

Investigator Guidance Series

International Research (HRPP 1.5)

Description:

This policy describes UNMC's requirements for research conducted with international sites.

General Considerations:

The shipping of human biological materials, hazardous materials, or dangerous goods, must comply with <u>UNMC Hazardous Material/Dangerous Goods Shipping Plan.</u>

The PI must comply with the UNMC Export Control Policy.

The PI is responsible for ensuring all necessary host country permissions are in place.

Non-Exempt International Research:

The following must be submitted for IRB review:

- IRB application
- Addendum T: International Research (*automatically populates within the application when international site involvement is marked*)
- Copy of the local IRB approval letter
- Copy of ICF approved by the local IRB translated to English
- Copy of ICF approved by the local IRB in native language
- Agreement between the international site and investigator and/or institution

Exempt International Research:

The following must be submitted for IRB review:

- IRB application
- Addendum T: International Research (*automatically populates within the application when international site involvement is marked*)
- Copy of the local IRB approval letter
- Copy of ICF approved by the local IRB translated to English
- Copy of ICF approved by the local IRB in native language

