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Thoughts on IRB vs Non-IRB Project Needs:

Many students, residents and faculty often question whether their 'research' project needs to go the IRB for review/approval. For some projects (e.g., very traditional federally-funded population-based research studies), the answer is typically clear. For many other projects (e.g., educational evaluations, program evaluations, and quality improvement projects), the answer is typically 'it depends'.

'Intent to Publish' (or present at a regional/national meeting) is NOT, in and of itself, the reason to submit a proposal to the IRB. In order for a project to require IRB review, it must involve Human Subjects AND qualify as Research. By federal guidelines…

- A *Human Subject* is defined as "A living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information."
- *Research* is defined as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

For many of the projects faculty in our department are designing and/or engaged in, the intent of the study is not generalizable knowledge – quality improvement projects being a great example. This doesn't mean, however, that you might find something very interesting and want to share with others once the project is complete and results are known. At that point, the IRB could be engaged to review/approve a proposal with secondary data that's been de-identified and now is serving to help further knowledge by sharing results with other investigators.

There are 4 levels of review that the IRB may make once a study's proposal is submitted to their office through the on-line eIRB UMMS system:

- A determination that the project is <u>NOT human subjects research</u>.
  - Example, the Barre Family Health Center's Scribe Project being completed as part of quality improvement/practice improvement initiatives at the health center.
- A determination that the project <u>IS human subjects research but EXEMPT</u> from formal review/oversight.
  - Example, a nationwide survey of medical school deans to determine the extent of oral health curriculum (current and future planned) within our nation's medical schools; the survey was anonymous.
- A determination that the project <u>IS human subjects research but requires an EXPEDITED review</u> by the UMMS IRB office/committee. These studies must be <u>no more than 'minimal risk'</u> to subjects.
  - Example, a statewide medical record review of children's PCPs assessing screening practices for behavioral health conditions, coupled with a review of medical claims data to further study utilization of services among those who screened positive.
- A determination that the project <u>IS human subjects research but requires a FULL review</u> by the UMMS IRB office/committee. These are studies that present <u>more than minimal risk to subjects and/or include vulnerable populations</u>.
  - Example, an intervention study at two local CHCs whose subjects are pregnant women who have screened positive for PTSD.

The IRB office is more than happy to be engaged in a conversation to help determine the level of review which may be required, once they have sufficient details of the project to make that determination. Both Michael Centola (IRB Manager; michael.centola@umassmed.edu or 508.856.5324) and Allison Blodgett (IRB Assistant Manager; allison.blodgett@umassmed.edu or 508.856.4271) welcome emails and phone calls before you spend significant time developing your proposal (i.e., the Investigator Study Plan). The IRB office will also accept a brief write-up of your proposal in order to make its determination of need, especially if you believe that your project is not Human Subjects Research.

Please note… The IRB office is prohibited (by federal guidelines) from reviewing a project retrospectively to determine what level of review 'would' have been required, if any. Early contact with the IRB office has saved numerous individuals significant amounts of time in the long run!

Within the Department of Family Medicine and Community Health, Judy Savageau is also readily available to answer your questions about IRB vs Non-IRB needs (judith.savageau@umassmed.edu or 774.442.6535). Judy can help you with a brief write-up, as noted above, to submit to the IRB office in lieu of the Investigator Study Plan if you believe that your project is either non-human subjects research or exempt from formal review. Examples of these are available for review/sharing.

If it's determined that you need to submit your proposal to the IRB office for review/approval, please remember to follow the department's policy of pre-review two weeks before your planned submission. This policy is in place to both avoid the potential for non-compliance with IRB guidelines as well as to help strengthen your application by clarifying questions that will ultimately expedite the review process by the IRB office.

The IRB website has a large number of resources available to you. Please visit the site at http://www.umassmed.edu/research/irb/.