FOSTERING ETHICAL RESEARCH COMPLIANCE IN INTERNATIONAL & CONSTRAINED CONTEXTS

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https://www.tc.columbia.edu/institutional-review-board/how-to-submit/guides--resources/documents-for-aer20/

BACKGROUND

Research administrators are familiar with the challenge of protecting participants in international settings. The existing literature summarizes four main challenges common to international research, though these challenges may also apply to domestic research.
Teachers College Institutional Review Board (TC IRB) conducted an in-depth assessment of these four challenges, identified gaps in procedural policies, and then responded with adaptive, relevant materials. This poster outlines TC IRB's design process addressing participant protection challenges in international settings.

TC IRB'S RESPONSE TO COMMON CHALLENGES IN INTERNATIONAL SETTINGS

1 Gather Researcher Knowledge of Research Sites, Contexts, Communities, & Cultures
- Gathered information from PIs and key experts to assess site-specific risks & plan appropriate responses
- Launched information sharing initiatives between international researchers across departments
- TC IRB and PIs engaged in community consultation with research sites and partners

2 Comply with Federalwide Assurance (FWA) & Local IRB Review Requirements
- Increased awareness of protocol adjustments to match research contexts and local site requirements
- Adjustments to witness signatures, verbal consent, permission, & assent to align with regulations
- Creation of checklists, a translator script, and guides

3 Strengthen Intercultural Communication & Informed Consent
- Produced examples of translated consent forms & streamlined approval procedures
- TC IRB & TC Information Technologies (TC IT) developed secure, private communications channels to strengthen relationships among researchers, sites, and participants
- Collaborated with international researchers to create a Data Transmission Checklist

4 Prepare for Limited Resources, Technologies, Access, & Options
- TC IRB consulted TC IT on creating an international Data Security Plan explaining best practices
- Developed a program evaluation to assess limitations & obstacles to participant protections in international settings

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 hygeine & safety language in external site permission forms & consent forms

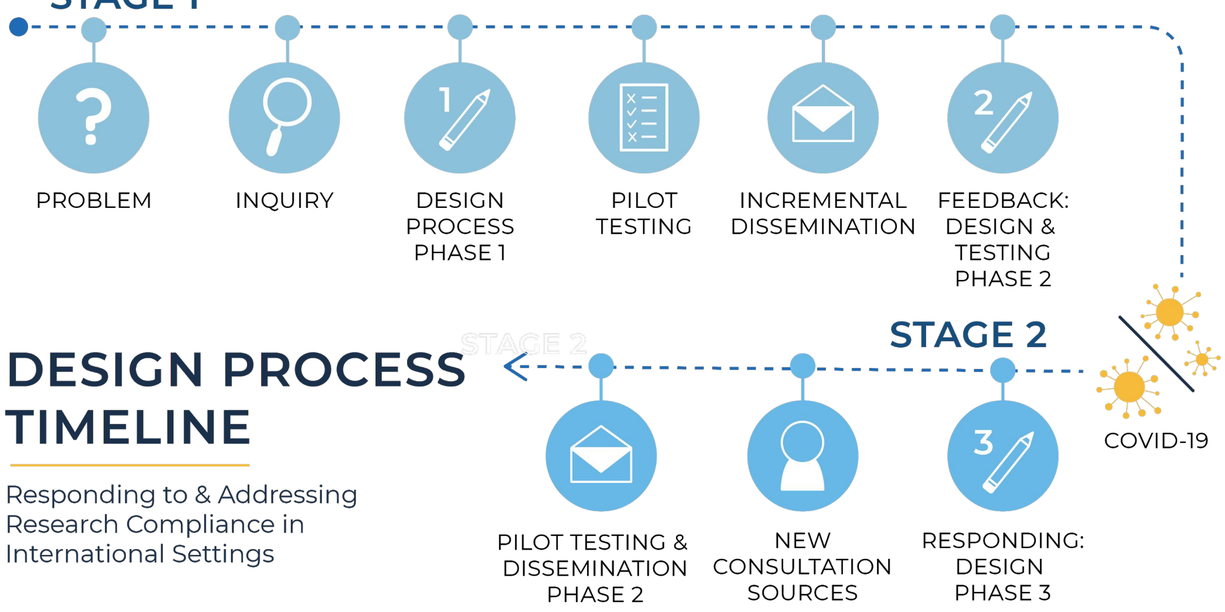
6 Protect Researchers and Participants Alike within Changing Circumstances through:
- Consulted with key experts to improve guidance
- Updated policies on documentation requirements in international settings
- Assessed the status of research in international settings

STAGE 1

PROBLEM & INQUIRY: Research Compliance Administrators have often grappled with addressing international research challenges. Common issues include: (1) Researcher Knowledge of International Sites, Contexts, Communities, & Cultures (2) Federalwide Assurance (FWA) and Local IRB Review Requirements (3) Intercultural Communication & Informed Consent (4) Limited Resources, Technologies, Access, and Options.

DESIGN PROCESS TIMELINE

Responding to & Addressing Research Compliance in International Settings



DESIGN 1: TC IRB systematically developed an **International Research Initiative** to weave stakeholders, campus departments, students, staff, and faculty researcher insights into a culturally appropriate, ethical, and feasible approach to participant protections (see Design Process Timeline). TC IRB collaborated with TC Information Technologies (TC IT) and other key experts to systematically respond to each issue as it related specifically to TC researchers and international participants or researchers engaged in constrained contexts (e.g., areas with limited resources).

PILOT TESTING: TC IRB tested designs for efficacy through classroom presentations, focus groups, and expert consultations. Results indicated areas of improvement with more specific procedural approaches and broader guidance for international research.

INCREMENTAL DISSEMINATION: TC IRB incrementally released deliverables (web-based guidance, educational materials, templates) to researchers to close gaps in participant protections and streamline processes.

FEEDBACK: Researchers critiqued the generalizability of TC IRB deliverables. This promoted a second, more comprehensive round of design, specifically questioning the status of international research at TC. TC IRB developed a **Program Evaluation, "***Empirical and Systematic Approach to Understanding Gaps in Protection of International Research Participants.***"** This theory-driven, evaluative approach aimed to identify starting points for identifying problems and engaging in inquiry.

STAGE 2

RESPONDING: The COVID-19 pandemic interrupted the **International Research Initiative** and introduced new concerns, including (1) how to promote hygiene and safety and (2) changing circumstances and evolving guidance.

In response to the changing research landscape, TC IRB revised the **Program Evaluation** to be *"Empirical and Systematic Approach to Protecting and Supporting International Research during Unprecedented Times"* in order to address past and rising issues in international research and constrained contexts.

NEW CONSULTATION SOURCES: Due to the complex nature of COVID-19 regulations and restrictions, TC IRB needed support in specialized areas. TC IRB sought guidance from key experts in fields related to COVID-19 issues including Environmental Health & Safety (EHS), Legal, and the Office of International Affairs.

PILOT TESTING & DISSEMINATION 2: Evolving federal and institutional policies resulted in a phased dissemination of resources. First, researchers were equipped to make COVID-19 modifications to in-person protocols. Second, a newly formed group, Research Compliance & Safety Committee, provided a Safety Assessment using OSHA standards applicable across research settings. TC IRB administrators updated templates and guidance to reduce viral exposure, mitigate risk, and convey limited mandated reporting guidance for public health contact tracing. Finally, research-specific training modules were disseminated to all researchers planning to engage in-person for data collection.

DISCUSSION

The Institutional Review Board (IRB) applies the same ethical and regulatory standards to domestic and international research. In international settings the IRB must understand if the protections in place are appropriate for the research setting, sociopolitical climate, and cultural norms. Researchers must balance implementing their institution's policies with respect for the relevant laws protecting human subjects in the host country and any requirements for local IRB approval.

Issues concerning international research include: (1) Knowledge of Research Context (2) Intercultural Communication & Informed Consent (3) Federalwide Assurance (FWA) and Local IRB Review Requirements (4) Limited Resources, Technologies, Access, and Options. This poster presentation outlined how we addressed these issues through a series of initiatives, and how we responded to the COVID-19 pandemic.

Institutions looking to improve guidance in these areas may benefit from our **International Research Initiative**.

The Initiative may be adopted to identify and address problematic regulations and assess many technological limitations in constrained contexts. IRB administrators equipped with knowledge about research in international or constrained contexts can assess risk and evaluate protections of human subjects under those parameters.

LIMITATIONS

Researchers working within international settings know that there is no one-size-fits-all approach. While the International Research Initiative provided temporary fixes, it was limited in its ability to address the cultural inflexibility of most federal and institutional regulations. Distribution of the International Research survey was delayed due to the COVID-19 pandemic.

RESOURCES

The **International Research Initiative** produced several of deliverables for Institutional Review Board administrators. Please follow the QR code contact the presenter at krk2148@tc.columbia.edu for sample copies.

1. Data Transmission Checklist
2. International Data Security Plan
3. International Research Guide
4. External Site Permission Form
5. Consenting Online Sample Template
6. IRB Reviewer Checklist

ACKNOWLEDGEMENTS & RESOURCES:

Dr. Karen Froud, Chair of the Institutional Review Board and staff from the Environmental Health and Safety, Office of Access and Support for Individuals with Disabilities, Office of the General Counsel, Office of International Affairs, Office of Risk Management, and TC Information Technology.

For more information, visit: Campus Life Curing COVID-19/Research Compliance & Safety or Teachers College, Institutional Review Board's