

# Ethics in International Collaborative Research & MTA

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## What is ICR

- International Collaborative Research (ICR)
  - Research (will be) done by local researcher & other researchers from other country(ies)
  - Multicountries study
  - *NOT for samples collection only*
- Usually:
  - Use/to explore local resources → *developing countries*
  - Research funding: from outside (or can be with local contribution)

## Aim of ICR

- To solve the local health problem
- To solve the global health problem (i.e TB, HIV)
- To develop/test the product of health technology (incl. drugs development, diagnostic test)
- To identify/observe specific agent of the global diseases
- Higher education (student & supervisor)

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## Why doing IRC?

- Moral responsibility (to the developing countries)
- Capacity building
- Finding the evidence for country-specific problem
- Finding the evidence for the global problem

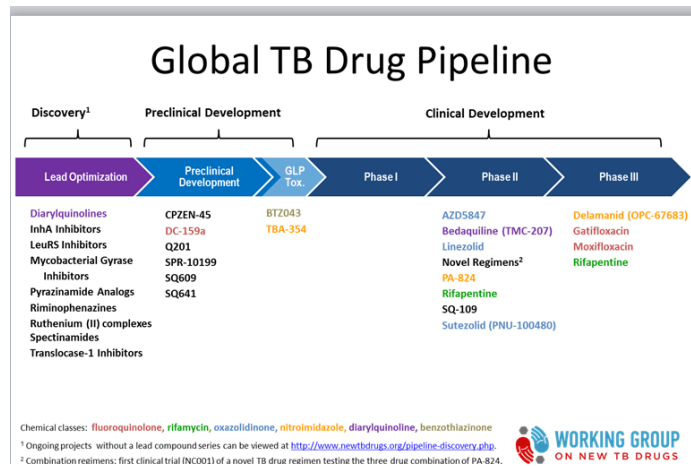


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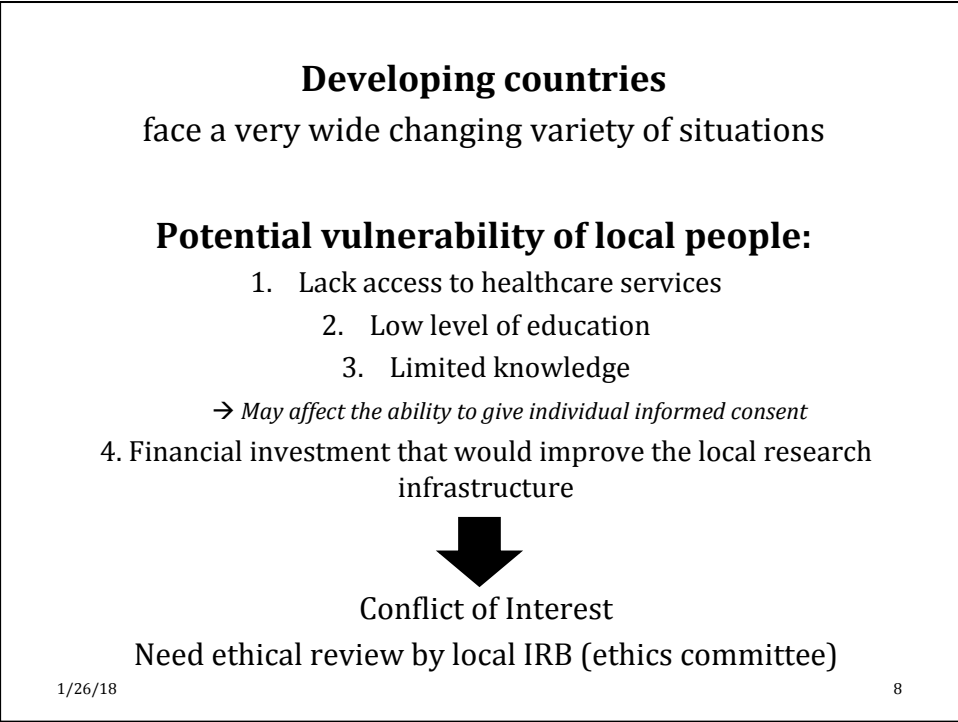
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# Research on the TB drugs



# Types of ICR





## Fundamental Ethical Considerations

The proposed research must :

1. Be responsive to the needs of the local country: added value for the health, welfare of participants/community
2. Scientifically sound
3. Relevant with international guidelines, such as Declaration of Helsinki

## Applicable legislation

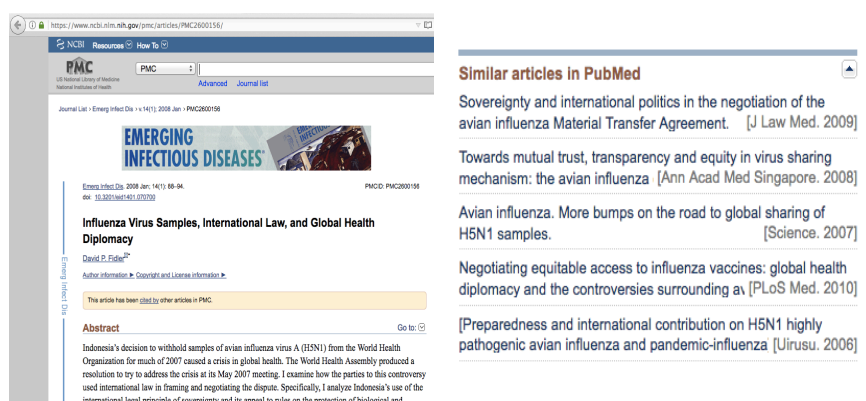
How does the research of comply with the relevant  
**international law/legal principle?**

How does the research comply with the relevant  
**national law/legal principle?**

## Benefit Sharing

1. Will the research contribute to the **development of local expertise**?
2. Does the research provide **benefits of participation** for the involved stakeholders?
3. May the research lead to the diversion of **local resources**?
4. Do **post study commitments** address of access of the participants, their communities country?

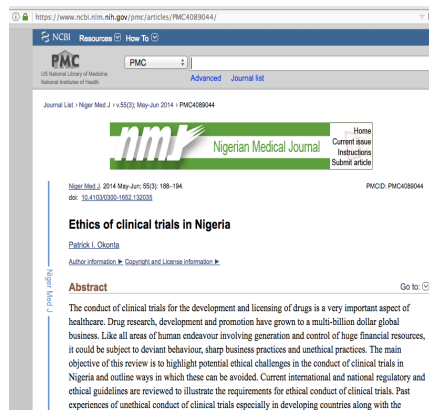
## H5N1\_Indonesian MoH\_WHO



The screenshot shows a PubMed article page. The main article is titled "Influenza Virus Samples, International Law, and Global Health Diplomacy" by David P. Sidel. The abstract discusses Indonesia's decision to withhold H5N1 samples from the WHO in 2007 and the subsequent international law implications. To the right, a "Similar articles in PubMed" section lists several related articles, including "Sovereignty and international politics in the negotiation of the avian influenza Material Transfer Agreement" and "Towards mutual trust, transparency and equity in virus sharing mechanism: the avian influenza".

# Pfizer\_Trovan\_Nigeria

Trial of new AB for Meningitis in children in Nigeria (1996)



The screenshot shows the Nigerian Medical Journal website. The article title is "Ethics of clinical trials in Nigeria" by Patrick I. Okonta. The abstract discusses the ethical challenges of clinical trials in Nigeria, mentioning issues like deviant behavior, sharp business practices, and unethical practices. It also notes that the main objective of the review is to highlight potential ethical challenges and outline ways to avoid them.



No consent  
Lower dose of drug in control arm  
Illegal trial of unregistered drug

## In Phase 1 study (drug development): subject is Healthy Volunteers

1. Potential **risks and benefits**
2. Any mechanism which can ensure that participants cannot be also enrolled in similar research at the same time
3. Standard of Care provided

## Ethical Review Process

1. Identify **local** independent relevant IRB (EC)
2. There will be **double ethics review** by the local IRB (EC) and the IRB of the sponsor's country

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## Informed Consent/Assent

1. **Written and well documented**
2. Involve **vulnerable populations?**
3. Potential **risks** clearly spelt out in the information documents
4. Potential **benefits** presented in balanced and objective way
5. **Inducement** rewards or compensation

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## Data Protection

Local PI should involve in:

1. processing of personal data
2. processing of genetic information or sensitive personal data
3. Data protection

Appropriately data ownership, storage and access

Appropriately biological samples ownership, storage & access

## MTA and MoU should be available in advance

- **MTA:** between the parties AND approved by NIHRD (Balitbangkes )
- **MoU:** between the parties (academic/research institutions, industry)

## MTA

- A contract that governs the transfer of tangible research material between parties to be used for research purposes.
  - Active compounds
  - Specimens (biological & research materials)
  - and accompanied data
- Defines the right of provider & recipients in terms of the materials & any derivate

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## Reason for MTA

- The test cannot be done in the country (**expertise/facility**)  
or...  
For **Quality Control**
- **Provider** has to be: the PI of the research
  - Need to declare the reason why sending samples outside
- **Recipient** has to make the TOR, addressed the mutual/  
sharing benefit
  - a written approval if want to send the material to the third party

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## Procedure for an MTA approval

- To the NIHRD (Balitbangkes) c.q Tim Penelaah MTA
- Attached:
  - Cover letter
  - Study protocol, Ethical approval
  - MoU
  - List of specimens ( number of tubes, @...ml, etc)
    - The purpose, test to be done
  - The draft of MTA

## 14 items in the MTA

- |                                        |                           |
|----------------------------------------|---------------------------|
| 1. Definition                          | 8. Confidentiality        |
| 2. Ownership of materials              | 9. Disclaimer of warranty |
| 3. Use of materials                    | 10. Indemnity             |
| 4. The research plan/protocol          | 11. Termination           |
| 5. Intellectual property right         | 12. Arbitration           |
| 6. Return of materials & modifications | 13. Notice                |
| 7. Publication                         | 14. Governing Laws        |

## Lessons Learnt

- Involvement in the ICR: **Do not be naïve** 😊
- Mutual collaboration:
  - Benefit sharing
  - Respectfulness
- Transparent, fair and equitable sharing of the benefits
- Role of the local IRB (and NIHRD) is substantial

*Thank you...*

