

The Case for an Arizona Community Institutional Review Board

Growth of Clinical Research in Arizona

Clinical research in Arizona is rapidly growing. The Arizona Biosciences Roadmap has galvanized a broad consortium, uniting community leaders with the academic, non-profit research and health care communities in the state around a vision and plan to build research capacity. A strategic objective of the Roadmap is to build that capacity in part through statewide, collaborative clinical research activities, including addressing infrastructure gaps found across Arizona. One of those infrastructure gaps is that many hospitals and non-university research institutions lack their own Institutional Review Board (IRB) resources.

This proposal for an Arizona-based non-profit community IRB is supported by Arizona Biomedical Research Commission and the Flinn Foundation.

Target Participants in an Arizona-based Community IRB

There is a broad community drawing on IRB resources. Already today in Arizona over 3,000 physicians are registered with the FDA to participate as investigators in clinical trials and well over 600 physician practices, hospitals, research centers and academic institutions conduct clinical research utilizing IRBs. However, there are not sufficient in-state IRB resources to serve this need. Many hospitals and independent research sites in Arizona—particularly those outside of Maricopa and Pima Counties—do not maintain their own IRBs. Many of these hospitals instead contract with commercial IRBs, most of which are based outside of Arizona. There also are many hospitals in Arizona that do not do clinical research on site at all, in part because of the complexity of establishing an IRB.

Why an Arizona Community IRB Would Help

We think a non-profit community IRB in Arizona would help support clinical research in Arizona for a number of reasons.

Local Knowledge: Ethical and regulatory standards require IRBs to have knowledge about the local communities in which research is conducted, including the state and local laws, medical practice standards, and demographics. Commercial IRBs serve research sites across the country, and there is much debate about whether geographically disparate IRBs can adequately represent local communities.

Expertise: Many smaller institutions will decide not to create their own IRBs. The initiation of an IRB is a complex and highly regulated enterprise that requires a great deal of expertise. Finding IRB members in rural areas is also difficult: the IRB must contain members with scientific training and the IRB must have sufficient knowledge about clinical research and study design to weigh the risks of a research study to the potential participants.

Cost: Most commercial IRBs are known for their expediency, yet often have substantially higher costs than institutionally based IRBs. Because most institutionally based IRBs do not contract with external, non-affiliated entities, that means many hospitals without their own IRBs use the commercial IRBs. That means higher costs.

Our state is flourishing with new biomedical, biotech, and liberal arts investigators who want to initiate their own research studies. These investigators often have minimal or no external funding and must personally cover the IRB fees to review their protocols. Higher costs mean less research in Arizona.

Reimbursement Concerns: Arizona law requires insurance entities to reimburse covered patient costs to participate in certain cancer clinical trials, but only if the study “has been reviewed and approved by an institutional review board of an institution in this state.” A.R.S. § 20-826.01.

Efficiency for Multi-Site Studies: Even though many study sponsors include IRB fees in their study budgets, the duplication of these expenses to initiate a study at several sites within Arizona is substantial. Many clinical trials are performed at multiple Arizona sites simultaneously, yet the sponsors must obtain each research site's designated IRB approval to initiate these multi-site studies, adding substantial costs, coordination, and time to the research implementation process. Where the participating research sites agree, the Arizona Community IRB could be a mechanism for more efficient review in these multi-site studies. More efficient review means less cost to the research sponsors, which then may be willing to do more research in Arizona.

What It Will Take to Create an Arizona Community IRB

Creating a new IRB will require space, an IRB coordinator and one administrative support staff, and general liability coverage. The IRB will seek volunteers to serve on the IRB who have expertise and training in IRB evaluation, regulatory compliance, research design, and clinical trials. Our preliminary estimates indicate that it will take about \$200,000 to start the community IRB, with annual operating costs estimated at \$100,000.

The Arizona Community IRB Planning Committee will be addressing a number of issues in upcoming months, including where the IRB panel or panels will be located, how it will be funded, how it will be governed, and how it will be managed. The Planning Committee is considering a variety of funding mechanisms, including foundation support for capital start up monies and a voluntary cooperative “membership” structure to cover operating costs. Organizations using the community IRB would contribute a base annual membership fee and then pay discounted rates for standard IRB services based on the number of studies reviewed annually. A financial model will be performed to set these fees at a reasonable level below the cost of utilizing commercial IRBs.

In summary, a non-profit Arizona Community IRB promises to enhance the clinical research enterprise in Arizona by increasing our statewide local IRB capabilities and offer a competitively priced IRB option. The Community IRB will be available for hospitals and other research institutions who do not maintain their own IRBs. It also will be available for institutions with their own IRBs to use in multi-site studies or other studies of their choosing. We intend this to be a collaborative, synergistic process reflecting a multitude of stakeholders.

If you have questions or suggestions about the Arizona Community IRB please contact:

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