International Projects: Rules, Regulations and Restrictions

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Or why if “UNMC is a public institution,

... are you making such a big deal about this international project?

or about this international scholar?”
Outline/Objectives

• Understand how US and other countries’ laws and policies impact international projects

• Learn how UNMC’s export control program helps us meet US export laws and regulations

• Understand the offices and processes available to prepare those traveling to or from other countries

• Know how the international checklist helps everyone better prepare for what will be needed for sponsored projects conducted in or with collaborators from other countries
Case Study 1

• A privately funded project focused on comparison of the genetic differences in inheritance of a common disease between the US and Country A

• A helpful visiting faculty offered to find a collaborator for the project in Country A, which has strict guidelines against export of human samples except for one’s own clinical care.

• Samples appeared one day in the laboratory out of the pocket of the staff member who had returned from the country after a visit to family.

• The investigator was told the samples were from an “established biobank” ready to be tested for genetic differences.

• Any concerns in this scenario?
Case Study 2

• A proposed project funded through a private source for a new method for rapid identification of an infectious disease, more common in Country B

• The faculty member contacted a hospital in Country B and proposed to bring in a novel US technology, not yet patented, to evaluate its effectiveness in the hospital on human samples

• The faculty member planned to bring the loaned new technology back along with some biologic samples known to be infected with a resistant micro-organism to characterize further in their laboratory

• Country B restricts export of any human samples, DNA or cells

• The faculty was asked to give a talk in Country B, and was asking for permission to travel to give the talk, and planned to bring over the technology at that time

• Any concerns in this scenario?
What is export control? Why does it matter at UNMC?

Export controls restrict export of goods and technology that could contribute to the military potential of adversaries and they directly impact our ability to

• Ship items out of the U.S. (including project deliverables)

• Collaborate with foreign colleagues/institutions

• Allow participation of foreign students or investigators in research activities

• Provide services (including training) to foreign persons

• Conduct research freely without having to implement restrictive and inconvenient security access control
We need to comply because . . .

• Growing foreign national employee and student populations involved in research

• Growing portfolio of defense-related research

• Increasing contractual restrictions on research

• Growing portfolio of international collaborations

• Failure to comply with U.S. export and sanction laws can result in severe penalties
Why does the U.S. have Export Control Laws?

• Restrict export of goods and technology that could contribute to the military potential of adversaries

• Prevent proliferation of weapons of mass destruction (nuclear, biological, chemical)

• Prevent terrorism

• Comply with U.S. trade agreements and trade sanctions against other nations
What U.S. agencies govern Export Control?

- U.S. Treasury Department
  - Office of Foreign Assets Control (OFAC)
  - Economic and Trade Sanctions
- U.S. State Department
  - Directorate of Defense Trade Controls
    - International Trafficking in Arms Regulations (ITAR)
    - Control of items primarily used by military (defense items, technical data)
- U.S. Department of Commerce
  - Bureau of Industry and Security
  - Export Administration Regulations (EAR)
  - Dual-use items – commercial and military applications
  - Bureau of the Census
- U.S. Department of Energy
  - Nuclear Regulatory Commission
Implications for shipping from or to another country

- All goods shipped must be classified
- End-user(s) and institution(s) must be screened
- End-use is important
- U.S. export licenses may be required depending on item and country
- Receiving country may require permits
- An MTA (material transfer agreement) may be required
- Shipper of record may need special training (such as biologicals and dry ice) or shipping by UNMC Chemical Safety for hazardous goods
- Goods valued > $2,500 require filing with U.S. Census Bureau
- Goods taken as checked baggage or carry-on must meet DOT/FAA/IATA regulations
Implications for travel to or from another country

• Are there embargoes/sanctions for the country?

• Are there Department of State travel alerts?

• Are you having any collaborations/transactions abroad?
  • Parties and scope of work need to be reviewed

• What are you taking along or bringing back?

• Electronic devices may need preparation by ITS
Implications for sponsored projects
SPA Guidance: International Sponsored Projects

• Alert us early

• Partner with SPA (and campus experts)
  • Project Development Stage
    • Share needed information (questionnaire)
  • Submission Stage
    • Allow 2 weeks for SPA’s application review
  • Award Stage
    • Vetting collaborators, meeting regulatory obligations and more
UNMC International Project Questionnaire

- Developed to help investigators and a variety of UNMC departments understand components of an international project that may require pre-approval
- Pre-approvals might include
  - Interactions with foreign institutions and individuals
  - Import of technology, including computers
  - Import or export of biologic samples, supplies, equipment
  - Approval of studies to be conducted
  - Intellectual property considerations
- *International Project Questionnaire* is needed if indicated by the *International Travel Checklist*
Sponsored Projects: Special Points

• Know about your collaborators and their roles
  • Need the names of personnel and their employer
  • Need a clear scope of work (the “end use” matters)

• Meet all UNMC policies and guidelines
  • Even if activities are being conducted solely by others in another country (e.g., IRB, IACUC, stem cell restrictions)

• Budget time for meeting regulatory obligations
  • U.S. and/or foreign countries may restrict the country of origin for purchasing or importing technology
  • Potential IP should be discussed with UNeMed before travel to or discussions with international collaborators
  • Transport of biologic samples in and/or out of a foreign country may require U.S. and/or foreign authorization
Implications for travel to a foreign country
International Travel

• Nebraska University Executive Memorandum 25 (EM25) governs international travel for students, faculty, staff and members of the general public.

http://nebraska.edu/docs/president/25%20Participation%20in%20Sponsored%20Travel%20to%20Countries%20with%20Travel%20Advisories.pdf

• EM 25 defines policy for travel to countries under an official travel advisory issued by the US Department of State and/or the Center for Disease Control and Prevention (CDC).

http://travel.state.gov/content/passports/english/alertswarnings.html
http://wwwn.cdc.gov/travel/notices/
International Travel

• **Travel Warning (US Department of State)**
  - UNMC students and members of the general public may not travel for academic credit or academic purposes when the US Department of State has issued a travel warning for that country.
  - Currently 37 countries are on the US Department of State’s list, including Nigeria, Mexico, Haiti, Honduras, and Venezuela.

• **Travel Alert (US Department of State)**
  - UNMC authorization for student travel is considered on a case-by-case basis for countries under travel alerts.
International Travel

- **Travel Warning (Centers for Disease Control and Prevention)**
  - Students and the general public are prohibited from travel to a country for which the CDC has issued a Travel Health Notice at Warning Level 3.
  - Currently there are Warning Level 3 Notices for Liberia, Sierra Leone, and Guinea.
  - Implications for faculty and staff travel to Warning Level 3 countries:
    - Prior approval must be requested in writing to the Chancellor who will make a recommendation to the President who will make a final determination.
    - Non-university-sponsored, independent travel to a CDC Warning Level 3 country must be reported to the Chief Academic Officer prior to departure.
    - Faculty and staff undertaking such travel will be subject to appropriate screening and health monitoring prior to returning to campus.
International Travel

- **EM25 Waiver Process for Students and general public**
  A waiver to the prohibition on university-sponsored programs in countries for which the US Department of State has issued a Travel Warning may be considered in exceptional circumstances. No waiver will be provided for travel to countries under a CDC Travel Health Notice at Warning Level 3.

- **Procedure**
  - Department unit completes written waiver request with detailed justification for deviation from standard policy.
  - Process a completed and signed (by student or member of general public) the University of Nebraska Informed Consent and Release of Liability form.
  - Waiver request and Release of Liability forms submitted to Chancellor.
  - Chancellor reviews and appoints a review committee.
  - If the review committee recommendation is positive, the request is sent to the NU President for affirmation or denial.
  - No further recourse is available.

- **Guidance**
  - Avoid countries with travel warnings.
  - Consider neighboring countries as alternative sites.
  - Demonstrate compelling need with waiver submission.
Implications for international visitors
Implications for International Visitors

• International visitors include
  • Any citizen of another country who is not paid by UNMC
  • Any citizen of another country who is not enrolled in a UNMC accredited program

• Host department provides
  • Completed registration form including scope of work for visit and sponsoring faculty member
    Visits < 7 days: 2 weeks in advance
    Visits > 8 days: 1 month in advance
  • Copies of passport, insurance, CV

• International Health & Medical Education
  • Screens visitors
  • Assures that immunizations are complete
  • Assigns compliance training
  • Requests campus network access, Blackboard, One Chart if required
Lessons learned through case studies
Case Study 1

- A privately funded project aimed to evaluate and compare the genetic differences in inheritance of a common disease between the US and Country A

- A helpful visiting faculty offered to find a collaborator for the project in Country A, which has strict guidelines against export of human samples except for one’s own clinical care

- Samples appeared one day in the laboratory out of the pocket of the staff member who had returned from the country after a visit to family

- The investigator was told the samples were from an “established biobank” ready to be tested for genetic differences

- Any concerns in this scenario?
Case Study 1

- No information to assure the patients sampled had the disease or whether the samples were obtained through an IRB equivalent process.

- The UNMC faculty had not applied for UNMC IRB approval, which is required for a collaborator even if the research is being conducted in another country.

- There are strict guidelines about how biologic samples should be transported on an airplane, which were not followed.

- Unclear the samples were carried in a manner that the DNA would be useable.

- While the visiting scientist thought they could study the samples and develop preliminary data, he understood that they could never publish the work because they had not requested and received approval for export of the human samples from country A.

- Even if it were legal and met regulatory guidelines, does it sound like a good use of resources or science?

- Were CDC permits obtained, if necessary?
Case Study 2

• A proposed project funded through a private source for a new method for rapid identification of an infectious disease, more common in Country B

• The faculty member contacted a hospital in Country B and proposed to bring in a novel US technology, not yet patented, to evaluate its effectiveness in the hospital on human samples

• The faculty member planned to bring the loaned new technology back along with some biologic samples known to be infected with a resistant microorganism to characterize further in their laboratory

• Country B, of note, restricts export of any human samples, DNA or cells

• The faculty was asked to give a talk in Country B, and was asking for permission to travel to give the talk, and planned to bring over the technology at that time

• Any concerns in this scenario?
Case Study 2

• Further information suggested that study of cultured and previously obtained sputum samples would not require IRB approval, although no one had asked.

• Technology being exported had not yet been patented so inconsistent with US export law of new technologies and at risk for losing patent and license by the inventor.

• Can’t assume equipment brought with you can be taken back out; the country may not allow it.

• No request of Country B to export samples or of U.S. to import potentially hazardous samples.

• The faculty hadn’t realized any of these risks and wouldn’t have been discovered except for the new International Project Questionnaire.
Summary and Take Home Messages

• Regulations that impact international projects are complex, often unique to that country, and can change frequently with little warning.

• UNMC policies/procedures for international projects are intended to keep everyone involved safe from legal actions, federal audits, fines, and potential hazards.

• These procedures take time, so plan early.

• If you have questions, please call!
Resources

• **Marsha Morien**, UNMC Export Control Officer, ITAR Empowered Official

• **International Health & Medical Education** for preparing for visitors/personnel/students to travel in or out of UNMC

• **Academic Affairs** to develop MOU, IRB or IACUC regulations

• **Vice Chancellor for Research**
  - **Sponsored Programs Administration** for grant application requirements
  - **UNeMed** for new invention notice, patent applications, license, and material transfer agreements
Weblinks

• Export Control
  • http://www.unmc.edu/academicaffairs/compliance/areas/export.html
  • International Travel Checklist
  • Shipping Chemical, Biological and Radioactive Materials

• Institutional Biosafety
  • http://unmc.edu/ibc/policies-procedures/export-control/index.html

• International Project Questionnaire
  • http://www.unmc.edu/spa/forms_templates.htm

• International Visitor Forms
  • http://www.unmc.edu/ihme/programs/international-visitors.html
  • http://www.unmc.edu/ihme/_documents/unmc-visitor-registration-checklist.pdf
Questions?