**450 CH.1 International Research Checklist**

Investigators conducting research in international settings must complete this International Checklist and submit it with the IRB application to ensure proper review and approval of human research being conducted in international settings. (See [IRB Policy 450 International Research](https://your.yale.edu/policies-procedures/policies/450-irb-policy-450-international-research) and associated guidance [[450 GD. 1](https://your.yale.edu/policies-procedures/guides/450-gd-1-international-research-required-documents-and-additional)] for supporting information.)

**Instructions**

* **If the research activities take place in any of the following countries/regions or recruit from Cuba, Iran, North Korea, Syria, and the Crimea, Luhansk, and Donetsk regions of Ukraine (Russian-occupied), contact the Director of Export Controls at** [**exports@yale.edu**](mailto:exports@yale.edu) **before submitting to the IRB.**
* Ensure that the protocol document and the *Technology – Data – Specimens* page in IRES IRB list the international locations where research takes place.
* If there is local IRB oversight, do not list the names of the external investigators in IRES IRB.
* If there is no local IRB oversight because there is no local IRB available, list the names of the external investigators engaged in the conduct of research on the External Team Member log. Upload the log in the External Team Member section of the Local Study Team Members page along with the unaffiliated investigator agreement requests.
* If available, upload the local IRB approval.
* Surveys, questionnaires, study information, informed consent document(s)/information sheet(s) must be submitted in English. Documents translated into the local language will have to be submitted when available along with the translation certificates or statements on who performed the translation services.
* If the research is not subject to GDPR (General Data Protection Regulation on data protection and privacy in the European Union and the European Economic Area) and collects identifiable information, ensure that the consent document includes the following statements:
  + *The data about you will be transferred to the United States of America. All of your responses will be held in confidence. However, the data protection laws here might be different than in your country. You have the right to ask that we delete your personal information. If we still have your personal identifiers, we will delete them to the extent we can and unlink the data from any information that could identify you. Contact me at your contact information. For further information about your privacy rights see our Privacy Statement at www.privacy.yale.edu or contact our Privacy Office at privacy@yale.edu.*
* Research collecting anonymous information should include the following statement in the consent forms/information sheets:
  + *The data about you will be transferred to the United States of America. All of your responses will be anonymous. However, the data protection laws here might be different than in your country. For further information about your privacy rights see our Privacy Statement at www.privacy.yale.edu or contact our Privacy Office at privacy@yale.edu.*

1. **Approvals**
   1. Name of local IRB/IEC/Ethics Board that will review protocol: Click or tap here to enter text.

* *Evidence of local approval by an IRB, Ethics Board, or Independent Ethics Committee (IEC) familiar with the local research context and local law, or a letter stating that such review is not possible and explaining why is required.* 
  + *If no local IRB or ethics board approval is possible, there should then be an endorsement/letter of support of the project by the local authority/institution involved in the research*
  + *If there is no local institution or authority involved an explanation as to why no approval or endorsement can be obtained is required.*
  1. Requirements of local IRB/IEC/Ethics Board: Click or tap here to enter text.
  2. Documentation required: Click or tap here to enter text.
  3. Local timeframe for review: Click or tap here to enter text.
  4. Fees for local IRB review: Click or tap here to enter text.

*Note: Some IRBs may have fees for review. Researchers should inquire about whether there are charges, and, if so, the amount of the charge.*

* 1. Local privacy regulations: Click or tap here to enter text.

1. **International Location Information**
2. Host Country: Click or tap here to enter text.
3. Is this a U.S. embargoed country or OFAC sanctioned region? Yes No

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1. Are there government standards for review of research?

Yes  No

1. Host Site: Click or tap here to enter text.
2. Host Site is:
   1. NGO  Hospital  School or University
   2. Other (please describe) Click or tap here to enter text.
3. Local Research Mentor: Click or tap here to enter text.
4. Local Research Mentor’s affiliation: Click or tap here to enter text.
5. Retention policies (e.g., what material, if any, must remain in the host country/site) Click or tap here to enter text.

*Note: This information should be included in the consent form, outlining confidentiality, storage and dissemination of the data.*

1. Describe any local laws that will relate to the conduct of this study. Click or tap here to enter text.
2. Describe any local social or political conditions that will related to the conduct of this study. Click or tap here to enter text.

**Investigators should review** [**IRB Policy 450 International Research**](https://your.yale.edu/policies-procedures/policies/450-irb-policy-450-international-research) **and** [**Guidance 450 GD 1 International Research: Required Documents and Additional Considerations**](https://your.yale.edu/policies-procedures/guides/450-gd-1-international-research-required-documents-and-additional) **for further information on additional considerations in the conduct of international research, and on securing data.**

**Revision History**

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| **Date** | **Revision** |
| 2/25/2022 | Updated list of sanctioned countries and provided language for consent forms/information sheets |