

Guidelines for Surgeon Investigators in the Use of Resources of the Surgical Outcomes and Applied Research (SOAR) Program

1. The SOAR program is a collaboration between the University of Colorado Department of Surgery (DOS) and the Colorado Health Outcomes Program (COHO). It involves research into the organization, delivery, processes, structures, costs and outcomes of surgical care. It does not involve basic science research in surgery. Surgeon investigators involved in the latter activity should seek biostatistical support from the biostatistics consulting lab within the Department of Biostatistics & Informatics, University of Colorado School of Public Health or the Biostatistics, Epidemiology and Research Design (BERD) group in the Colorado Clinical & Translational Sciences Institute (CCTSI).
2. The COHO staff can assist surgeon investigators in many aspects of their research. This might involve the following:
 - a. Development of research hypotheses
 - b. Protocol development
 - c. Design of clinical trials or observational studies
 - d. Grant development
 - e. Comparative effectiveness studies using large databases
 - f. Meta analyses
 - g. Database development and data management
 - h. Design and conduct of surveys
 - i. Planning for statistical analysis, sample size, and statistical power
 - j. Manuscript writing
 - k. Manuscript reviewer response
 - l. Qualitative research
3. We would like surgeon investigators to come to the SOAR program with a clear understanding of the objectives of their research. This will help to prevent unproductive “fishing expeditions.” We ask that the investigators develop a 2-3 page proposal presenting background for their research, hypotheses, patient population to be studied, potential design of the study, data sources to be used and variables to be analyzed, publication plan, and timeline. It is important to do a preliminary literature review to determine if the proposed study will add to the literature in a meaningful way. COHO staff can help the investigators to refine their ideas and protocols, and develop the plan for sample size, statistical power, and statistical analyses.
4. Surgical residents conducting a research project needing SOAR resources should first have their project vetted by their surgical faculty mentor prior to contacting the SOAR program.
5. Interactions between surgeon investigators and COHO staff should represent a 2-way educational process, in which the surgeon educates the biostatistician about the surgical topic under investigation and the biostatistician educates the surgeon about design and analysis concepts. Sharing of articles from the literature can help this process.

6. It is important that the surgeon investigator consult with COHO staff early in the research process. COHO staff can not only do the statistical analysis for the study, but can also advise the investigators in all aspects of their protocol development and conduct of the study.
7. If the research will involve the collection and/or analysis of data eventually resulting in a presentation or publication, the protocol must be reviewed and approved by the Colorado Multiple Institutional Review Board (COMIRB) prior to COHO staff conducting any data collection or analysis. COHO staff involved in the research should be listed in the COMIRB application. The surgeon investigators should also have all of their required research training up to date.
8. COHO staff are simultaneously involved in multiple research projects. Surgeon investigators need to engage COHO staff early and allow for reasonable time for the COHO staff to execute their responsibilities. For example, it is not reasonable to expect COHO staff to conduct statistical analyses in support of an abstract with an abstract deadline of a few days.
9. COHO staff are professionals who rely on presentations and publications for their annual evaluations and for promotions. It is reasonable to expect that COHO staff who devote a significant amount of work and effort (for example, one week's worth of time or more, or participation in regular research meetings) in support of the research of the surgeon investigator to be considered a co-investigator and co-author on presentations and publications.
10. It is the hope and expectation of the Chairman of the DOS that the SOAR program will eventually become self-sustaining. Therefore, when grants are developed for funding using SOAR resources, COHO staff should be included in the budgets of the grants to help support the SOAR program.
11. SOAR senior staff have an obligation to report the time COHO staff spend working in the SOAR program, and to report on productivity in terms of abstracts and presentations at professional meetings and manuscripts published. The surgeon investigators need to keep the COHO staff with whom they are working informed about the submission, reviews, and eventual publication of all abstracts and manuscripts.
12. If a surgeon investigator wants help from COHO staff in responding to journal reviews of a manuscript, he/she should present the COHO staff person with the submitted manuscript and full review of the manuscript, so that the COHO staff person can maximize the help provided to the investigator.
13. All surgeon investigators should read and understand the CONSORT, STROBE, and PRISMA statements – see associated links. These are excellent articles that present guidelines for the design, conduct, and reporting of clinical trials, observational studies, and systematic reviews (meta analyses), respectively.