CENTER FOR RESEARCH TRAINING

PROTOCOL DEVELOPMENT

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Research Protocol

DOCUMENT THAT DESCRIBES THE BACKGROUND, RATIONALE, OBJECTIVES, DESIGN, METHODOLOGY, STATISTICAL CONSIDERATIONS, AND ORGANIZATION OF A CLINICAL RESEARCH PROJECT

Protocol should include

BACKGROUND

Literature review with your objectives/purpose

STUDY DESIGN

Subject selection, intervention and data collection details, project timeline

SAFETY

Adverse events, data safety monitoring board

STATISTICS

Quality control and assurance

Protocol templates

NIH

https://grants.nih.gov/policy/clinical-trials/protocol-template.htm

UF IRB

https://irb.ufl.edu/irb01/forms/forms1.html

MENTORS

Ask for examples!

ORA PORTAL

https://ufl.qualtrics.com/jfe/form/SV_3dvfjMe4Wd0qMgl

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Study Design

- logical and sequential format
- clear and concise description of the treatment, intervention or observation
- Describe all information that will be collected, by whom, and where
- Describe any drug, device, or instruments proposed

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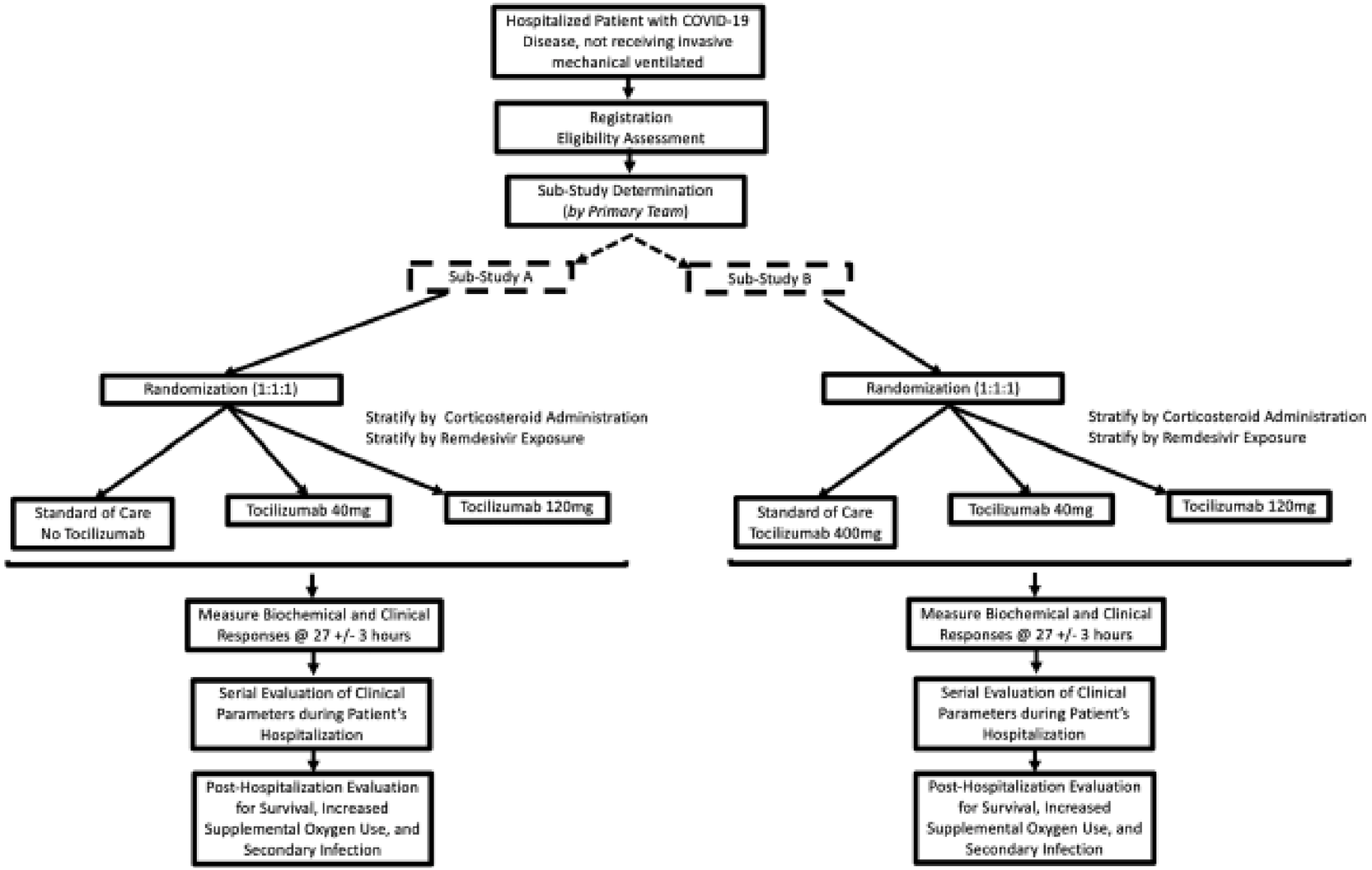
Study Population

- Inclusion/exclusion
- Recruitment plan
- Differences from standard of care

OVERALL STUDY SCHEMA:



APPENDIX 2.0 – SCHEDULE OF ACTIVITIES

Activity	Enrollment Visit	Stool Sample Collection	Colonoscopy	End of Study / Withdrawal
Informed Consent [1]	X			
Medical History and Demographics	X			
Enrollment	X			
Obtain Stool Sample		X		
Colonoscopy Procedure			X	
Submission of all reports			X	
Adverse Event Reporting [2]		X		
Discontinuation [3]				X

Footnotes for Schedule of Activities

1. Informed Consent: Must occur prior to undergoing any study specific procedure
2. Adverse events will only be recorded for events that occur during or otherwise associated with the stool sample collection procedure.
3. Subjects will have completed the study once the colonoscopy procedure has been completed or subject meets the withdrawal criteria.

H. TIMELINE

	Year 1				Year 2				Post – Award
Activity	**Q1**	**Q2**	**Q3**	**Q4**	**Q5**	**Q6**	**Q7**	**Q8**	
IRB review	X								
Pilot testing of data collection tools	X	X							
Preparation of database	X	X							
Subject recruitment		X	X	X	X				
Data collection		X	X	X	X				
Follow up assessments		X	X	X	X	X			
Data analysis					X	X	X		
Report writing and dissemination								X	X
Preparation of K application						X	X	X	

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Statistical Considerations

- Justify sample size and power
- Describe analysis and interim analysis, if conducting
- Data Safety Monitoring Board

Risks and Benefits

Physical, psychological, social, and/or economic

References / Appendix

Relevant literature and citations for all publications

After you think you are done...

Get a second opinion!

ask colleagues outside the primary research team for a peer review of the protocol

IRB pre-review request in ORA portal - IRB related request

Research staff

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Company Numbers

9 OUT OF 10

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