**Community IRB / Community Council Proposal**

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### **Background/Issue**

Institutional Review Boards or IRBs attached to academic institutions (public and private) are time-consuming, burdensome, and resource-intensive.[[1]](#footnote-0) These review committees, while well meaning and important to ensure the welfare of people involved in research, may apply inappropriate evaluative lenses to research outside of the scope of biomedical research. IRBs tied to academic institutions must follow Federal regulations about research conduct, including what must be involved in the IRB process and requirements that must be met[[2]](#footnote-1). University IRBs have purview whenever a researcher, employed by an academic institution, uses institutional resources or cites their academic affiliation in any publications. Furthermore, academic institutions are risk averse and cautious of liability and may see the IRB review process as a mechanism to protect its research reputation. External/Private IRBs are an alternative option, but this does not guarantee relevant and streamlined procedures. Furthermore, these review bodies can be cost prohibitive, costing between $1,500 to $3,000+ for an initial review.[[3]](#footnote-2)[[4]](#footnote-3)

### Proposed Solution

Establish an ad-hoc 4-person Community IRB that includes two community members from the location in which the study will take place, and two academic and/or independent researchers. For training and credentialing, community partners can complete the University of Illinois at Chicago’s Center for Clinical and Translational Science [CIRTification](https://ccts.uic.edu/tools/cirtification/) training for free. Academic/independent researchers can leverage their existing training and/or certifications (e.g., CITI program, etc.). Community IRB documents for review can be limited to a total of six pages consisting of the following documents:

* Research procedures (6-7 grade reading level, single-space, 2 pages max)
* Informed consent document (6-7 grade reading level, single-space, 1 page max)
* Appendices (up to 3, 1 page max for each, 6-7 grade reading level, single-space)

Community IRB members can meet virtually for 1.5 hours to review documents and make a determination. Determinations can range from: a) approve, b) follow-up/clarification needed, c) revisions needed, or d) not approved in current iteration. Determination “b” could involve the Community IRB meeting with the research team to gather more insight about the research approach. The Community IRB can also provide feedback in a variety of ways and with the goal of not overwhelming research teams nor producing a large volume of work for the Community IRB to complete. Community IRBs can deliver feedback in a variety of forms and may include video, audio, text or combination or any other means deemed suitable for all. Community IRB members can be compensated $250 per meeting for a total of $750 (initial review, revision review, and continuing review). Fees can be negotiated among the group. If more than three meetings are required members should also be compensated for additional meetings.

### Bandwidth + Resources

The goal is to create an alternative system that does not burden researchers nor community partners (i.e., do not reproduce the problem). Respect for people’s time and intellectual contributions will be important agreements to uphold. Depending on interest and bandwidth, we have a few options to implement the proposed solution:

**Option 1**  - Individual IRL teams establish their own Community IRBs and may use the format proposed above or one of their choosing/creation. Some suggested agreements to decide upon: language, length of submissions, review timeline, and compensation.

**Option 2** - IRL alums and active cohorts establish an ad hoc IRB with leaders rotating into service to review submission using the format proposed above or one of their choosing/creation. It may also be helpful to reach out to specific IRL alumni depending on background and expertise to align with research projects.

**Option 3**  - a combination of option 1 and option 2. Each team establishes their own Community IRB and members can include community partners outside of the IRL team, IRL team members, and IRL alums.

### Administration + Format

Community IRBs can use cloud-based storage such as GoogleDrive or Dropbox to store and manage documents. As a precaution, Community IRB submissions should avoid including any personally identifiable information (PII) if stored in the cloud. An alternative would be to engage IRL Directors and staff about the feasibility of creating an internal portal within [www.irleaders.org](http://www.irleaders.org). However, this may be too much of an engineering lift.

An important consideration will be designating one or two people (ideally two), to assume responsibility of document management and scheduling key dates for meetings and deadlines. One important process to manage will be providing updates to the community about the research. This could be a “continuing review” in the parlance of University IRBs, or set agreed upon cadence to provide updates. Document management and responsibility could also be a rotating responsibility among members of the Community IRB. Ultimately, Community IRBs should determine internal governance.

### Dependencies

1. We need buy-in from IRL Leadership and Staff
2. We need buy-in and support from IRL alumni and the communities in which we work
3. If option 2 or option 3 is preferred, we’ll need someone/some people to steward the process.

### Sustainability

Community IRBs can scale into Community Councils where community partners and trusted stakeholders of their choosing constitute a formal body to evaluate research with them and/or about them or that will impact them now and in the future. These Community Councils can be activated when necessary and perhaps for reasons beyond research activities.

### FAQs

1. **Where does the money to compensate the Community IRB come from?**
Community IRB funding can be a line item in the budget for the $125,000 research project award.
2. **How often should the Community IRB meet?**That depends on the time and energy of members who will serve on the Community IRB. This should be an internal discussion.
3. **What if we cannot find anyone in the community willing to serve on the Community IRB?** Determine if any barriers or blockers to participation exist and try to mitigate and eliminate them. Also consider a peer support model to help acclimate a community member to the work and process. Community members should be a part of building the process. You can also streamline the work or tailor it to a person’s interest and bandwidth. Also consider reaching out to IRL alums for assistance.
4. **When should the Community IRB be in place?**By April 14, 2023, when our final research proposals are due. At minimum, having a plan or procedure will help. This will help with communicating to target audiences (i.e., community members, participants, etc.) what you are doing and why. Remember the Belmont Report principles: [respect for persons, beneficence, and justice](https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html#:~:text=Three%20basic%20principles%2C%20among%20those,of%20persons%2C%20beneficence%20and%20justice.)[[5]](#footnote-4).
5. **Do any templates or documents exist for the research procedures, consent form, and appendix?**Nope, not yet. However, adapting IRB documents and forms from any University–whether you are affiliated or not–may be a useful starting place. Below are some available forms/templates to draw from:
	1. [Temple University](https://research.temple.edu/research-compliance/institutional-review-board-irb/irb-forms-standard-operating-procedures)
	2. [Dartmouth College](https://www.dartmouth.edu/cphs/tosubmit/forms/index.html)
	3. [feel free to add]
	4. [feel free to add]
1. Grady, C. (2015). Institutional review boards. *Chest, 148*(5), 1148-115 doi:[10.1378/chest.15-0706](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4631034/) [↑](#footnote-ref-0)
2. Office for Human Research Protections (OHRP), U.S. Food and Drug Administration (FDA), International Council for Harmonisation (ICH), U.S. Department of Education (ED), Department of Veterans Affairs (VA), National Institutes of Health (NIH), U.S. Department of Health and Human Services (HHS) [45 CFR 46], U.S. Department of Defense (DoD), U.S. Department of Energy (DOE), National Science Foundation (NSF). [↑](#footnote-ref-1)
3. <https://usm.maine.edu/orio/wp-content/uploads/sites/361/2022/08/IRB-External-Reviews-Fee-Schedule.pdf> [↑](#footnote-ref-2)
4. <https://research.uic.edu/compliance/human-subjects-irbs/general-information/irb-fees/> [↑](#footnote-ref-3)
5. <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html#:~:text=Three%20basic%20principles%2C%20among%20those,of%20persons%2C%20beneficence%20and%20justice>. [↑](#footnote-ref-4)