North Park University Investigator:

On behalf of the Institutional Review Board (IRB), I would like to provide an outline of the IRB review process. The board reviews studies involving human subjects carried out by faculty, students and staff from North Park University. Such studies may take place on our campus or at another location.

All research that deals with human subjects is of concern to the Institutional Review Board, but paradoxically not all research requires equal attention or involves the same processes. The NPU IRB has worked hard to streamline the attached applications to make them more user friendly and intelligible while still staying in compliance with both the spirit of the federal regulations and the letter of the law.

To summarize the NPU IRB position on the role of the procedure, it is to protect human subjects from avoidable harm during the research process as much as is possible. The law is long, and dense, and very smart and well-meaning people will disagree with the specific interpretation of it. We will generally err on the side of caution. If we can conceive of possible harm to the research subject, especially in protected or vulnerable populations, all the caution flags will come out on the track. That said, we also recognize that we are not primarily a research institution, and do not engage in massive pharmacological or medical research. All institutions have very similar concerns, but ours are thankfully on a more manageable scale than those of our larger, heftier, and better funded cousins. We will stick to the basic truths; those are not to be altered.

There are three categories of approval listed for all IRBs. Research may be categorized as

1. Exempt
2. Expedited review
3. Full review.

You should look over the Exempt Review Application to determine if your study may be exempt. There are six categories of potential exemption listed within this document. If you find that your project corresponds to one or more of the exemptions, please follow the instructions provided for this streamlined application. The category of “Exemption” does not imply an absence of needed IRB approval to proceed with your study. Instead, it changes the type of application form you need to submit. Even if you think that your research falls into one of the listed categories, you must still fill out at least an EXEMPT application and receive IRB approval.

If your research does not qualify as Exempt, then you will have to submit an application for Expedited or Full Review (starting with Section IV). The difference between expedited and full review is essentially based on the perceived risk to the research subject. For research that involves minimum subject risk there is an expedited review which will permit the chair or the chair's designate to approve of the research without a full meeting of the IRB committee. Research which requires greater risk or involves protected categories of subjects requires approval from the full committee at a regularly scheduled meeting.

As noted previously, the law is complex with LOTS of room for interpretation; some research involves conditions which were not even envisioned when the law was passed. For example, are Avatars in Second Life humans in the meaning of the act? Some possible research and choice of population will require special handling that is not covered in the attached forms, i.e, those dealing with vulnerable or protected populations. ("I would like to study adolescents incarcerated in Cook County Jail.") We would never summarily say "no" to such a request, but please understand that this type of proposal would require involvement from all kinds of external agents and stakeholders, such as inmates or counselors for them, and will take significantly more time and effort to resolve than an expedited application. When in doubt, ask the IRB, and we can discuss the ramifications of the request.

The intent with the forms we have provided here is to speed up the process as much as is possible, to cover the vast majority of the cases that the committee is likely to see, but yet to stay within the spirit and letter of the law.

Your explanation may not fit into the provided boxes. We are aware of the limitations. If you need more space, please provide supplementary narrative which clearly addresses the question or concern that the question raises.

Also provided in this packet or on the IRB Sharepoint site are a ***sample consent form*** and a handout entitled ***Key Elements Of A Research Protocol***. The committee has found that if the applicant is aware of the IRB review concerns this simplifies the application process and reduces the likelihood for revision and/or resubmission.

Please note that ALL investigators also must submit the following documents: a) a copy of all survey materials and b) a current (<3 years old) certification of completion of human subjects training with the application. If you have not yet completed human subjects training, please complete the CITI training. See the CITI training document on our website for full instructions.

https://www.citiprogram.org/

If you have a current (<3 years old) NIH training certificate on file with the IRB that is sufficient until it expires. At that time please take the full CITI course.

Thank you for your interest in developing a proposal for submission to the IRB. Please contact the IRB chair at IRBChair@northpark.edu.

Sincerely,

Chairperson,
Institutional Research Board.