# STREAMLINING MINIMAL RISK STUDIES: CREATING A REQUEST PROCESS, COMPREHENSIVE DATABASE, AND GOVERNANCE STRUCTURE

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## BACKGROUND

Due to a lack of standardized processes, minimal risk study submissions have been a source of confusion, inefficiencies and frustration for research coordinators, PIs, database managers and the IRB. Additionally, there is an opportunity to improve the centralized governance and escalation regarding the compliance of minimal risk studies.

## GOALS

Streamline the process for minimal risk studies:

1) Create a formal submission process for investigators
   - Improves efficiencies by reducing email communications

2) Create a comprehensive database of all minimal risk studies
   - Provides an avenue to identify and reduce overlapping projects and/or data collection efforts

3) Provide centralized oversight and governance of minimal risk projects with clear escalation and approval mechanisms

## SOLUTIONS & METHODS

**Process:**

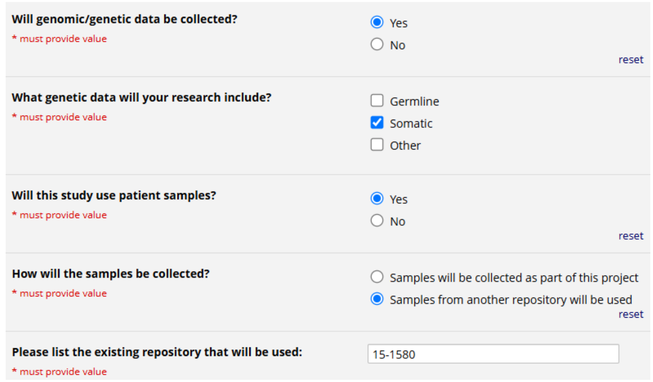
A REDCap survey was developed to streamline project intake by gathering key information such as funding sources, data variables and protocol details. This form is completed by the investigator and/or a study team member to ensure the project is organized appropriately and has all necessary approvals. This streamlined and proactive approach minimizes delays, prevents duplication of efforts and reduces research coordinator labor hours.

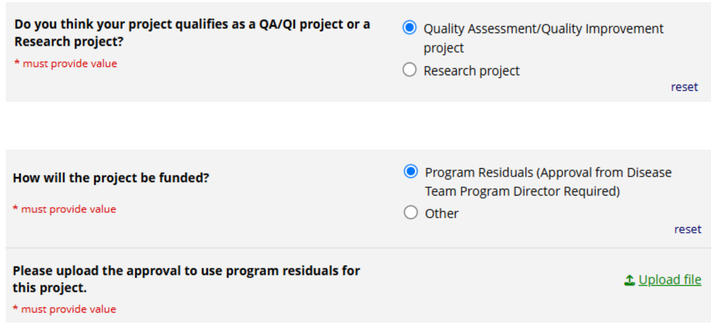
This survey will serve as a trigger for the intake team to:
- Notify relevant stakeholders of new projects (i.e., medical scientific writer, database developers, genomics program manager)
- Facilitate the assignment of research coordinators to individual projects
- Ensure all necessary approvals and funding are in place

These surveys will then feed into a comprehensive database that can be utilized to identify overlapping projects and/or data collection and will aim to provide administration with insight on research coordinator metrics based on study assignment.

**Governance:**

This survey will also serve as a mechanism to collect all necessary approvals and documentation. By standardizing the request and approval processes, we can create and enforce a governance and escalation framework.




## OUTCOMES

We plan to initiate this process in the next few months.

## LESSONS LEARNED & FUTURE DIRECTIONS

A future goal of this project is to incorporate a quality improvement decision tree to capture an approval process regarding whether a project is a quality improvement versus human subjects research. This addition will align with the goal of improving the governance structure of similar projects.

There are no relevant conflicts of interest to disclose.