QI Protocol Format

Clinical Effectiveness and Patient Safety Small Grants Program -
University of Colorado Hospital and the School of Medicine

Please use the following format for the protocol: maximum 10 pages (excluding references); size 12 font; single spaced:

I. Abstract. (1/2 page) Provide a brief overview of the project by summarizing sections 2-4 below.

II. Goals and Objectives (1/2 page) The grant program encourages initiatives that put evidence into practice, enable local process improvement, and/or enhance skills and knowledge of healthcare providers, with the goals of improving patient safety, and/or enhancing the quality and cost-effectiveness of health care delivery. Clearly state the project's overarching goal(s) and the specific objectives for accomplishing these goals.

III. Background/Motivation/Impact (1 page) Describe the problem that this topic addresses, what is known about this topic, and why you chose to perform this project at UCH. Describe what knowledge you expect will be gained by completion of the proposed project and how the project will improve clinical care or operations at UCH. Background data about the scope of the problem at UCH and the potential impact of the project should be included if it is available.

IV. Project Design and Procedures. (5-6 pages).

a. Setting. Describe the clinical or other settings in which the project will take place and what impact the project will have on current operations. Describe the size and nature of the patient population served. UCH managers and medical directors must approve the project if it involves their area. It may be useful to mention whether this setting is representative of others, whether the setting has any special features, which make it a particularly attractive site.

b. Target population. When patients or staff are involved, this subsection should be used to indicate and explain the criteria for eligibility (or exclusion) and the anticipated number of participants. Preliminary data about the target population (size, characteristics, etc.) is of particular interest.

c. Performance Measurement

a. Measures: Measures and methods for measurement should be described in detail. If pre-existing data (administrative data, registries, EMR queries) are to be used, these should be described and their selection justified (including issues of reliability and validity). If new data are to be gathered, the data collection instruments to be used (e.g., questionnaires, interview schedules, medical record abstracts) should be described or, if available, included as appendices. Any plans for testing and assuring data quality in the proposed study should also be described. These could include pilot
tests, duplicate data collection for some or all subjects, crosschecks of one data source against another, or other techniques.

b. Data collection: Where applicable, the procedure and sequencing of data collection activities should be described in as much detail as possible. For instance, if a chart review is proposed, who will be conducting it, over what timeframe and with what data collection tool (attach if available). A schematic diagram is particularly helpful when many instruments and/or repeated applications over time are involved. If data are being assembled from multiple sources (e.g., patient interviews, medical records, administrative data bases) a table summarizing the data items and sources may be useful.

d. Intervention.

a. Description of intervention: The intervention to be implemented or evaluated should be explicitly described in detail. Multicomponent interventions should describe each component. Educational programs should be described and sample materials should be provided if available. Electronic decision support should provide sample algorithms. If the intervention will be designed based on preliminary data collection (such as focus groups, surveys, or PDSA cycles), please provide a description of anticipated or possible interventions.

b. Implementation plan: Who, what, when, where of your intervention planning and roll out. Specific use of QI planning and implementation methodologies should be described (Lean methodology, process mapping, failure mode effects analysis, PDSA cycles). If provider education or simulation is provided, who will be the educator, how many sessions will be offered, how will the trainees be assessed.

e. Data analysis. Extensive analysis of data is not expected. In most cases data analysis will consist of descriptive statistics and unvaried comparisons. In some cases, qualitative data may be evaluated. This subsection should briefly mention what comparisons are planned. More extensive data analysis can also be described including how the data will be manipulated or summarized and the statistical techniques to be employed. It is often helpful to address each of the specific objectives listed in section II in turn, showing how the data would be analyzed to meet that objective.

A sample size calculation is not required in all instances, however, in some cases, the statistical power (i.e., the probability that the intervention will allow detection of a difference or effect of a specified size) may be crucial to deciding whether the project should be undertaken. For most projects, this issue should be addressed in the proposal and, where possible, calculations of the study's sample size should be provided. Often the requisite data for this purpose can be gleaned from the literature or, if not, "educated guesses" can be made. Statistical consultation can be particularly helpful at this stage.
f. **Limitations.** Every project has limitations. The most important anticipated limitations of the proposed project, the reasons for them, and the design "tradeoffs" which make them necessary, should be briefly discussed in this subsection.

V. **Time line.** (1/2 page) Develop a time line for the entire project including "startup" time; pilot testing of instruments; subject recruitment; implementation and analysis; and dissemination plan (presentation/abstract/manuscript) (if indicated).

VI. **Itemized Budget/resources.** (1/2 page) The anticipated human resources and other costs of the proposed project should be tabulated, with a brief budget justification if necessary. Brief mentions may also be made of other sources of support for the proposal project.

Sample budget line items include (this is not comprehensive):
- PRA for data collection/project support (requires justification)
- Consultant: for programming for computer decision support; external QI or other expertise
- Equipment: integral to performance of program – you may be asked to justify why it was not purchased by the clinical unit.
- Supplies: laminated cards or posters
- Food (for educational program or reward for reaching QI goal for staff)
- Incentives: for survey or focus group participation (must follow all University rules)

**Prohibited costs:**
- Faculty or UCH staff PI effort (only PRA time as above)
- Travel – please do not budget for travel, poster, or meeting costs at this time. If you have funds left over at the end of the grant, you may ask for permission to use the funds for such costs.

VII. **Quality Improvement Status.** (<1/2 page) Please present a brief justification of why this project qualifies as quality improvement activities (i.e. generally exempt from IRB oversight) and not human subjects’ research. Please refer to Table 1 for guidance.

VIII. **Team.** (<1/2 page) Rarely is QI a solitary endeavor. Provide a brief statement of the principal investigator(s) and collaborator(s) qualifications. Multidisciplinary teams are encouraged. For junior faculty or staff, provide evidence of appropriate mentorship.

X. **Future Plans and Sustainability** (1/2 page) Outline how you will use the information from your project to disseminate additional change and/or how you will sustain the changes made (e.g. do you plan to seek further funding from other sources to sustain your program, do you anticipate the program will be self-sustaining, will education be incorporated by the clinical unit on an ongoing basis).

IX. **References**
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<thead>
<tr>
<th>Purpose</th>
<th>Research</th>
<th>QI/QA</th>
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<tbody>
<tr>
<td>To test a hypothesis OR to establish clinical practice standards where none are already accepted</td>
<td>To assess or improve a process, program, or system OR to improve performance as judged by established/accepted standards</td>
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<tr>
<td>Starting Point</td>
<td>To answer a question or test a hypothesis</td>
<td>To improve performance</td>
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<tr>
<td>Benefits</td>
<td>Knowledge sought may or may not benefit current subjects, but may benefit future patients</td>
<td>Knowledge sought directly benefits a process/program/system, and may or may not directly benefit patients</td>
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<tr>
<td>Risks/Burdens</td>
<td>May put subjects at risk</td>
<td>Does not increase risk to patients, with exception of possible privacy/confidentiality concerns</td>
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<td>Data Collection</td>
<td>Systematic data collection</td>
<td>Systematic data collection</td>
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<tr>
<td>End Point</td>
<td>Answer a research question</td>
<td>Improve a program/process/system</td>
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<tr>
<td>Testing/Analysis</td>
<td>Statistically prove or disprove hypothesis</td>
<td>Compare a program/process/system to an established set of standards</td>
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