ETHICAL CONSIDERATIONS FOR ECONOMIC/FINANCE/PROJECT EVALUATION/HEALTH SYSTEMS STUDIES

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RATIONALE

Should Research Ethics Committees (RECs) require researchers to incorporate/expand their existing standard operating procedures (sops) on how they intend to protect individuals who will be providing financial information which may include:

Illegal

Waste

Fraud/Corruption

Immoral

Illicit/Bribes

Unsafe

Abuse of funds/Financial Management Act

WHICH STUDIES WOULD BE AFFECTED?

Implementation sciences
- Compliance to Guidelines
- Barrier Assessments
- Health Systems Strengthening/Health Economics/Human Resource for Health
- Quality Improvement/Assurance through large scale Audits

Medical sciences
- Clinical Trials (reimbursements/consent forms)

Pharmacy
- Stock Management and Logistical flows

Public Health/Prevention Health
- Criterias not followed for life saving preventative interventions

Service Delivery Evaluation/Scoping studies
- Patient satisfaction surveys

Social Worker/Social Behaviour sciences
- Dealing with homelessness, vulnerable children, addictions etc.

RATIONALE

THE POST-COVID AGENDA

THERE HAS BEEN A SHARP INCREASE IN 'RESEARCH' SINCE COVID-19 PANDEMIC. THAT OCCURRENCE ALONE HAS EXPOSED PARTICIPANTS AND RECS TO REVOLVING AND UNFINISHED BUSINESS WHICH MAY NEED TO BE REVISED, EVALUATED AND PERHAPS IN THE FUTURE COMMISSIONS ESTABLISHED.

SEVERAL AGENDAS WILL ARISE POST-COVID SEEKING TO BETTER UNDERSTAND, MEASURE AND PREVENT:

- EFFECT ON PEOPLE & GOVERNMENTS
- VIRUSES AND HOW THEY SPREAD
- LONG-TERM HEALTH OUTCOMES FOR VACCINATED VS UNVACCINATED PEOPLE

R&D Blueprint

International Clinical Trials Registry Platform (ICTRP)

COVID-19 Emergency Use Listing Procedure

Regulatory update on COVID-19

Unity Studies: Early Investigation Protocols
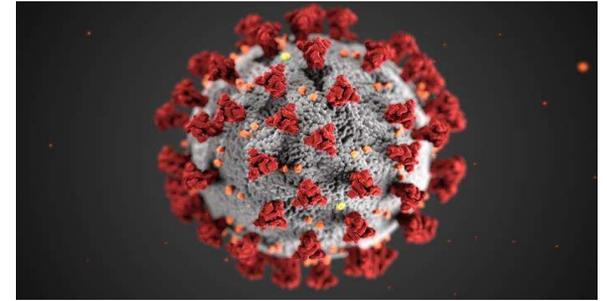
" The short-term implications of this global challenge are evident everywhere, but the long-term consequences of the pandemic — how it will reshape health and development institutions, occupations, and priorities — are still difficult to imagine.": Devex article

IS THIS EVEN A PROBLEM?

THE IGNORED PANDEMIC OF PUBLIC HEALTH CORRUPTION: A CALL FOR ACTION AMID AND BEYOND SARS-COV-2/COVID-19

ABSTRACT

Corruption in healthcare is on the rise. When corruption infiltrates global health, causes embezzlement of public health funds, malfunctioning medical equipment, fraudulent or ineffective health services such as expired medicines and fake vaccines that could have life-or-death consequences. A corrupt healthcare system, amid global health crises like the COVID-19 pandemic, when resources are in constraint and trust is in high demand, can lead to devastating, though avoidable, health and economic consequences. It is imperative for policymakers, health experts, patients, caregivers, and global health funders to promptly acknowledge and address corruption in healthcare. The current pandemic generates an emergency and disorder state on health care systems across the globe, especially in low- and middle-income countries, where a weakening of control measures is evident, creating the perfect storm for corruption. This paper builds on existing research to examine processes that support essential stakeholder engagement in anti-corruption efforts. In this context, an extensive review of literature has been conducted by using various databases such as PubMed, Science direct, SCOPUS, Research Gate, and Google Scholar and a total of 45 articles and documents on corruption and COVID-19 were screened and selected by authors independently. To fill the knowledge gaps about the need for actions to be taken during a pandemic like COVID-19, we propose an anti-corruption grassroots movement that focuses on changing the social norms surrounding corruption in healthcare. By pushing forward a practice that normalizes conversations about corruption in everyday health practices and involving more stakeholders in the protection of public health resources, we argue that not only local health systems can become more resilient and resistant to corruption, but also global health initiatives can become more effective and efficient to improve individual and global health.

IS THIS EVEN A PROBLEM?

Review > Cochrane Database Syst Rev. 2016 Aug 16;(8):CD008856.
doi: 10.1002/14651858.CD008856.pub2.

## Interventions to reduce corruption in the health sector

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Affiliations + expand

PMID: 27528494   PMCID: PMC5014759   DOI: 10.1002/14651858.CD008856.pub2

Free PMC article

Difficult to quantify due paucity of published work
No guidelines for RECs
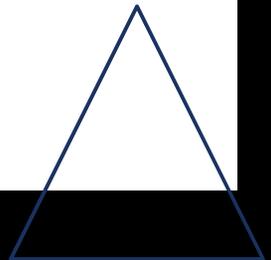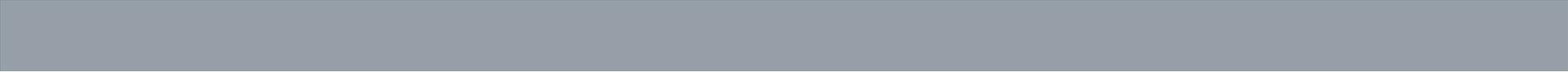
WHAT COULD BE THE ROLE OF RESEARCHERS

WHAT ROLE DO RESEARCHERS HAVE?

- Declare conflict of interest truthfully
- Incorporate independent reviews of protocols before REC
- Follow legal routes/guidelines about reimbursements/payments
- Scale the risk level of your study properly
- Employ research staff with enough experience for the work to be done
- Update relevant ethics certificates and possibly invest in the latest ethics trends

WHAT COULD BE THE ROLE OF REC

WHAT CAN REC DO?

Ireland's first national research ethics committees established

Published 15 July 2021

The Minister for Health has appointed the membership of Ireland's first National Research Ethics Committees (NRECs) in the areas of Clinical Trials of Investigational Medicinal Products (NREC-CT) and Clinical Investigations of Medical Devices (NREC-MD).

In total, 18 members have been appointed to each of three NRECs - two in clinical trials and one in medical devices. The members include eminent experts from legal, academic and medical backgrounds.

The NRECs will review applications submitted through the National Office for Research Ethics Committees, and the National Office will support the new Committees in their work. Established last year, this new office is playing a key role in the reform of the research ethics review framework in Ireland, in partnership with the Department of Health.

The committees will be responsible for reviewing the ethics underpinning research proposals in these important areas of health research, with the aim of providing single national ethics opinions that are respected nationally.

The establishment of these NRECs comes at an important juncture, as Ireland will soon be required to meet new obligations under two upcoming EU Regulations: the EU Medical Device Regulation, which came into force on 26 May 2021 and the EU Clinical Trials Regulation which will come into operation on 26 May 2022.

Have within its processes robust benchmarking: 4 main types - **Performance, Practice, Internal & External**	Have internal policies that require **broader representation** including Health economics/Quality Improvement or Assurance etc
Having an updated **Whistle-blower SOP** which is known by Researchers and the public	Have **public learning resources** with links for real-time assistance
Have **anti-corruption & transparency** declaration pop-ups frequently in the website	Establish **mentoring programs** for junior, inexperienced & upcoming researchers (perhaps matching their CVs)

DISCUSSION & Q/A

DISCUSSION: LOOKING FORWARD

- Is your study a high-risk in that it might expose any corruption relating to running of state funds/mismanagement in service delivery?

- What can RECs and Researchers do to protect participants in such contexts?