



Working with Foreign Collaborators

**NIH Regional Seminar on
Program Funding and
Grants Administration**

**Las Vegas, Nevada
June 25 & 26, 2009**

United Kingdom



“The National Health Systems IRB in the UK has stated that because of their license under the Human Tissue Act, it is not in their IRBs authority to give Human Subject Approval for samples collected from US and African consortium”



Human Tissue Act 2004

2004 CHAPTER 30

CONTENTS

Appropriate consent does not apply to:

... an activity of a kind mentioned there if it is done in relation to—

- (a) a body to which subsection (5) applies, or
- (b) relevant material to which subsection (6) applies

(6) This subsection applies to relevant material if—

- (a) it has been imported,
- (b) it has come from a body which has been imported, or

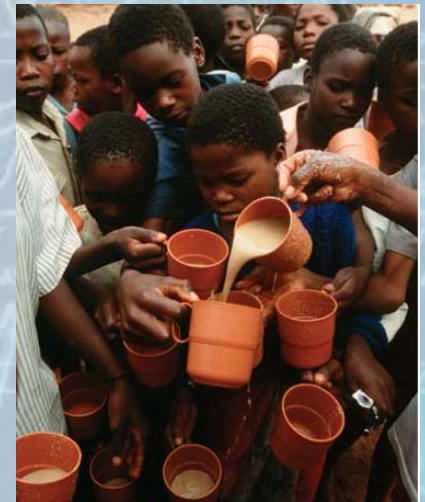
(c) it is material which has come from the body of a person who died before the day on which this section comes into force and at least one hundred years have elapsed since the date of the person's death.

Zimbabwe

“Prior to expending the funds I receive, can I invest the grant funds to help defray the cost of inflation”

Zimbabwe: Inflation Dips to 6 500 Percent

**Financial Gazette (Harare)
19 September 2007**



Issues for discussion



- **Communications**
 - Language
 - Time Zone
- **Funding**
 - Collaborators
 - Independent
- **Infrastructure Costs**
 - Personnel Equipment
 - Patient Care Other
 - F&A
- **Grant Requirements**
 - Knowledge of requirements
 - Conflicting Requirements

Communications

- **Time Zone issues**

When it is 9:00 **am** in Washington DC it is 9:00 **pm** in Beijing, how can you have an in depth conversation with foreign organizations?

- **Language Differences**

The PI generally speaks English, but the administrators do not. How can you be assured that administrative issues are understood and addressed?

Funding

- **Fluctuation of Currency – only allowed prior to award, any flexibility?**
- **Can we only fund the traditional way? There are options for both foreign collaborators and foreign awards:**
 - **Tradition subcontracting – What else**
 - **Treasury Checks – What else?**

Funding Collaborations

- **Traditional Subcontract/Consortium**
 - Who has authority to sign for the organization?
 - Will the collaborating organization understand the general terminology “follow the rules and regulations of the ...”?
 - How will funds be disbursed?
 - How will fund use and progress be reported?
- **Independent contractor**
 - How and should this differ from a traditional subcontract/consortium?

Funding Collaborations

- **Selected support of costs, no formal relationship.**
 - Purchase service for expenses?
 - What about the foreign organization's responsibilities?
- **Off campus site.**
 - Is it truly part of the grantee?
 - What will be the administrative responsibilities of the grantee?

Cost Issues

- **F & A –**

“NIH provides limited F&A costs (8 percent of total direct costs less equipment) to foreign institutions and international organizations to support the costs of compliance with NIH requirements including, but not limited to, protection of human subjects, animal welfare, and research misconduct. NIH will not support the acquisition of, or provide for depreciation on, any capital expenditures, or support the normal, general operations of foreign and international organizations”

- **What if the foreign site takes a percentage off the “top”?**
- **What if they wish to pay as a direct cost a compliance expense – IRB, audit... ?**

PERSONNEL ISSUES

- **Salary at the foreign organization is minimal how can they compete with the compensation of Drug Companies?**
- **Commitment levels to perform work above and beyond 100%?**
- **Staff hired within or outside work of the project?**

Equipment

- **What types of equipment is acceptable?**
How about a Vehicle? Copier? Desks and chairs?
- **Exempt verses Non-Exempt? Can foreign organization meet the exempt criteria?**
- **Accountability?**

Insurance

- **What kind of insurance could be allowable on a grant?**
- **What happens if the international organization or country requires insurance?**
 - **Clinical trial insurance**

Research Patient Care

- **Can Research Patient Care be part of a foreign grant or foreign consortium?**
- **Negotiation of Patient Care is at the grantee level. How should it be negotiated?**

Other Costs

- **Alterations and Renovations – unallowable? Why and what can be done?**
- **Travel – must take US carriers or US code carriers. What if it is more expensive?**
- **Duties and VAT – Unallowable, any flexibility?**
- **Fluctuation of Currency – only allowed prior to award, any flexibility?**

Requirements

- **Foreign grantee may be aware of programmatic requirements but are they aware of grants management requirements.**
 - **Rule of Thumb: If the grantee is receiving our funds we must make sure they are following our rules.**
 - **What we expect administratively can also be very different from their normal way of doing business, be very aware and help them avoid making expensive errors.**

Compliance Issues

- **Financial Conflict of Interest – What if they have none? How will you know?**
- **A-133 Audits – Does a subcontract need to comply?**
- **Banking – How can you help when dealing with tremendous inflation and/or currency fluctuation?**
- **What happens if Select Agent research is proposed?**

Select Agent Requirements

- **Awardees who conduct research involving select agents must provide information satisfactory to the NIH that a process equivalent to that described in 42 CFR 73 for US institutions is in place and will be administered on behalf of all select agent work sponsored by NIH funds before using these funds for any work directly involving select agents.**

Select Agent Requirements

- **Must address to NIH satisfaction key elements prior to use of funds. The key elements:**
 - **Safety**
 - **Security,**
 - **Training,**
 - **Procedures for ensuring only approved/appropriate individuals have access to the select agent**
 - **Any applicable local laws equivalent to 42 CFR 73**

NIAID INTERNATIONAL WEB SITE

<http://www.niaid.nih.gov/ncn/grants/int/default.htm>

NIAID International Grants and Contracts

Welcome to the International Grants and Contracts section of the [NIAID Funding Web site](#), providing funding, policy, and other timely information for NIAID's international extramural research community.

Application Resources

- [Who Can Qualify for an NIH Grant?](#)
- Electronic applications: See the [Grant Application Guide in the funding opportunity announcement](#).
 - [Grants.gov Registration Instructions for Domestic and Foreign Organizations](#)
 - [NIH eSubmission Tips for International Applicants](#)
 - [NIAID Electronic Application Resources](#)
- Paper applications: See the [PHS 398 Grant Application](#).

NIAID Resources

- [Biodefense Information](#)
- [Extramural Standard Operating Procedures](#)
 - [Foreign and International Grants and Components SOP](#)
 - [Foreign Workers on NIH Awards SOP](#)
- [Human Subjects Information](#)

Contact Information

Please use English when calling. You may email us in other languages; allow time for translation.

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NIAID Research Funding Links

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