

**Fostering Ethical Research Compliance in International Settings
Transcript of Programmatic Poster Presentation at the 2020 Advancing
Ethical Research Conference**

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Fostering Ethical Research Compliance in International Settings

Welcome to Teachers College Institutional Review Board's presentation on Fostering Ethical Research Compliance in International Settings. My name is Kailee, Research Compliance Coordinator for Teachers College IRB and I'll be sharing some of the challenges of protecting participants in international settings. I'll also be sharing our in-depth assessment of these challenges, our process of design and implementation, and then any adaptations or changes we made in response to the COVID-19 pandemic.

BACKGROUND/PROBLEM

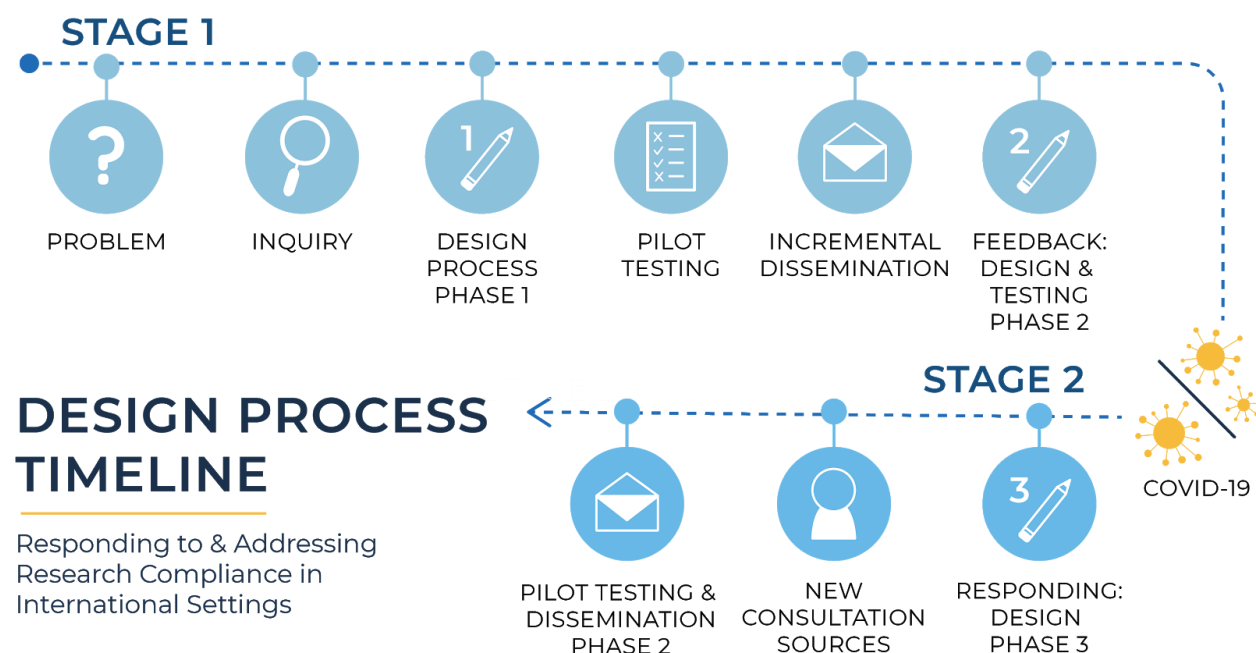
Informed Consent: We were prompted to explore the nuanced challenges to international research by a researcher in Africa. She alerted the IRB that potential participants were insulted when a paper-based consent form was presented to them for a signature. In doing so, the researcher was adhering to the U.S. informed-consent procedures, but this approach prevented the development of researcher and participant relationships and inhibited recruitment efforts.

Data Security: In an unrelated event, a researcher was collecting data at a refugee camp that consisted mainly of tents as the primary building structures. She did not have the standard "locked filing cabinet and restricted private office" to keep her data in. This situation prompted us to think about strategies for securing physical and digital data within constrained contexts.

INQUIRY AND DESIGN PHASE

Based on these experiences and others like them, we realized we needed to do a better job of understanding the challenges and opportunities that researchers face in international contexts.

This commitment to support researchers led us to develop our International Research Initiative.



I would like to draw your attention first to the design process timeline in the center of the poster which highlights the route we took to design these initiatives.

We first started with the **INQUIRY** phase. We wanted to know, what challenges were researchers experiencing in the field?

We engaged in informal conversations with researchers and conducted a literature review. We also got feedback from researchers about the readability and feasibility of IRB policies in international settings.

We looked for previously documented ethical challenges in international research and matched those instances with TC researchers and their populations of interest. We asked scenario-based questions like, “What mode of communication would your population of interest prefer?” and “How might your research participant respond to a standard consent form versus a verbal script; or emailed recruitment materials versus a flyer?” By contrasting cases in this way, we were able to develop a focused approach to support international researchers.

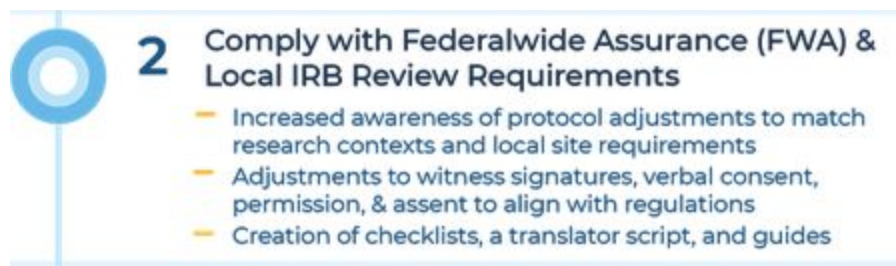
We also sampled from other IRB websites to see their guidance on these topics. This gave us insight to common challenges and how other institutions handled them. In our conversations with researchers, we uncovered the potential for

protocol deviations or adverse events (loss of confidentiality) as researchers felt pressured to deviate from Western-centered research compliance in favor of local customs (e.g., not collecting informed consent signatures).

We came away from these conversations with four main challenges. If you look on the left side of the poster at the TC IRB's Response to Common Challenges in International Settings graphic, you'll see the first four items were questions that came up in the literature and among our researchers.



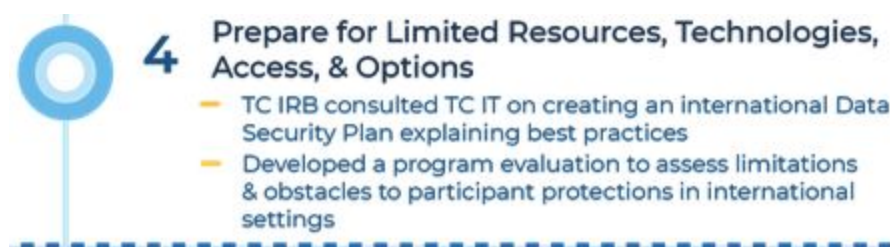
First, there was a lack of knowledge in IRB about the research sites, contexts, communities, and cultures where international researchers collected data. We made a concerted effort to gather information about the sites and cultural groups that TC researchers engaged with and we met with departments specializing in International Affairs on campus. We also engaged in information sharing initiatives across departments.



Second, we grappled with how to adhere to FWA and Local IRB requirements while simultaneously maintaining cultural sensitivity and avoiding a power-over approach to compliance. Some of our standard IRB procedures did not fit within cultural norms; as a result, we made adjustments to improve and protect data transmission processes and participant privacy.



The third challenge communicated by our researchers and the literature centered around intercultural forms of communication and the process of informed consent. Like with our researcher mentioned earlier, we explored ways to remain compliant, but flexible to the needs of potential research participants, such as providing the option for verbal consent or witness signatures.



The fourth and final challenge is not necessarily unique to international locations. Oftentimes, external sites have limited technology, constrained access to resources, and few options for conducting research. All of these required that we assess the needs of the specific sites and develop an appropriate response.

PILOT TESTING PHASE

I'll now draw your attention back to the Timeline. We designed materials in response to these four challenges and then entered into the **PILOT TESTING** phase, where we gave classroom presentations, held focus groups, and conducted discussions with key experts in the field, all the while modifying materials in response to feedback.

INCREMENTAL DISSEMINATION/FEEDBACK


Once the materials were finished, we gradually **DISSEMINATED** them for testing and critique by our researchers. We wanted to know were these materials truly

generalizable? Or were they a quick fix to a larger problem? Based on **FEEDBACK**, we realized we needed to take a step back and look at the Status of International Research from a bird's eye view. We designed a program evaluation, called Empirical and Systematic Approach to Understanding Gaps in Protection of International Research Participants, which I'll refer to as the International Researcher Survey.

RESPONDING

As we were preparing to launch the International Researcher Survey, the COVID-19 pandemic began, and we entered into a Research Shut Down, with the immediate pause of all research, including international studies that were being conducted in-person. Our primary focus at the time was mitigating risk to participants and protecting the researchers.

From March to November, we realized that if we were going to restart international research, we needed to broaden our questions and responses within the international research initiative. We modified our Program Evaluation to include Empirical and Systematic Approach to Protecting, Understanding, and Supporting International Research during Unprecedented Times. We also included the following questions into our program, which you can review on the left graphic, under the break.

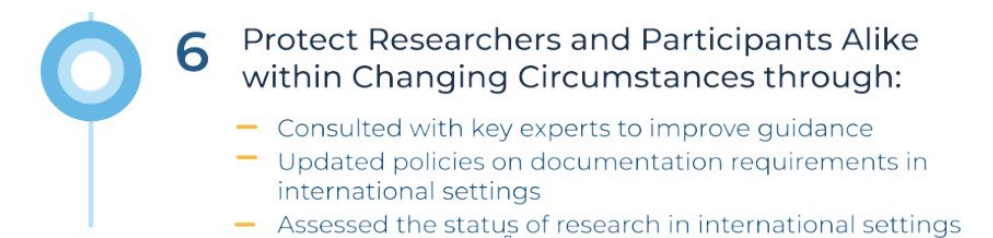


5 Promote Hygiene and Safety in International Settings and Research Contexts

- Updated policies to address limited international travel, varied COVID-19 restrictions, and external resources
- Supported changes to in-person data collection with revised hygiene & safety language in external site permission forms & consent forms

With the new COVID-19 restrictions and viral spread, traveling posed a much greater risk to health than before. We grappled with inconsistent site, city, and country regulations around hygiene requirements. We also had to consider how to safely disclose risks that were related to COVID-19. More recently, we have been working with researchers to prepare for a return to in-person research.

KEY EXPERT CONSULTATION



The evolving nature of COVID-19 made it difficult to write guidance that protected researchers and participants alike. At the time of the shut down, the college did not have a structure in place to support these changes. In response, we created a ramp-down checklist for our researchers and consulted with key experts, such as Information Technologies, Environmental Health and Safety, and the Legal Department in order to support all areas of research at Teachers College.

DISSEMINATION 2

After addressing these two challenges, we had a new round of deliverables to **DISSEMINATE** to researchers, including a Research Compliance website in response to COVID-19, Consenting Online Sample Template, and homegrown Training Modules. All of these items and more are available for download on TCs website.

LIMITATIONS & FUTURE IMPLICATIONS

While the materials created for the International Research Initiatives addressed the four challenges, we recognize there is a continual need for self-evaluation, engagement with researchers, and assessment of the materials.

With the changing landscape of COVID-19, we expect that our international research initiative will continue to grow and expand. We hope that this information was helpful for IRBs and institutions looking to support their international researchers. If you would like any of the deliverables, you can scan the QR code on the poster or click the link which will direct you to a webpage with the downloadable items. If you have any questions, please feel free to reach out to the

email on the poster. Thank you for participating and enjoy the rest of the conference.