Only Training validation functionality will be included in the "Submission" Workflow. SIRC will not seek to duplicate any training management function currently offered via HRMS (official U of M training mgmt system).	# Queries Managed = Approx. ▪ 50-75 Extensions ▪ 7,811 auto-generated and 200+/yr User generated Training Records Verifications (8,011 total) *NOTE: For RCR Training only.*

3. Project Description

For each area below, provide sufficient detail to define this project adequately:

3.1 Project Scope – see Product Scope in 3.6 below

- Planning deliverables
- Analysis deliverables
- Design deliverables
- Test deliverables
- Deployment deliverables
- Training deliverables
- Project close deliverables

Does Not Include (in addition to items mentioned above):

- Migration
- third party system integration, beyond providing information to best practices.
- custom development, beyond the scope of this agreement.

3.2 Project Completion Criteria:

3. Project Description

All deliverables produced and user acceptance testing has been successfully executed.
3.3 External Dependencies:
Consultant partners - Key Solutions
3.4 Assumptions:
Key stakeholders will adjust schedule as needed to meet project timelines
3.5 Constraints:
Large stakeholder group at disparate locations

3.6 Product Scope

#	Functionality, Workflow or Process	Description	Statistics
1	**Submission Workflow**	"Submission Workflow" includes activities that are performed to prepare and submit an application for research to be performed under the purview of one of the in-scope compliance areas (Table A). The generic workflow to be configured for all Submissions includes: 1. Submission Preparation Process 2. Submission Risk Assessment Process 3. Meeting Preparation Process 4. Committee Review Process 5. Post-Committee Activity Process 6. Training Validation Functionality included in these workflows are: Preparation, amendment and submission of applications; evaluation of risk factors and assignment of appropriate oversight reviews, guidelines and regulations; preparation of submission for Committee Review meetings including setting and amending agendas, providing additional information for committee consideration, and documentation of minutes and committee actions; and post-review follow-up and study lifecycle management. All elements include creation, distribution and receipt of communications about those submissions as well as status tracking. These generic workflows will also contain customizable sub-processes such as: Controlled Substance Registration; Embryo Registration; and Training validation(view of completed training). <u>In-Scope System Development includes</u>: 1. Development of a generic, stable, flexible Submission Workflow that is supported by eProtocol and is adaptable to all In-scope compliance areas. 2. Development of uniquely configured and/or customized electronic submission processes (based on the generic Submission Workflow (Item 1)) that will replace existing processes and administrative systems for: a. IRB b. IACUC c. IBC d. UFRA This level of development will include both automation and process improvements for existing processes and include (but not be limited to): consistent end-user experience; information sharing across included committee submission functions; and automated reporting and notification capabilities and utilization of data currently residing in Enterprise data systems.	As-Is Information: Institutional Review Board (IRB): # Records Managed = Approx. ▪ 8,400 active ▪ 17,200 inactive ▪ 25,600 Total Institutional Animal Care and Use Committee (IACUC): # Records Managed = Approx. ▪ 1,300 active ▪ 6,800 inactive ▪ 8,100 Total Institutional BioSafety Committee (IBC): # Records Managed = Approx. ▪ 550 active ▪ 1,000 inactive ▪ 1,550 Total **Unfunded Research Agreements (UFRA):** # Records Managed = Approx. ▪ 700 – 800 agreement requests per year

#	Functionality, Workflow or Process	Description	Statistics
		Out-of-scope: 1. Submission of a PRF and Grant Proposals.	
2	**Post-Approval Inspections/ Monitoring Workflow**	"Post-Approval Inspections/ Monitoring Workflow" includes activities that are performed to ensure that research performed under the purview in-scope compliance areas meets guidelines or regulations established by their specific oversight entities. The generic workflow to be developed for all compliance includes "Prepare Review Process, "Perform Review Process" and "Manage Review Process" – each of which contains several sub-processes. Functionalities include the ability to identify and select research projects or elements of those projects; create, distribute and receive communications about those projects, create and track events and data related to those projects and collect information, create reports and disseminate information about projects. In-Scope Systems Development includes: 1. Development of a generic, stable, flexible Compliance Workflow that is supported by e-Protocol and is adaptable to all existing OVPR committee compliance functions. 2. Development of uniquely configured and/or customized electronic compliance processes (based on the generic Compliance Workflow (Item 1)) that will replace existing processes and administrative systems for: a. Human Subjects Research Compliance b. Controlled Substances c. OAW Compliance This level of development will include both automation and process improvements for existing processes and include (but not be limited to): consistent end-user experience; information sharing across included committees and compliance functions; and automated reporting and notification capabilities and utilization of data currently residing in	As-Is Information: Human Subjects Research Compliance (HSRC): # Records Managed = Approx. 70 reviews/ reports per year Office of Animal Welfare (OAW) Compliance # Records Managed = Approx. 600-700 reviews per year Controlled Substance Compliance: # Records Managed = Approx. ▪ 150-200 Reviews per year ▪ 150-200 Reporting reminders (Annual Inventories due at time of audit)

#	Functionality, Workflow or Process	Description	Statistics
		Enterprise data systems. Out-of-Scope: Biosafety Research Compliance (BRC): BRC function is not a currently existing RIOP compliance process, will not be developed in Phase II Unfunded Research Agreements (UFRA) Compliance: UFRA compliance is not a currently existing process, will not be developed in Phase II.	

4. Project Approach

4.1 Primary Plans - Will the project have formal written plans – i.e., project schedule, budget, quality, risk, etc.? Describe briefly in the space below:

The SIRC project will have several associated plans:

1. Workplan (in ITG Center)
2. Change Management Plan
3. Communication Management Plan
4. Issue Management Plan
5. Test Plan (Strategy/approach)
6. Deployment and Transition Plan
7. Budget

4.2 Scheduled Status Meetings (Insert rows as needed):

Meeting	Purpose	Frequency
Executive Sponsors	Project update, issue escalation, change that require significant budget or schedule change	Quarterly
Project Management Team	Review project progress, issues, risks, scope.	Weekly
BPOs	Business decision on designs, conference room pilots, business process,	Bi-weekly
Functional Team		
Change Management Team		Bi-weekly

5. Authorizations (*Modify lists as needed*)

The Scope Statement, WBS, Project Schedule, Risk Management Plan and Project Budget are approved by the:

- **Project Sponsors**
- **Project Director**

Project performance baseline changes will be approved by the:

- **Project Director**

Project deliverables will be approved/accepted by the:

- **Project Director**
- **Project Oversight**
- **Key Stakeholders**

Specific task responsibilities of project resources will be defined in the *Responsibility Assignment Matrix*.

6. Project Scope Statement Approval / Signatures

Project Name:	SIRC
Project Director:	Garfield A. Bowen

The purpose of this document is to provide a vehicle for documenting the initial planning efforts for the project. It is used to reach a satisfactory level of mutual agreement among the Project Manager, Project Sponsors and Owners with respect to the objectives and scope of the project before significant resources are committed and expenses incurred.

I have reviewed the information contained in this* Project Scope Statement *and agree:

Name	Role	Signature	Date (MM/DD/YYYY)
Tim Mulchahy	Executive Sponsor		
Steve Cawley	Executive Sponsor		
Moira Keene	Project Oversight/BPO Chair		
Garfield Bowen	Project Director		

The signatures above indicate an understanding of the purpose and content of this document by those signing it. By signing this document, they agree to this as the formal Project Scope Statement *document.*