

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

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

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 administrati with insight on research coordinator metrics based on study assignment.

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.

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SOLUTIONS & METHODS

Process:

Governance:

Will genomic/genetic data be collected?	Yes	
* must provide value	○ No reset	Do Res
What genetic data will your research include?	Germline	* m
* must provide value	Somatic	
	Other	
Will this study use patient samples?	Yes	Hov
* must provide value	O No	
	reset	* mu
How will the samples be collected?	Samples will be collected as part of this project	
* must provide value	Samples from another repository will be used reset	Plea
Please list the existing repository that will be used:	15-1580	* mu
* must provide value		



OUTCOMES

	•	nitiate this process in the ext few months.	
		NS LEARNED & E DIRECTIONS	
on incorporation treated a quality implementation and the subjects regardless of the subjects of the s		goal of this project is to the a quality improvement ree to capture an approval garding whether a project is inprovement versus human esearch. This addition will the goal of improving the ance structure of similar projects.	
hink your project qu h project? ovide value	alifies as a QA/QI project or a	 Quality Assessment/Quality Improvement project Research project 	
		reset	
l the project be funde	ed?	 Program Residuals (Approval from Disease Team Program Director Required) Other 	

upload the approval to use program residuals for

provide value

reset

Upload file