QI and IRB Considerations

If you are completing an IRB application for a quality improvement project and you are new to quality improvement, have someone with experience in quality improvement and the IRB process review your application before you submit. IHQI Staff and Faculty are happy to help.

Should the IRB review my quality improvement project?
Yes, if your project includes research and your project involves any risk to human subjects.

1. Is your project research?
   - Quality improvement work may or may not involve/be research
   - Research is a systematic investigation to generate new knowledge

Guidance:
   - “Quality Improvement Activities Frequently Asked Questions” (on HHS.gov)
   - “Research/QI Differentiation Tool” (Medsurg Nursing, Jun 2008, Vol 17/No3, p167)
   - “Determination if an Activity Constitutes Human Research Subject to UNC-Chapel Hill IRB Review” (UNC OHRE Standard Operation Procedure 8 – on OHRE website)

2. Are human subjects involved?

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<th>Subject to Review</th>
<th>Probably Exempt</th>
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<td>• Data collected through direct interaction with individuals (e.g., in person, or via mail, email, web survey, or telephone)</td>
<td>Data limited to secondary analysis of data, records or specimens that are either publicly available, de-identified or otherwise impossible to be linked to personal identities.</td>
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<td>• Data from human subjects for which the researchers will have access to identifiers</td>
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Types of Review
1. Convened Review (UNC OHRE SOP 11)
2. Expedited Review (UNC OHRE SOP 13)
   - Involves no more than minimal risk or minor changes in previously approved research
3. Exemption from Continuing Review (UNC OHRE SOP 15)
   - IRB determines the work is not research and/or involves no risk to human subjects

Review Process
Online application with lots of help text and links
Expeditied or exempt from continuing review usually takes 10 days

UNC Resources
IRB and Office of Human Research Ethics (OHRE) – 919-966-3113
http://research.unc.edu/offices/human-research-ethics/
Standard Operating Procedures (on OHRE website, huge document, well-organized, easy-to-navigate)

When in Doubt
• The IRB does not have the option of granting “retroactive” approval after research is done; you should err on the side of submitting or consulting with the IRB if there is any doubt.
• Call the IRB/OHRE office – very helpful, want to guide