**CoULD Study Guidelines**

**Single- Center Studies:** Group members are entitled to use their own submitted data to perform a single center research study.

1. As a courtesy, we ask that members notify the Research Committee at the initiation of the study and again prior to submission or presentation.
	1. Power of the proposed research
	2. The newsletter and a website will allow easy reference to ongoing studies (both single and multi- institutional)
2. We request that an acknowledgement be placed in any manuscript or any presentation, “Data for this investigation was collected using the CoULD Registry.”
	1. A CoULD logo or a CoULD slide deck may be utilized.

**Multi-Center Studies:** Group members interested in performing a multi-center study should follow the following guidelines

1. For investigators to initiate and complete a CoULD study, their own institution’s data must be complete and clean. While we envision complete data (including follow- up data), focus will be on the proposed study.
2. Investigators may send a query request (to CAG) if they are considering a study on a particular diagnosis and need to better understand patient numbers. If they investigators decide to proceed based on this information, they should proceed with formal research proposal (see point 3).
3. CoULD investigators who wish to perform a research study utilizing the CoULD database fill out a “CoULD Research Proposal Form”.
	1. The investigator will initially answer questions 1-6
	2. The CoULD Research Committee will vet the study proposal on how novel, ethical, and relevant it is and provide a preliminary FINER score. The committee will also consider timing within the overall CoULD research vision, as well as overlap/conflict with other study proposals.
	3. If the Committee gives preliminary approval, the investigator will contact the lead study coordinators in Boston and St. Louis for preliminary data to complete the Research Proposal Form. The Research Committee will then reconsider the completed proposal for feasibility and complete final FINER score.
	4. Study can be approved, declined, or put on hold (based on an insufficient number of enrolled patients).
4. Based upon the study question and patients to be evaluated, the CoULD Research Committee Team may instruct the investigators to reach out to other PI’s for collaboration on the proposed study. This may be based on a high percentage of enrolled patients or a special interest of one investigator.
5. All CoULD investigators will be notified about the study proposal and given a chance to comment. The Committee will consider the comments together with the relative scientific contributions as it may affect authorship. This step is meant to engage PIs and thought leaders in our field.
6. After the Research Committee approves the study, the specific data request (full data) will be sent to the lead study coordinators in Boston and St. Louis and, within 3 weeks, the data requested will be released to PI (e.g. Dr Smith)
7. Authorship and order of authors is established as follows:
	1. Study PI must be a CoULD member, should conceive and develop the study idea alone or in collaboration, and should guide the project through presentation and publication. Failure to guide the project in a timely fashion may lead to relinquishment of the PI role.
	2. Consideration for co- authorship will be at the discretion of the Research Committee in collaboration with the study PI and will consider:
		1. Those who help develop protocol, analyze data, and write/edit manuscript. Editing alone does not qualify for authorship.
		2. CoULD Study Group will be recognized on each presentation or publication as an acknowledgement for patient contribution and manuscript preparation (short of fulfilling requirements for co- authorship).
		3. There are no ‘limits’ on the number of authors from the lead site but greater than 3 such authors requires approval from Research Committee with clear communication of the rationale.
			1. This should include core authors as well as authors that contribute in a more secondary fashion – the second group of authors could be shifted to the CoULD study group line based on journal requirements (i.e., max number of authors).
		4. We continue to encourage involvement of many sites, if appropriate engagement can be established
		5. Establish authorship plan at time of FINER submission. This is the second portion of the FINER form, after initial approval by the Research Committee.
		6. Advocate with journal to list all primary and secondary authors by name and reserve CoULD Study Group for minor contributors
		7. Every paper should include CoULD Study Group
		8. Trainees, coordinators, statisticians are appropriate named authors if they contribute fundamentally to the study (i.e., coordinators and statisticians must contribute beyond their daily work requirements)
8. Authors (or prospective authors) must respond with all of the following within 2 weeks of request:
	1. Comments/edits of manuscript draft(s)
	2. Completion of all disclosure forms
	3. Completion of all copyright transfer forms, etc.
9. Standard language will be provided by the Research Committee for funding, acknowledgements, and methods sections of the manuscript to describe the registry and participating sites in a uniform manner in all CoULD manuscripts.
10. A copy of the abstract or manuscript will be provided to the Research Committee prior to submission for consideration of manuscript:
	1. Publication
	2. Presentation (podium or poster)
11. Research presentations will be presented on CoULD Powerpoint Template.

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