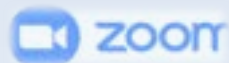




# Bioethics during COVID-19



MAESTRÍA EN BIOÉTICA

EN LÍNEA



## July 3-4

2020

15:00-18:30

Rome Time






# Ethical Challenges in Biomedical Research of COVID-19 Vaccine and Therapy

Zoom Webinar

**Prof. Alberto García Gómez**

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# OUTLINE

- 1. COVID-19 Challenges Research: Prevention and Treatment**
  - 2. Researchers' Shared Concerns**
  - 3. Shortenting the Terms: Fast Pace in Vaccine Development? Possible? Ethical?**
  - 4. Ethical Standards for Research During Public Health Emergencies**
  - 5. Some principles in respect of human dignity and human rights: Autonomy, Safety, Security, Efficacy & Justice**
- 

## COVID-19 Ethical Challenges Research

prevention & treatment

1. **Vaccine development**: to shorten the terms
2. **Massive vaccine production**: produced on a scale never before known
3. **Vaccination campaigns**: secure and massive
4. **Treatment using new and/or current drugs in combination**: Internationally, there are an estimated 200 new drugs under investigation

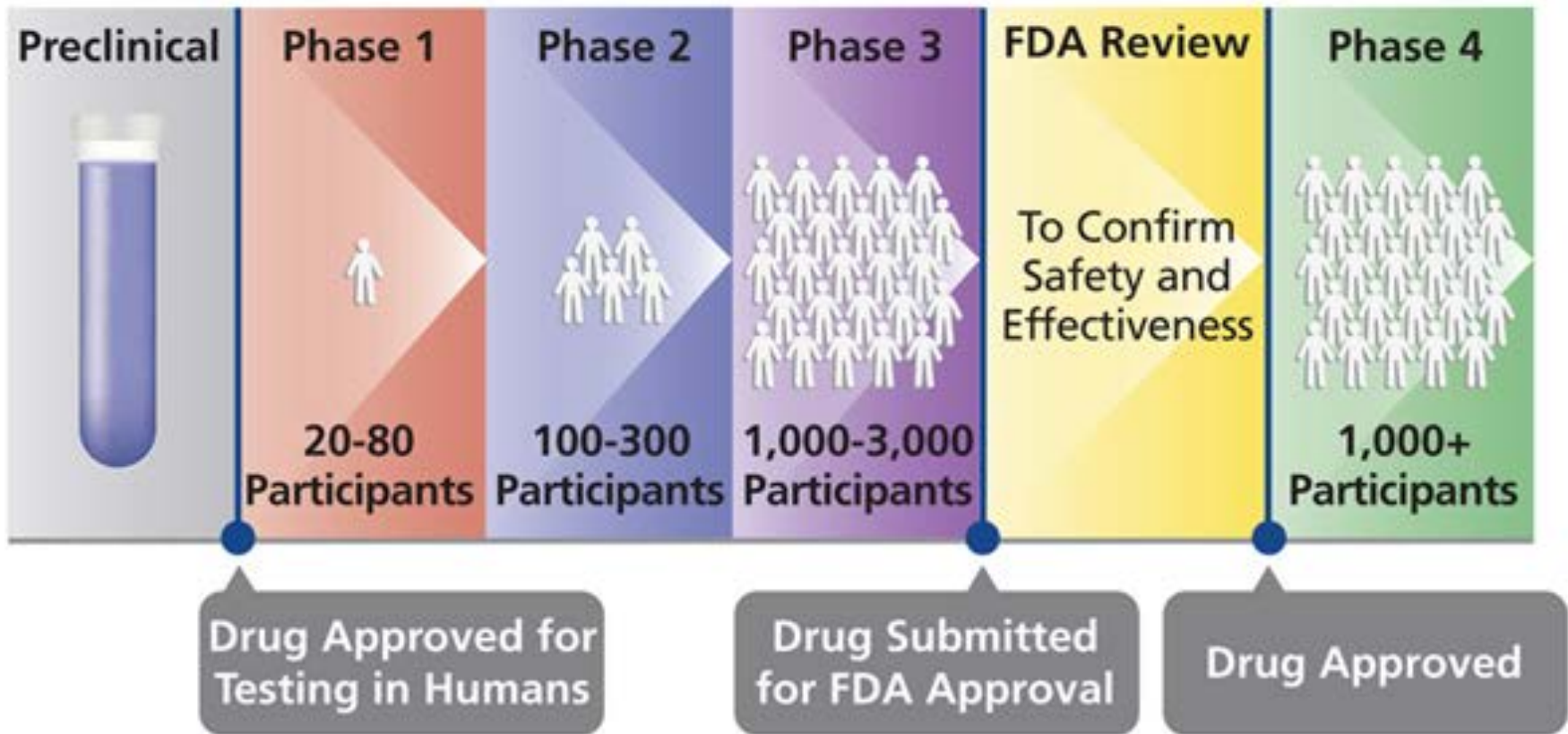
## Researchers' Shared Concerns & Ethical Challenges :

- **Arrive on time** (accelerate processes): efficacy vs success and notoriety
- **Union of forces:** comunitarian cooperation vs individual (company) profit

# Shortenting the Terms

## Biomedical Research Phases

### Clinical Trials

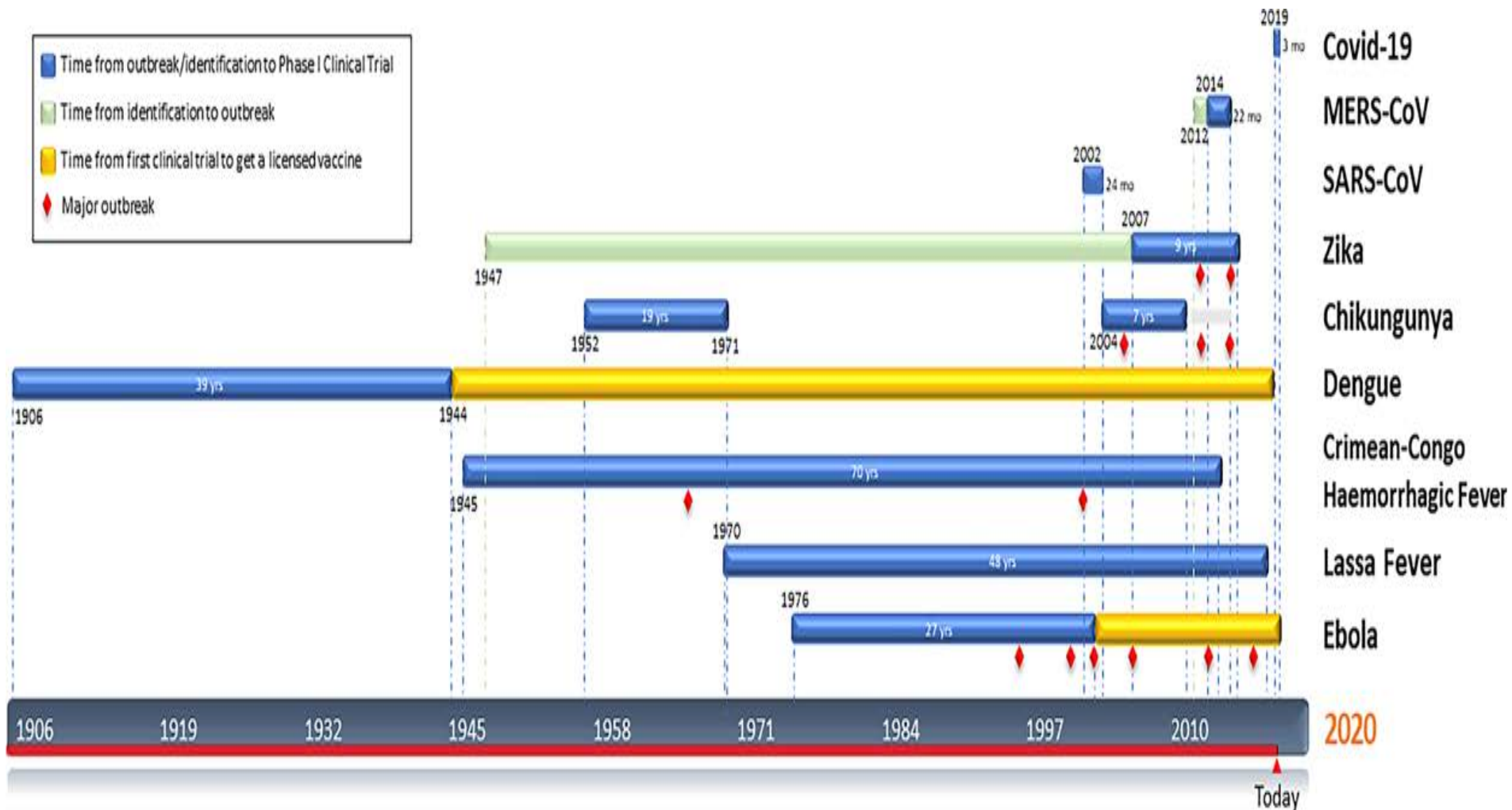
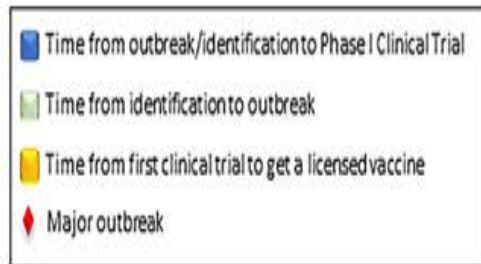




# Shortenting the Terms

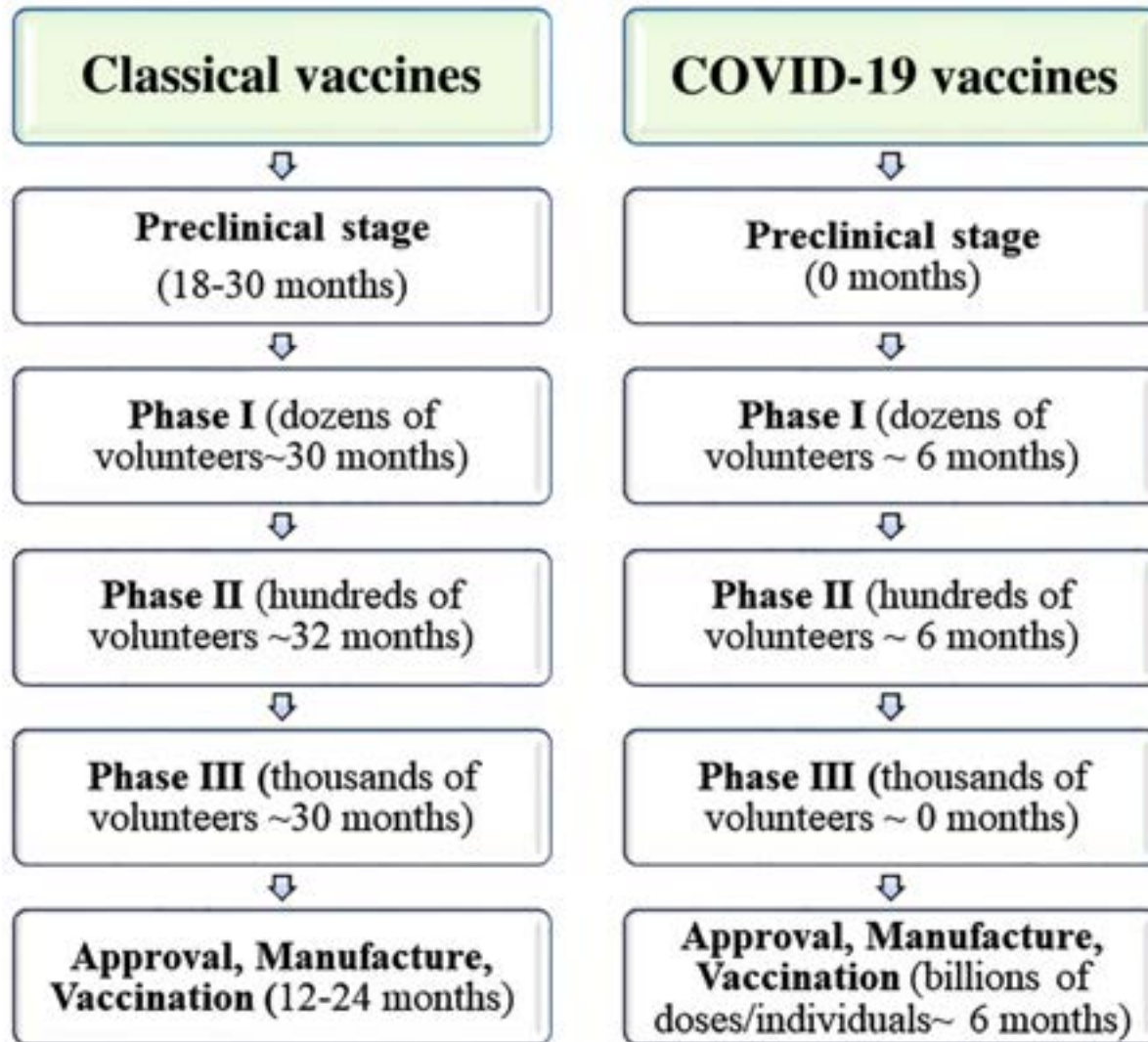
## New emerging diseases vaccine development timeline

Source: **nature**research



# Shortenting the Terms

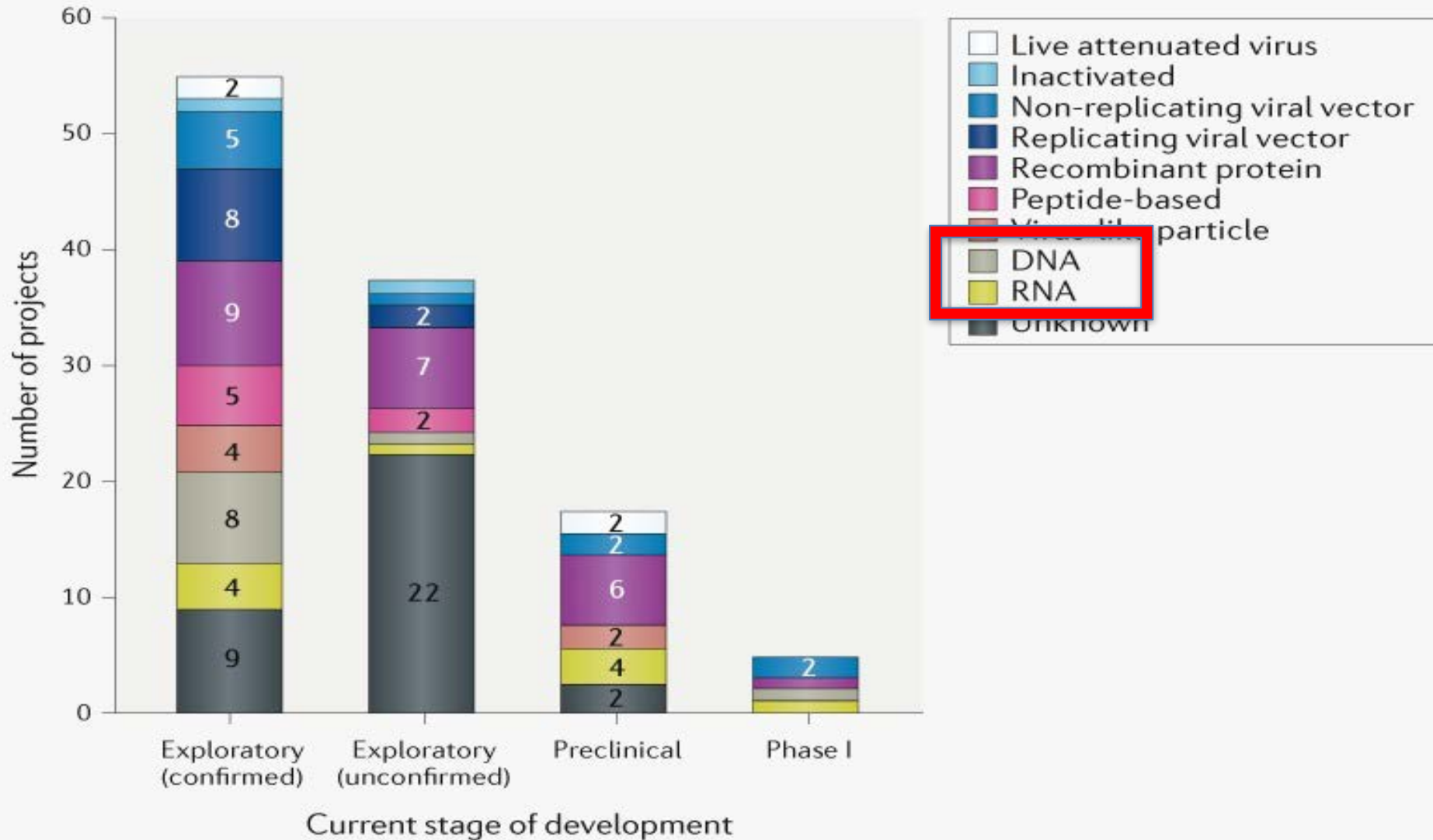
## Classical vs COVID-19 vaccines





# What is going on?

## COVID-19 vaccine R&D landscape



# A new era in vaccinology?

## COVID-19 vaccine R&D landscape

**Recombinant genetic technology has contributed to setting an unprecedented fast pace in vaccine development, clearly demonstrated during the recent COVID-19 pandemic:**

- Control of epidemics has been achieved successfully thanks to vaccines developed using various technologies, predominantly by classic pathogen inactivation or attenuation. This has worked efficiently for Cholera, Typhoid, Polio, Measles, Plague or Tetanus
- The pace of these vaccine developments is comparatively slow to that imprinted by 21st-century vaccines that use recombinant genetic technology. During the recent pandemic of COVID-19, six vaccine candidates encoding or presenting SARS-CoV-2 antigens have entered phase I clinical trials

# Ethical standards for research during public health emergencies:

Scientific validity	Social value
Collaborative partnership	Reasonable risk-benefit ratio
Fair and voluntary participation	Independent review
Equal moral respect for participants and affected communities	

- They should be adhered to by researchers, review bodies, funders, publishers, and manufacturers during an emergency
- These universal ethical standards may be adapted to particular circumstances and contexts.

# Ethical standards for research during public health emergencies:

1. Research should be conducted only if it does **not impede emergency response** efforts.
2. Research projects should be **coordinated** nationally and internationally to avoid wasteful duplication and underpowered studies
3. Fair and meaningful community **engagement** and inclusive decision-making.
4. Research involving human participants requires independent **ethics review**.
5. **Informed consent:** reasonable scientific basis to believe that the study intervention is likely to be safe and efficacious and that risks to participants have been minimized to the extent reasonably possible.

# Vulnerability in biomedical research

- Engagement of people as participants in clinical research is key in providing solutions to, and understanding of, medical problems afflicting humankind
- The **interests of researchers and subjects are not always aligned** as they are in the relationship between healthcare professionals and patients
- Strong desire to pursue useful generalisable knowledge gives rise to the **temptation to under-protect or ignore the participants' well being**



## What we should do in respect of the vulnerable?

- To **identify** individuals and groups exposed to be negatively affected: harmed, threatened or at risk in their well-being and basic needs.
- To assume **commitment to identify threats** to well-being and appropriate means to foster human dignity, human rights and fundamental freedoms
- To **mitigate threats** to the vulnerable persons, or **eliminating the conditions** that underlie vulnerability.
- To **protect** from all forms of exploitation or abuse, but at the same time must not be excluded from potential benefits of research



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