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# Ethics Committee Review of International Research

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More and more research studies and clinical trials are being conducted to economically underdeveloped countries.

This shift overseas is driven by:

- Cost;
- Reduced regulatory oversight; and
- Ease of participant recruitment and retention.



NIH-funded studies conducted overseas must undergo ethics committee review in both the US and country where the trial is taking place.

The local review should follow procedures and processes that provide protections that are at least equivalent to those provided by the Common Rule (as per 45 CFR 46.101(h)).

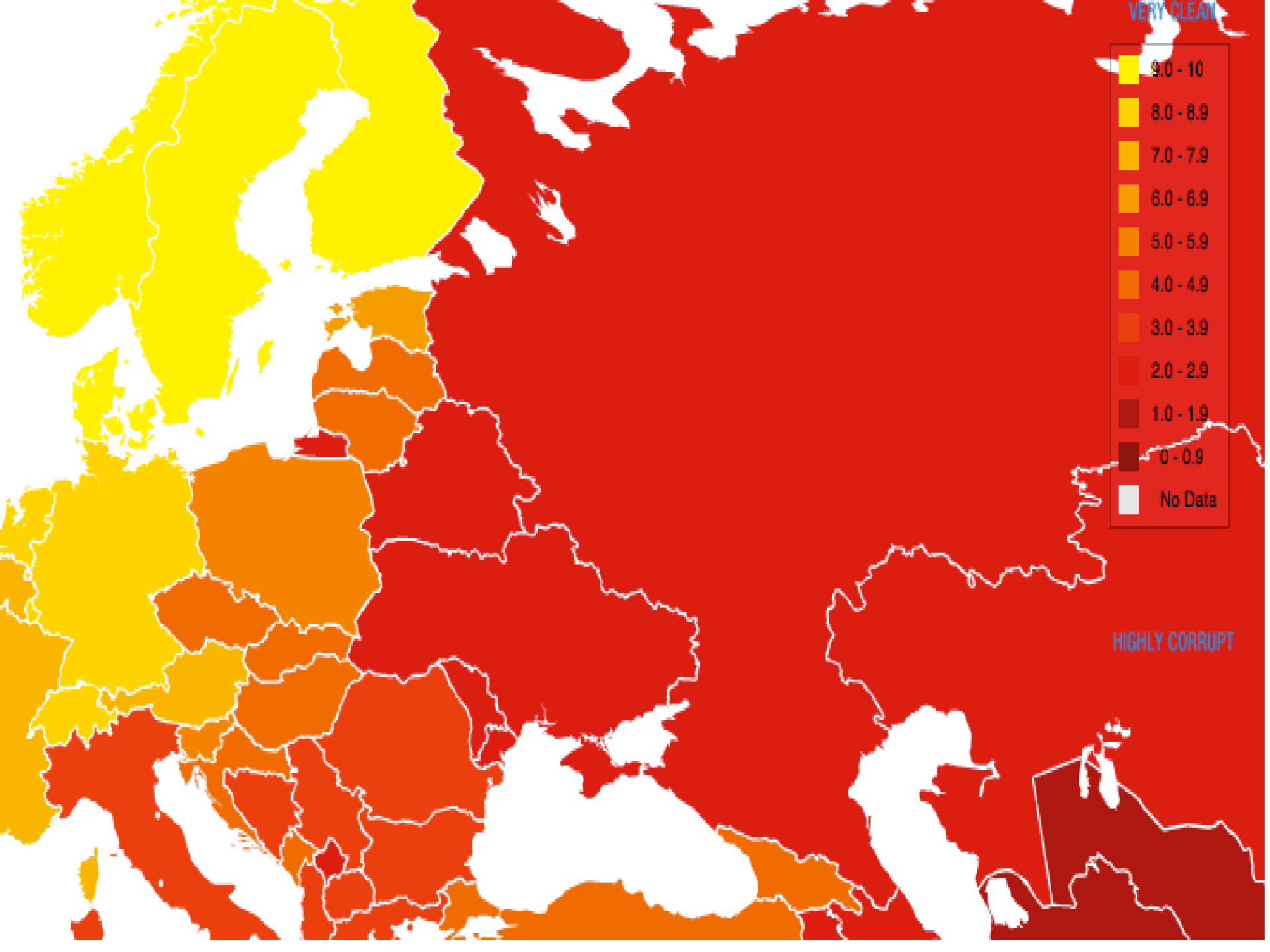
This duplicative review requirement can lead to inefficient and/or ineffective review of protocols.

- Additional bureaucracy;
- Conflicting demands from different committees;
- Regulatory or administrative delays; and
- Uncertain benefit for subjects, particularly in countries with little ethics infrastructure.

Most regions report having ethics committees and review requirements, but empirical data on research ethics review and oversight in many countries is fragmentary.

Known problems include:

- Lack of clear regulations, policies and legislation;
- Lack of political and institutional support;
- Lack of training and resources;
- Biomedical vs. social/behavioral science;
- Decentralized systems of ethics review; and
- Corruption.



Though contextually similar, the three Baltic states have different systems of ethical review:

- Estonia: Two research ethics committees based at medical schools in the country.
- Latvia: Seven committees that vary in their institutional affiliation and the types of protocols reviewed.
- Lithuania: Two-tier system with a National Bioethics Committee and two regional committees.

Though well developed, structural asymmetries in the system for research ethics review and oversight exist in all three countries.



Most institutions have research ethics committees, although there is little empirical data on how well they function.

Significant problems are known to exist:

- The ideological 'heritage' of the totalitarian past;
- Limited resources (manpower, access to international literature, lack of dedicated funding);
- Other institutional constraints; and
- Lack of public or political support.

Disparities in resources and capacity exist between US and international research ethics committees.

Committees in the US and abroad differ in structure, process, authority and function.

There can be substantial differences in US and international regulations.

Consider the following list of concerns that might be raised by a committee in the US or abroad:

- Study procedures are culturally inappropriate.
- The consent form is not in the local dialect.
- The consent form is too complex.
- The standard of care to be provided is inadequate.
- The research is not responsive to local health needs.
- The intervention won't be available locally.
- Voluntariness is compromised.
- Participant confidentiality is compromised.

# Concerns more likely to be raised by a committee in the US:

- Study procedures are culturally inappropriate.
- The standard of care to be provided is inadequate.
- Voluntariness is compromised.
- Participant confidentiality is compromised.

# Concerns more likely to be raised by a committee in a country like Georgia:

- The consent form is not in the local dialect.
- The consent form is too complex.
- The research is not responsive to local health needs.
- The intervention won't be available locally.

The most common barriers to efficient and effective joint review of protocols tend to fall into one of four categories:

- Regulation;
- Communication;
- Education; and
- Culture.

Reviewing protocols efficiency while ensuring adequate protection of subjects requires careful consideration of:

- Committee responsibility and authority;
- Political and cultural context;
- Logistics and communication;
- Mutual support and respect.