IRB Concerns

Items in this document reflect comments made in a meeting in September 2021 at which faculty and administrators in Health Sciences, Public Health, Nursing, Communication Sciences & Disorders, and other units were in attendance.

1. Excessive time taken to receive IRB approval
    a. For a lab-based intervention study, this often requires 3-4 rounds of meetings = 3-4 months or more
2. Meeting only once per month is highly problematic – responses to contingencies can be completed in a few days but investigators then need to wait 2-3 more weeks before the board even meets again
3. Vague contingencies – investigators are not certain how to respond and if not done correctly according to the IRB, the same contingency returns the next month
    a. When clarification on contingencies is requested, there needs to be a quick response. In the past, we have had to follow up multiple times to get answers. We contact Kellie who then contacts the reviewer, and then either they didn't get back to her or Kellie didn't get back to us. Contingencies on specific wording should include the actual wording in the document, not an approximation. Additionally, if there is a contingency asking for clarification, it needs to specifically list everything they want addressed. For example, asking if something is x or y is the case. If they want justification if y is the case, or if y is an issue for the board-it should be explicitly stated and the reason why (what information are they basing it off). As we aren't at the meeting, we only address the initial request and wouldn't know there is an issue with y, which makes it hard to address or alter the methods to make it acceptable, resulting in multiple cycles to address what the board actually wanted from the start.
4. New items that were not previously mentioned come up at each meeting and delay approval
    a. If this is related to contingencies, this could be resolved with more information provided with the contingency, if it isn't than that signifies the first review wasn't as thorough as it should have been. If it's because there are different people at the meeting that weren't at the last-this would be fixed with increased attendance.
        i. Need to have less research-naïve reviewers on the panel. Sometimes these additional requests seem rather petty and superfluous. This could easily be rectified by having a content representative present at these meeting or allowed to judge if the additional comments are justified.
    b. This is one of the main issues in my experience. Subsequent reviews should primarily be focused on whether or not the investigator(s) addressed the previous contingencies and not bring new, oftentimes unimportant, contingencies
5. Condescending tone in response sometimes provided to investigators
6. I would also add inconsistency in reviews. While different projects may give rise to different questions, there needs to be some consistency. A good example is the addition of COVID guidelines. For each project different requirements (which health questions had to be asked, how it had to be documented, how detailed we had to be on which sanitizing products would be used, etc. continually changed). The only initial guidance provided was vague guidelines on the website. If there are certain, specific expectations, they should be outright stated.

7. Some items should not necessarily be contingencies, as they aren't directly affecting the safety of the subject. They could be listed as recommendations (e.g. font size, wording choices, or stating the consent form is too wordy /repetitive.)

8. If the legalistic nature of the concerns results in a too complicated form, it surely contributes to all the problems listed, resulting in delays. The mere fact that the template is many pages long suggests that virtually any IRB submission will take weeks to evaluate, and it seems inevitable that it will take months to approve. The template includes:

9. Repetitiveness, with the same issues being raised at different points.

10. Redundancy such that a single statement could often easily render all the items under a heading (or even multiple headings) irrelevant. Yet the template insists on statements for each of the irrelevant subcategories.

11. A style of language that seems designed to discourage participation because its level of detail suggests enormous complications for participation.

12. A style of language that is surely not understandable to much of the public due to the reading level required. To the extent that we may end up having participants who sign documents they do not understand, we are exposing ourselves to significant liability. To the extent that we must exclude participants whose reading levels or even oral comprehension of the conditions required by the consents prevent them from understanding those conditions, we violate one of the most fundamental principles of our Human Subjects regulations: that the entire public should be represented in the catchment of the research to the extent that it is possible.

    a. There could be a determination about the length of consent forms. A 20 minute research project should probably have a consent form that takes less time then the actual experiment (some slow-reading participants can take 30 minutes to go through the consent). I also think that if you are administering an experimental treatment, service, or education that requires extensive time on the participant, then a longer consent is reasonable. Consent should match the study.

13. The bureaucratic requirements of this process are not only slowing approvals down and preventing us from being able to compete for research funding, they are surely preventing many from even starting the process of seeking funding for research with human subjects. This applies to both faculty and students.
    a. In some areas, MS and PhD students are being discourages from performing original research, simply because of the cumbersome process of IRB approval. Rather, they are relying on secondary data analysis, which does not provide the same experience as an original human subject investigation.

14. Reciprocity agreements are not being handled appropriately. Two anecdotes:
    a. I wrote an R01 with a colleague from Michigan State University. That university held the original IRB. UofM has a reciprocity agreement with MSU that states that MSU's IRB is the main IRB. This suggests that if MSU approved the IRB, that UofM agrees to the MSU's review. However, I had to complete an entirely new IRB here at the UofM and it

had to go through a full review. So, I am not sure about how this agreement improves IRB load. It would have made more sense for me to complete an agreement form (or something similar) with the approved MSU IRB. Then because we have this agreement, the IRB should simply go through administrative review – not a full IRB review. I got the impression that these shared IRBs are not really fleshed out well here at UofM. When talking to my other colleagues on the grant, they did not have to complete the entire IRB form, their process was so much simpler. Maybe someone from the IRB could see what other institutions do?

b. I wrote an IRB here at the UofM based on a CORNET grant (shared UTHSC/UofM grant). The UofM grant was approved but I couldn't use any of the funds until the UTHSC IRB was approved. That took four additional months and it only gave us 6 months to complete a 12 month project. I know the UTHSC and UofM have a joint agreement where UTHSC has the parent IRB. However, when the research was conducted here at the UofM. So I wonder if the IRB at UTHSC could defer to our IRB? Many of the collaborations my department has with UTHSC is through the medical school and MDs are notoriously bad at getting IRBs pushed through the system – something about taking care of sick patients . . . . Additionally, the actual experiments happen here on our campus. I wonder if there could be more transparency between the two IRBs where if one IRB is approved at the institution where the study is to take place, the other institution simply does an administrative review?

Proposed Solutions

Some potential solutions are proposed below. These are meant as a starting point for discussions by DRI, UMRC, and research-engaged units across campus, with the goal of facilitating faster turnaround of IRB protocols while supporting the IRB mission of protecting human subjects.

1. Simplify IRB application and Consent Form; consider having word count limits for each section; there is much redundancy throughout application, which makes these longer to write and longer to read; applications are far too cumbersome and consent forms are far too long
    a. Some suggest that consent forms at other institutions are limited to one page
2. Have 1 or more pre-reviewers (trained by the IRB to conduct the work and fully understand what is needed) *embedded within each college* (or department, if significant proposals are arising from that area)
    a. These people would review the applications of PIs in their college
        i. The PI could send the Word doc directly to this person prior to Cayuse submission
        ii. Cayuse submission could then happen one week prior to actual meeting, in case a board member wanted to look at protocol
    b. They would work directly with the PI, in a *partnership*, and make certain that all items are addressed before the application is presented to the board
    c. This person would serve as an advocate (or navigator) for the PI, with the goal of doing all they can to get the application approved on the first review
        i. They would review the proposal and then meet with the PI to make corrections prior to the board meeting

        ii. They would attend the meeting (at a designated time) and present the corrected proposal, along with a 2nd reviewer if needed
        iii. They would take their own notes based on the comments provided during the meeting. The notes/contingencies would be provided to the PI *the next day* and the advocate would meet with the PI to address these, as needed
    d. The application would be corrected, reviewed by the advocate, approved in theory, and presented to the board at the next meeting
        i. The goal would be to have all protocols approved in no more than two board meetings
        ii. The advocate would be appointed by the dean or department chair, and must have either significant prior experience with IRB applications as PI, or currently be involved in regular IRB protocol submissions as PI or Co-I
        iii. The advocate would allow for an open communication channel between the PI and IRB—with the goal of helping the PI to receive approval on each protocol
        iv. The advocate may receive a stipend for their efforts (and/or course release)
3. Meeting frequency would increase to twice monthly (there may be two groups of reviewers, so each group meets only once per month)
    a. The physician member does not necessarily have to be present and voting on protocols at all meetings. The major exception to this is if use of the DXA is proposed, in which case he is required to be present.
    b. For comparison, the IRB at UTHSC meets once per week
    c. If we are planning to be a R1 institution, the IRB process needs to change – it is a barrier for far too many investigators, both faculty and students
        i. Meeting twice per month will help
4. Board members need to attend meetings as scheduled; if they make a commitment to serve, they need to honor that commitment so that a quorum can be reached
5. Board members, including the MD member but not including the community member, should preferably have *recent or current* human subjects research experience as PI
    a. A review of each member should be done; members without relevant experience should be removed from their appointment
        i. We cannot afford to have people with little to no research experience evaluating the work of research-intensive faculty
    b. New members should be carefully vetted and recommended by the college deans
        i. Specific incentives should be provided (course release, stipend, etc.) and agreed upon between dean and faculty member
6. Minutes for each protocol (names could be removed) would also be helpful to help understand the thought process/concerns since the contingencies aren't providing enough information.
7. Make better use of "approval with conditions" for minor issues, rather than issuing contingencies. Revisions can then be approved by the advocate (ideally) or the chairperson, acting for the board, rather than waiting for another full board meeting to approve minor changes.
8. If the advocate position is not instituted for some reason, contingencies should be returned to investigators by Wednesday of the week following the full board meeting. When this is followed,

that leaves at least two weeks for revisions. Contingencies returned outside this window should trigger an additional meeting automatically.

9. The IRB should make use of the Primary Reviewer method as described above, which allows one member (who is housed in the PI's home department) to do a full review, which they then present to the remaining members for discussion. The remaining members would ordinarily then just look at the informed consent prior to the meeting, although they would have the full materials available to them as usual. The primary reviewer should then be tasked with drafting the contingencies and providing these to the PI the following day.
10. For HIPAA related work, have the legal department draft a template that can apply to most studies and allow the PI to work with this as they build the application; send to Latosha for a pre-review prior to submitting.
11. Don't rely on one medical expert to opine on all protocols and influence the views of others.
12. Consider a data sharing agreement template.
13. Consider standard template for secondary data analysis – can this be streamlined to not need a full IRB proposal?
14. Guidelines provided for program evaluations and needs assessment – can this be streamlined to not need a full IRB proposal?
15. For protocols that require a rapid turn around time (e.g., those that have already been funding or will be funded soon, students who need to graduate) there should be a request for rapid review – prioritize the review in order to save the funding opportunity
16. Work with UTHSC to develop an agreement by which approval at one institution allows for approval at the other, without so much effort
17. The review should focus on human subject protection and safety; not scientific rigor and research design
    a. This is especially true for a funded project; if the sponsor and their scientific team determines that the work needs to be done, the IRB (with little knowledge in the area) should not determine that the work does not need to be done or should be done differently
18. OSP needs to release a funded project to grants accounting once it is funded and not once the IRB application is approved – this delay of months causes problems for PIs and their research team