









CONFLICT OF INTEREST IN HEALTH RESEARCH

TOOLKIT

Introduction and Brief Overview

Presentation by Dr Amina Jakoet Saban

Tues 24 and Thurs 26 September 2024



Getting the green light for ethical health research

A toolkit to identify, address, manage and mitigate conflicts of interest

Dr. Amina Jakoet Saban Prof. Leslie London

AUTHORS and CONTRIBUTORS

Dr. Amina Jakoet Saban, University of Cape Town
Prof. Leslie London, University of Cape Town
Prof. Marc Blockman, University of Cape Town
Prof. Keymanthri Moodley, Stellenbosch University
Prof. Stephen Okeyo, Great Lakes University of Kisumu
Prof. Godfrey Tangwa, Cameroon Bioethics Institute
Prof. Jihad Makhoul, American University of Beirut
Mr Abraham Opare, University of Cape Town
FUNDER: IDRC

AIM OF TOOLKIT

To provide:

Guidelines to identify and manage Cols in health research

Tools and mechanisms to strengthen institutional capacity to address Cols



Mainly staff of RECs and SGCs in SSA

But, can be used by others/elsewhere engaged in health research

TOOLKIT IMPORTANCE

To protect integrity of health research from Cols

To ensure researcher independence

To preserve the spirit and purpose of science

TOOLKIT GOALS

1

Increase awareness of CoI in health research

2

Provide access to resources to manage Col

3

Build/increase capacity to address Col

WHY FOCUS ON RECs and SGCs?





These institutions are pivotal in scientific research process

RECs review/assess research protocols, SGCs manage funding



Can determine policies for research engagements and partnerships

Can preserve research integrity and partnership equity

TOOLKIT SOURCES



1. Project experiences and findings



2. Literature



3. Expert opinion



4. Other toolkits

TOOLKIT STRUCTURE

Intuitively logical

Introduction

Context

0

Funding sources

Assessment process

Step 1: Assess risk of potential internal conflicts of interest

Step 2: Assess risk of potential external conflicts of interest

Step 3: Assess for conflicts of interest in the research process

Governance processes

Each section contains a table with strategies for management. The tables use a traffic light system, with







Prohibit

Disclose and manage

Throughout the toolkit icons are used to indicate:







Definition

Case study

Checklist

We have also added resources with links for easy access.



Toolkit: more details

https://health.uct.ac.za/school-public-health/conflict-interest-health-research

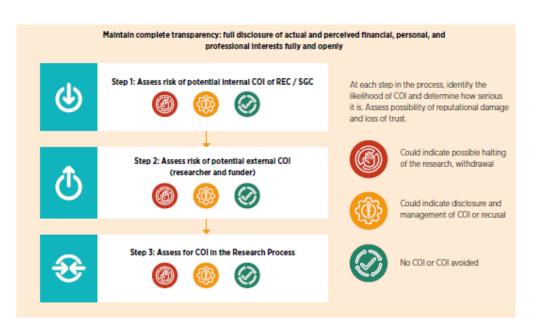
Getting the green light for ethical health research

A toolkit to identify, address, manage and mitigate conflicts of interest

- Definitions
- Case examples
- A guide to the assessment process

Red Light	Amber light	Green Light
Moral certainty – No go	Moral uncertainty – make an assessment	Moral Certainty – ok to go
Funding from organisations whose products are health harming; and have interest in outcome.	May have interest in outcome but no financial benefit; or funding topic unrelated to its business	funder has no interest in the study outcome and does not produce health harming commodities

Assessment – is there any internal COI?pg17/18



Management actions

Screen members; exclude if employment conflict

Disclosure, recusal, whistleblow mechanism

Policies to protect REC independence

- Will anyone on the REC / SGC benefit financially from the research or from having the research protocol approved or rejected?
- Is anyone on the REC / SGC associated in any way with the funder or research community?
- Is anyone on the REC / SGC associated with a third party (e.g. family member) who stands to benefit financially from having the research proposal approved/rejected and/or having the research conducted/postponed/cancelled?
- Is anyone on the REC / SGC engaged in research similar to, or associated with, the content of the research protocol?
- Does anyone on the REC / SGC serve as a consultant for an organisation involved in the funding or implementation of the proposed research?
- Will anyone on the REC / SGC be associated with the drafting and/or dissemination of findings and outputs of the research?

Assessment – is there any external COI?pg20

Financial:

- Will a third party) benefit financially?
- Will anyone avoid a financial loss as a result?
- In whose best interest is the research/ contract?

Material:

- Is research quality compromised to favour anyone?
- Is process to select the preferred product provider fair?
- Are the research funder's products known to produce harm?

Opportunity:

- Why is a particular community selected?
- How were the collaborating partners / funders selected?
- What process was followed in selecting research staff?

Outcomes and Outputs:

- Who will manage the data analysis?
- Who will draft outputs (manuscripts, policy briefs, media statements)?
- Will researchers retain independence in the conduct, analysis and write up?

Management actions



Disqualify from part / all
Prohibit problematic sponsor relationships
Proscribe any funder veto on publication



Disclosure, recusal, whistleblow mechanism



Independent committees to review

Training to researchers to identify and avoid accepting COI

Assessment – is there COI in the research process? pg22

- Is the research question appropriate to the problem?
- Is the design likely to give only one result?
- Are all the data authentic and accessible?
- Does the researcher hold a position in the enterprise likely to benefit?
- Does the cost-benefit ratio consider harms or benefits to the broader community and the health system?
- Have key stakeholders been deliberately overlooked?

Management actions



Exclude funder from participating in study design or write-up

Exclude researchers failing to follow COI SOPs

Disciplinary procedures where indicated.



Disclosure to participants; conference audiences; regular reporting by researcher; monitoring by REC; extend to journals in their review process



Independent committees to monitor study; contract must ensure access to anonymised data; capacitate junior researcher(s)



TOOLKIT: PERTINENT PAGES



Page 9: Actual/Perceived/Outcomebased COI

Page 14: Managing Funding Sources

Page 17: Checklist to Identify COI

Page 18: Internal COI

Page 20: External COI

Page 24: Governance and Policies

SOME RESOURCES

Toolkit and online course on COI at https://health.uct.ac.za/school-public-health/conflict-interest-health-research

Governance, Ethics and Conflict of Interest in Public Health Network (GECI-PH) at https://www.aub.edu.lb/fhs/Pages/GECI.aspx.

WHO: Safeguarding against possible conflicts of interest in nutrition programmes at https://apps.who.int/gb/ebwha/pdf files/EB142/B142 23-en.pdf

Attitudes and practices of public health academics towards research funding from for-profit organizations: cross-sectional survey. International Journal of Public Health 2020;65(7):1133-1145 at https://link.springer.com/content/pdf/10.1007/s00038-020-01416-0.pdf

A call to advance and translate research into policy on governance, ethics, and conflicts of interest in public health: the GECI-PH network. Global Health. 2021 Jan 25;17(1):16 at https://globalizationandhealth.biomedcentral.com/articles/10.1186/s12992-021-00660-0

Contact <u>asaban@mweb.co.za</u> for more information

NEXT STEPS





PRACTICAL USE OF THE TOOLKIT

SKETCHED SCENARIOS/
INTERACTIVE SESSION

