

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 [UNMC Hazardous Material/Dangerous Goods Shipping Plan](#)
- 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 (or equivalent)
- Copy of consent form approved by the local IRB translated to English
- Copy of the consent form approved by the local IRB in native language
- Agreement between the international site and investigator and/or local IRB, confirming:
 - Continuing reviews are done at least once a year
 - Site is monitored post-approval if needed
 - Any problems, complaints, or deviations are reported to the UNMC IRB
 - Serious problems with the research are also reported to the UNMC IRB

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 consent form (*if required*) approved by the local IRB translated to English
- Copy of the consent form (*if required*) approved by the local IRB in native language

If Shipping Materials Internationally:

If your international study involves shipping human biological materials, hazardous materials, or dangerous goods, the PI must comply with the [UNMC Hazardous Material/Dangerous Goods Shipping Plan](#).

For more information, contact:

- UNMC Biosafety Officer
- UNMC/NM Environmental Health & Safety
- ORCA (UNO)

Export Control Compliance:

If your research involves export-controlled materials, data, or technology, you must follow:

- [UNMC Export Control Policy 8005](#), or
- [UNO Export Control Policy](#)

For more information, contact:

- UNMC Export Control Office
- UNMC Chief Compliance Officer
- ORCA (UNO)

Local Permissions:

The PI is responsible for making sure they have all required local approvals in the host country. These might include:

- Institutional
- Governmental or ministry-level
- IRB/Ethics Committee
- Tribal or community permissions