
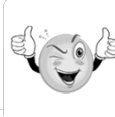


International Research
Does it keep you up at night?

Disclaimer



Conflict of Interest
We have no relevant personal/professional/financial relationship(s) with respect to this educational activity.



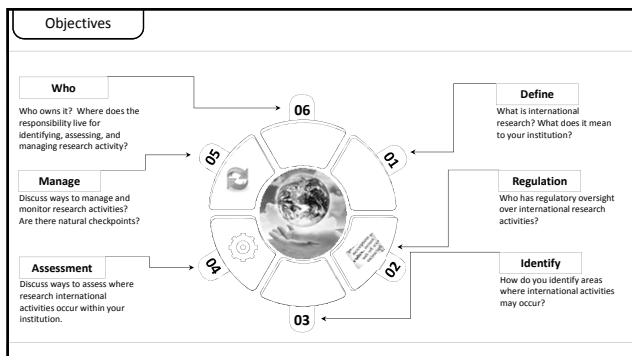
Commitment
This is intended to be an educational discussion to enhance awareness of international activity as it relates to research.

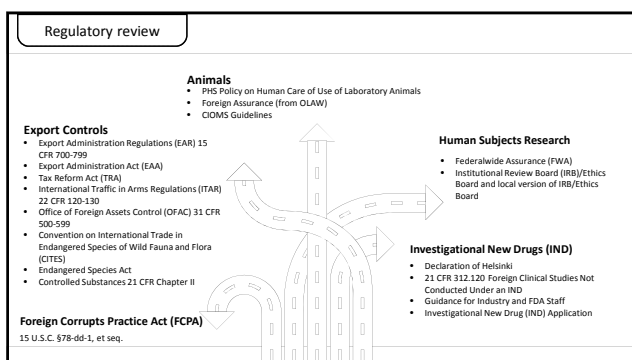
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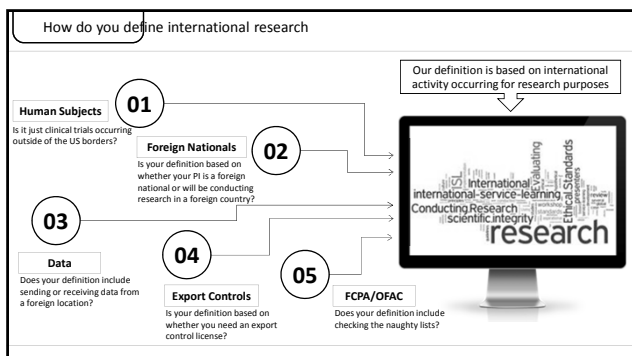
Perspective
There is no one way to implement an international research program. This presentation is from the perspective of one institution highlighting success stories as well as lessons learned.

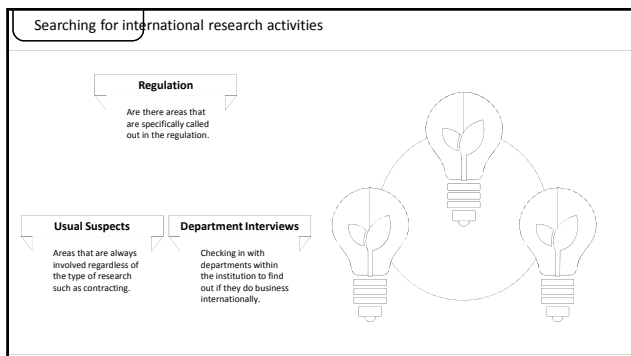
Institutional Journey

This presentation is intended to give you an insight into the process of defining, creating, and monitoring international research activities. The information here is based on the journey that my institution took with some lessons learned. There are many ways to approach this process based on the type of international activity, resource allocation, and the risk tolerance of your institution.

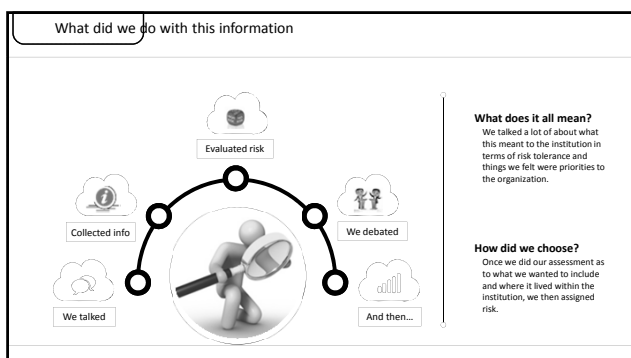











- What did we find**
- Animals
 - Bench research
 - Contracting
 - Data management
 - Employment/Taxes
 - Finance
 - Foreign Nationals
 - Grants
 - Human Subjects Research
 - IS/IT
 - Labs
 - Licensure
 - Privacy/HIPAA
 - Purchasing/Vendors
 - Shipping
 - Signing Authority
 - Visas



We wrote a policy

Easy right?

Where to start?

Who is going to own it? Who will draft it? Does it need to be a research policy? Who needs to be involved?

What to include?

Do we put every topic we can think of? Do we do bare bones? Do we just put a general framework? Do we only put the big stuff?

How much detail

Do we put everything in the policy? Do we have appendices? Do we do a SOP? Do we have guidelines?

Where we landed

Animal Subjects Research

Instructions that conduct animal research on live, vertebrate animals with Public Health Service (PHS) funds are required by the PHS Policy on Humane Care and Use of Laboratory Animals (PHS Policy) to have in place an Animal Welfare Assurance with the Office of Laboratory Animal Welfare (OLAW). If the research is being conducted outside the U.S. with PHS funds, the PHS Policy requirements are applicable to the research (or the foreign entity must provide evidence to PHS that acceptable standards for animal care and use will be met). A Foreign Assurance from OLAW must be completed by the foreign institution and the foreign institution must comply with CIOMS Guidelines. Review the section below entitled Export Controls, Animals and Animal Products for additional information.

See Appendix A for additional information on Animal Subjects Research.

Appendix A
Animal Subject Research

The BIDMC Investigator is responsible for the following:

The BIDMC Investigator must submit the research proposal to the BIDMC IACUC for approval. When submitting an application to the BIDMC IACUC that includes foreign animal research, the BIDMC investigator should include:

- veterinary qualifications at the foreign site,
- IACUC/oversight body requirements at the foreign site,
- animal pain/distress considerations in the host country, and
- whether the foreign site has a Foreign Assurance from OLAW.

The BIDMC Investigator should comply with the following policies and procedures:

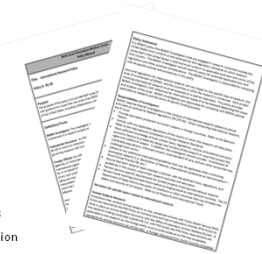
- Investigator's Training Manual
- Animal Welfare Act

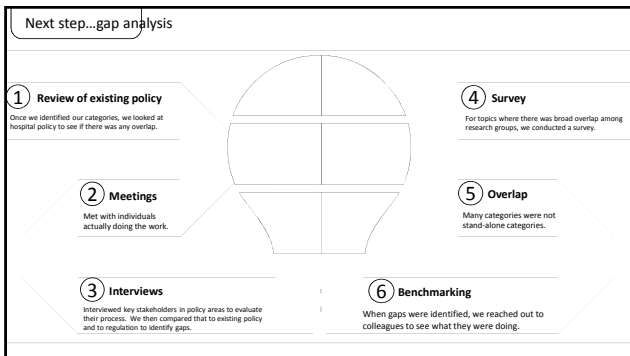
For assistance on animal research issues at foreign sites, the BIDMC Investigator should contact the BIDMC Veterinarian at _____.

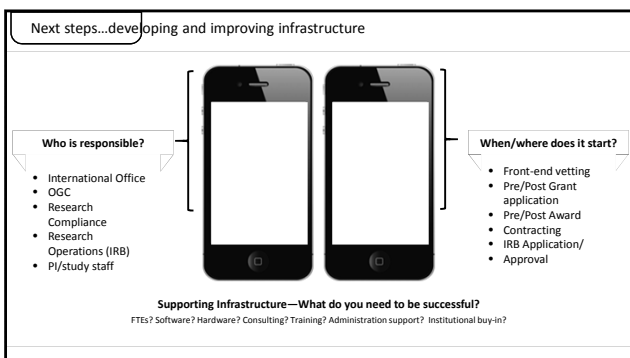
What we included in our policy

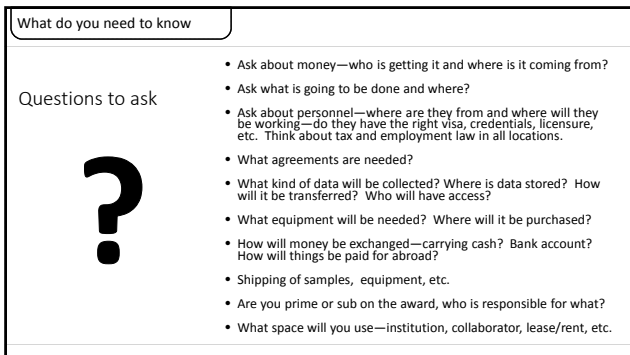
- Responsibilities of the investigator
- Animal Subject Research
- Employment and Taxes
- Export Controls
 - EAR
 - Anti-boycott
 - ITAR
 - OFAC
 - Animals and Animal Products
 - Controlled Substances
- FCPA
- Funds
- Human Subjects Research
- FWA
- IRB/Ethics Board

- Investigational New Drugs (IND)
- Foreign Laws and Regulations
- Licensure
- Visa
- Privacy/HIPAA
- Securing Data
- Paper files
- Electronic data
- Local researchers/translators
- Location of data collection
- Signing Authority
- Shipping









How do you monitor

Internal
Depending on your institutional risk tolerance and resources may determine what types of internal resources you have to monitor your international research program.

External
Some external may be requested like outside counsel or a consultant and others may invite themselves such as governmental agencies. Again, depending on resources, you may be able to enlist outside services to help with monitoring. The key with the external monitors is to be able to demonstrate due diligence.

What can go wrong

- Harvard research in China**
https://www.washingtonpost.com/archive/politics/2002/03/30/harvard-research-in-china-is-faulted/5a9a2538-93ea-43b4-b66d-6c1498f0468d/?utm_term=.41304c710ecd
- Pfizer Trovan study in Nigeria**
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4089044/>
- AZT trials in Africa**
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4089044/>
- Clinical trial regulations in India**
https://clinregs.niaid.nih.gov/country/india#_top

Other ideas, questions

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