Getting the **green light** for ethical health research

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

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Foreword by Dr Lindiwe Elizabeth Makubalo, Assistant Regional Director, World Health Organization Africa Office (WHO-AfrO)

The ethical conduct of health research is essential for ensuring the safety and well-being of research participants, as well as the integrity and credibility of the research itself. The increased demand for research as a result of globalization, emergence of pandemic diseases and technological advances emphasizes the need for this toolkit to guide ethical conduct in the endeavour of research, and to identify, manage, and mitigate conflicts of interest (COI). Conflicts of interest can arise in various forms, such as financial, professional, or personal, and can have a significant impact on the conduct and outcomes of research.

This toolkit is designed to provide guidance 'at a glance' for individual researchers, research institutions, and funding organizations, and covers a wide range of topics, including the definition and types of conflicts of interest, the identification and assessment of conflicts of interest, and the development and implementation of policies and procedures to manage and mitigate conflicts of interest.

The World Health Organization and many other institutions, have provided various forms of guidance on the ethical conduct of research. This toolkit provides further practical guidance to protect the integrity of health research from COI and ensure that researcher independence is not dominated by third party interests that oppose the spirit and purpose of science.

This toolkit is a valuable resource and will contribute to the advancement of knowledge and the improvement of health outcomes and truly contribute to achieving 'Health for All'. It is recommended to researchers, research institutions, and funding organizations as a valuable resource for ensuring the ethical conduct of health research.

Preface by Dr Ahmed Ogwell Ouma, Acting Director, Africa Center for Disease Control and Prevention (CDC)

Thank you for putting together a group that has been working on this very important area of work on health research, around building the skills and the capacities for ethics committees and the science councils in Africa.

Let me start by confirming to you that the Africa CDC is a true partner in ensuring that we build our capacities for health research on the continent of Africa. One of our very key mandates is generating evidence and using it for prevention, preparedness and response to disease threats. This work is extremely valuable in the way that we are going to plan and execute our mandate as Africa CDC.

I am also pleased to be part of the Advisory Committee for this project on building the capacities for our regulatory bodies for health research here on the continent, and I am really looking forward to seeing the progression in capacity from now to the time after we have engaged and intervened here on the continent.

The importance of research cannot be gainsaid because, without it, we cannot generate new ideas; we cannot generate new paths of thought and action, particularly within the health sector. Research is key to progress. Health research similarly is not just key to progress, but it is critical to ensuring that we protect human life and that we protect our environment.

We must do research that is relevant to our situations and contexts, and we must use that research in a way that improves the way in which we live.

Evidence generated, evidence used, results in better lives for all of us; and this speaks directly to our mandate as Africa CDC to safeguard the health of Africa.

We need to tighten regulation on the continent so that our research can improve in terms of design, and, therefore, the results of this research will be exactly what you intended them to be. We do not want research that will not be able to withstand the test of professional scrutiny.

We also want our research and ethics institutions to provide oversight. Oversight is extremely important because we are dealing with human life; and while working to improve health, we need to make sure that institutions have the right tools, the right experience, the right government structures, and the right support. We must ensure that all these are present, so that our research within Africa is at a level that can compare with the best standards globally.

At the continental level as Africa CDC, we are committed to making sure that the evidence being produced here on the continent can withstand any professional scrutiny. We are committed as Africa CDC to support our member states in ensuring that there is oversight, and guidance for research.

We do this because our mandate provides us with the right opportunity to contribute to better research generation here on the continent. We are also doing this, not just because it is our mandate, but also because this continent needs good research.

We have many health challenges; we have many challenges within the environment and the communities, and we must ensure the research happens smoothly and is adapted to our needs and contexts.

We are persuaded that, for us to be able to achieve more, and achieve it faster and more effectively, we must do things differently. We capture this in our vision.

The New Public Health Order has five pillars:

The first pillar is to strengthen institutions on the continent, whether they are Public Health Emergency institutions, agencies of health at national level; we need stronger institutions to generate good evidence and to use that evidence.

The second pillar is the strengthening of our health workers. We need to train all cadres that are necessary for public health emergencies. This includes researchers, and we must train them and give them the right tools.

The third pillar is local manufacturing of all health products. Research will ensure that we innovate and generate intellectual property.

The fourth pillar is domestic financing. We must get our governments, private sector, to invest in health, including research.

The fifth pillar is respectful action oriented partnerships. Partnerships must be functional, and action-oriented, and must be based on the needs and priorities of our countries; let us base it on the needs of public health.

The New Public Health Order is being implemented currently by Africa CDC and member states across the continent, and I am asking you, as researchers, to join us in ensuring that every researcher is going to look at African public health based on our priorities, and is part of the capacity building of local institutions here in Africa.

I would like to wish you the very best.

Thank you.

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ABBREVIATIONS

COI Conflict of Interest
REC Research Ethics Committee
SGC Science Granting Council

Introduction

This section outlines the aim, audience, goals, and importance of the toolkit. It indicates why we have chosen to focus the toolkit for Research Ethics Committees and Science Granting Councils, and provides a breakdown of the structure of the toolkit.

WHAT IS THE AIM OF THIS TOOLKIT?

The aim of the toolkit is to provide:

- a set of guidelines, case examples and checklists to identify, address, and manage conflicts of interest in Health Research
- tools and mechanisms to strengthen the capacities of Science Councils and Research Ethics Committees

WHO CAN USE THIS TOOLKIT?

The toolkit is a user guide for staff in **Science Granting Councils and Research Ethics Committees**, particularly in sub-Saharan Africa. However, these guidelines may also be useful for institutions outside of the sub-Saharan African region, as well as for institutions other than those engaged in health research, such as funders of research, governments and other stakeholders. We welcome feedback on the toolkit from all users.

WHY IS THIS TOOLKIT IMPORTANT?

The guide serves to:

- protect the integrity of health research from conflict of interest
- ensure that researcher independence is not dominated by third party interests that oppose the spirit and purpose of science.

WHAT DO WE HOPE TO ACHIEVE WITH THIS TOOLKIT?

The toolkit has several goals:

- Knowledge-sharing – to **raise awareness** on conflicts of interest in health research, and to provide access to resources.
- Capacity building - to increase the capacity of institutions to **recognise and identify** conflicts of interest.
- Facilitating resource production - to increase the capacity of institutions to **respond** to conflicts of interest and **mitigate** the potential effects of conflicts of interest.

WHY IS THIS TOOLKIT NECESSARY?

Research findings from an online survey and in-depth interviews with senior representatives from sub-Saharan African Science Granting Councils and Research Ethics Committees indicated **the need for an increase in capacity to identify, address and manage conflicts of interest** in their institutions.

WHY FOCUS ON SCIENCE GRANTING COUNCILS AND RESEARCH ETHICS COMMITTEES?

Organisations such as Science Granting Councils (SGCs) and Research Ethics Committees (RECs) play key roles in sustaining science and health research. These organisations may represent the interests of a government but may also take account of the interest of the country's scientific community. The roles of SGCs and RECs provide a unique **opportunity for these organisations to develop policy, and assess, manage and enforce rules affecting research partnerships**. They may also help to protect independent health research and the reputation, integrity and equity of research partnerships.

WHAT ARE RESEARCH ETHICS COMMITTEES

Research Ethics Committees, known in some countries as Institutional Review Boards, are usually attached to academic, commercial or government institutions. They review research proposals and provide guidance for ethical and scientific standards.

WHAT ARE SCIENCE COUNCILS?

Sometimes referred to as Public Research Institutes[1], Science Councils drive, catalyse and accelerate research and development, and serve State and other stakeholders' need for new knowledge[2]. When they provide funding for research, they serve as Science Granting Councils (SGCs), that review, approve and monitor research grants. The exact terms of reference of SGCs are usually country-specific.

WHAT SOURCES HAVE WE USED FOR THIS TOOLKIT?

This toolkit is drawn from several sources:

- the findings from an online survey and in-depth interviews conducted with senior representatives of sub-Saharan African SGCs and RECs
- findings from related literature
- expert opinion
- other toolkits and/or guidelines on the topic or on similar/related topics

WHAT ARE THE GUIDING PRINCIPLES FOR THIS TOOLKIT?

The toolkit is guided by the general principles for the ethical conduct of research. In addition, it is important to take note of[3]:

- **Place:** use in a relevant context
- **People:** use is intended to respect and benefit people
- **Principles:** use is guided by good practice and values
- **Precedent:** use is guided by evidence

The toolkit is intended for use as a dynamic asset as part of an iterative process guided by findings from its practical application in institutions.

WHAT IS IN THE TOOLKIT?

The toolkit is divided into several sections:

- Introduction
- Context
- Funding sources
- Assessment process
  - » Step 1: Assess risk of potential internal conflicts of interest
  - » Step 2: Assess risk of potential external conflicts of interest (between researchers and funders)
  - » 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, adapted from previous attempts to address COI by characterizing sources of funding by colour code[4] or to present a heuristic shortcut that obviates the need for the user of the research finding to read the usually long COI statement[5]. Red signals prohibition; Green signals resolution or mitigation achieved; while Amber / yellow signals the need to manage the COI through disclosure and other methods. However, we also use the colour codes to flag the directionality of moral reasoning in evaluating the risk-benefit ratio.

Prohibit

Disclose and manage

Resolve / Mitigate

Both "Prohibit" and "Resolve / Mitigate" represent situations where there is moral certainty in deciding. In the former case, the clear decision is to prohibit the study; in the latter, the clear decision is to allow the study to proceed but with measures to resolve or mitigate. In the middle condition (amber colour – "disclose and manage"), there is moral uncertainty. Here, there must be careful consideration of the case, drawing on ethical codes, local and national policies, legal principles and ethical reasoning, to decide the best course of action.

Throughout the toolkit icons are used to indicate:

Definition

Case study

Checklist

We have also added resources with links for easy access.

We hope that this toolkit will help you to develop policy frameworks and operating procedures for conflicts of interest, or to refine existing policies and procedures.

The central goal of conflict of interest policies in health research is to **protect the integrity of professional judgment and to preserve public trust** rather than to try to repair bias or mistrust after it occurs[6]. The disclosure of individual and institutional financial relationships is a critical but limited first step in the process of identifying and responding to conflicts of interest. If health institutions do not act voluntarily to strengthen their conflict of interest policies and procedures, the pressure for external regulation is likely to increase.

WHAT SHOULD YOU CONSIDER FOR DEVELOPING A CONFLICTS OF INTEREST POLICY FRAMEWORK?

The following list provides points to consider when developing or refining a policy framework:

- Identify the goal and scope of the policy.
- Develop an operational definition of conflicts of interest for the organisation or institution.
- Identify possible situations of conflicts of interest applicable to the institution, both internally within the organisation and in the institution's engagement with external partners.
- Develop mechanisms to prevent, identify and manage conflict of interest in health research, including guidance on matters requiring recusal from decision-making and other strategies to limit conflict of interest.
- Guidance should also be explicit on situations where COI is severe, cannot be remediated and therefore the research should not be approved.
- Provide processes that implement the policy (e.g. standard operating procedures or SOPs).
- Pay attention to confidentiality for those involved in conflict of interest.
- Provide training in the identification, prevention, and management of conflicts of interest (which should be done as part of ethics training in general).
- Demonstrate commitment to policy from management and obtain written agreement from staff.
- Establish a culture of security and trust to facilitate conflict of interest disclosure.
- Develop mechanisms to assess and monitor implementation of the policy.
- Develop mechanisms to identify breaches of policy.
- Engage all stakeholders and secure their buy-in for the development of the policy.

Context

This section explains different types of conflicts of interest and explains how they may threaten research integrity. It looks at the importance of managing collaboration between industry and health research institutions.

Research is key to promoting and improving health and preventing disease. The role of research is vital for addressing the rapid rise in non-communicable diseases[7]. This is particularly important in regions such as sub-Saharan Africa[8] where public health endeavours can benefit from collaborative partnerships between clinicians, medical researchers, scientists, engineers, pharmaceutical companies, biotechnology and medical device companies. However, the skilful, ethical and efficient conduct and management of these partnerships and collaborations are essential in preserving scientific rigour and research integrity.

An important way to preserve scientific rigour and research integrity is to address **Conflict of Interest (COI).**

WHAT IS CONFLICT OF INTEREST (COI)?

COI can be defined as a conflict between the private interests and the official responsibilities of a person in a position of trust (Merriam-Webster), where circumstances create a risk for professional judgements or actions regarding a primary interest to be unduly influenced by a secondary interest[9]. A COI involves a ***potential for a breach of trust*** *and can occur independently of any impropriety actually taking place. COI can, therefore, be defused, managed or avoided by intervention that precedes impropriety[10]. However, this requires that the potential or risk for a COI, or the COI and its potential consequences, be identified, recognized, acknowledged and managed effectively[11].*

ARE THERE DIFFERENT TYPES OF CONFLICT OF INTEREST?

There are three different types[12] of COI

- An **actual** conflict of interest is when a stakeholder has the potential to overly influence research through the monetary or material benefits it presents to other research partners.
- A **perceived** conflict of interest is when a stakeholder has the potential to overly influence research through the non-monetary or non-material influences it has on other research partners.
- An **outcome-based conflict** of interest is when a stakeholder, involved in the policy-making or policy-implementation process, looks for outcomes that are inconsistent with the demonstrable public interest. This applies to issues where there is consensus on the public interest and where a particular stakeholder pursues goals that are in contradiction with that interest.

HOW DO CONFLICTS OF INTEREST THREATEN RESEARCH INTEGRITY?

COIs, if not identified and appropriately managed, can have serious and far-reaching consequences. These include:

- undermining of public health policies
- reputational damage to researchers and/or research institutions
- putting human research subjects in harm's way
- failure of research systems to protect the independence of researchers from third party pressures if independent research findings are unpopular or disruptive to powerful entities in society.

HOW DO RESEARCH PARTNERSHIPS WITH INDUSTRY RELATE TO CONFLICTS OF INTEREST?

An extensive literature points to the role of corporates involved in the tobacco, alcohol, gambling and ultra- processed food and drink industries in seeking to influence public health policies so as to protect the company's profitability[13, 14, 15]. This has translated in the research arena into corporate efforts to influence how research into non-communicable disease can be shaped to avoid or limit adverse impacts on their commercial interests[16, 17].

However, not all industry-funded research is inevitably questionable. Industry-funded research can be conducted transparently and without interference and can lead to important scientific contributions[18]. However, it is important for research partnerships to be carefully analysed to avoid, minimize or manage any conflicts of interest.

The case study[19] below provides an example of an industry related COI.

CASE STUDY: REVIEW OF VITAMIN D SUPPLEMENTS AND SUSCEPTIBILITY TO SARS-COV-2 INFECTION OR COVID-19 OUTCOMES

A systematic review of studies that assessed vitamin-D supplementation with COVID patients found no robust evidence of the association between vitamin-D levels and severity of symptoms or mortality due to COVID-19. However there were clear indications of bias towards prescribing Vitamin-D.

COI: Associations with the pharmaceutical and/or food industries.

It is particularly important to manage collaboration between industry and health research institutions when the core business of the involved industry is to increase sales of its products, and the nature of the industry's products is known to have the potential for harm (such as the products of the tobacco, processed food and beverage alcohol industries). This could compromise research partnerships. Thus, it is important that organisations and institutions, as potential research partners with industry, are well-trained and adequately-resourced to identify, address and manage COIs, if and when, they occur.

Other examples of how industry can undermine or influence research integrity are outlined as follows:

- Funding research by recruiting scientists with a good reputation to benefit from their credibility.
- Association with organisations that have credibility and securing opportunities to influence research protocols.
- Funding research using questionable methods[20] that contradict results of existing credible science, causing doubt and confusion[21] amongst consumers of research findings.
- Deliberately stalling policies to mitigate against the effects of harmful products.
- Intimidation of critics. For example, in Colombia and Mexico, researchers who proposed a tax on sugary drinks received threatening phone calls and had their computers hacked[22].
- Receiving funding from an organisation that is known to produce products that cause harm when used/consumed, and, thereby, compromises research integrity by being complicit in the harm, providing the organisation with authority.
- Pressuring researchers to publish findings that favour the research funder, and to withhold findings that reflect the funder in a negative light, under threat of funding withdrawal.

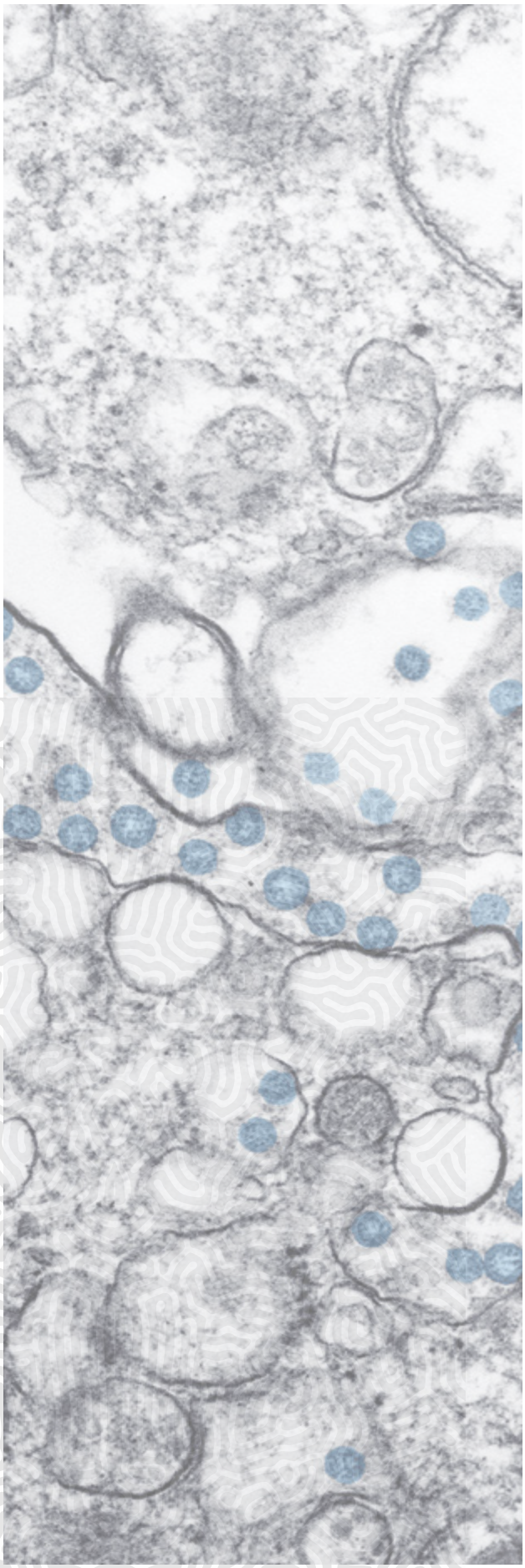
- Engaging with institutions of higher learning and offering increased revenue to institutions that are financially constrained, while seeking to influence the conduct, conclusions, and dissemination of the institution's research, to the industry's advantage[23].

WHAT STRATEGIES CAN BE USED TO ADDRESS CORPORATE DOMINANCE?

Conflict of interest in health research needs to be identified, recognised and acknowledged so that it can be effectively addressed. Public health scholars, Research Ethics Committee members and Science Granting Council staff and representatives need broad knowledge of the research context, including: (a) the social and commercial determinants of health; (b) an understanding of the diverse systems (political, legal and economic) that underpin, drive, enable and perpetuate public health outcomes; and (c) collaborative strategies to address COI, which we hope everyone will be prepared to engage in.

Here are some strategies[12,22]:

- Promote **public health political activism** to counter corporate control of policy making and research processes.
- Advocate for use of state levies and taxes on tobacco, alcohol, and sugar-sweetened products to **fund research and health promotion resources** to counter business-led initiatives.
- **Share information** between public health institutions on corporate strategies that undermine public health initiatives.
- Develop, and exercise **resources, and strategies** to safeguard institutions and researchers from conflicts of interest.
- Use **media exposure** to raise awareness and establish a culture that stigmatizes corporate tactics to exert undue influence.
- Foster **social participation** by increasing the ratio of civil society and academia representation in any multistakeholder body, and establish criteria for civil society representatives (e.g., particularly vulnerable groups).
- Ensure **effective protection for whistle-blowers** and introduce post-employment rules to address "revolving doors" between government and industry.
- Increase **public funding** for research and policy development.

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Funding sources

This section looks at the complexities of funding sources and provides questions to consider in order to decide about whether to accept funding from a particular source.

Financial support for research may be from many sources. The responsibility for ensuring that the funds are from ethical sources rests with researchers and with ethics review committees[24]. SGCs have a particular role in overseeing funding and ensuring that COIs are avoided, identified, mitigated and managed. No research is truly independent as the money must come from somewhere.

WHAT ARE THE COMPLEXITIES OF FUNDING SOURCES?

- Industries are fundamentally driven by the need to sustain or increase their profit share[25] and, therefore, do not have public health interests as primary concerns. The Tobacco and beverage Alcohol industries produce commodities that are known to cause harm, and, as with other industries, always aim to increase sales of their products.
- Industries such as the Pharmaceutical and the Food Industries produce commodities that are both needed (life-saving medication; nutritional food) as well as products that are harmful or are harmful in excess (harmful drugs or drugs used inappropriately as in the opiate epidemic; sugar-sweetened beverages).
- Large corporations have extensive budgets, unlike many research institutions, particularly in low- and middle- income settings. This funding could enable necessary research to proceed but could also compromise the nature of the research or the findings.
- Remember also that government or large NGO funding sources may also be involved in putting pressure on researchers and their institutions to conduct research in certain ways and find favourable outcomes. This is particularly the case when they have a vested interest in a project they have supported or wish to introduce.

When faced with a decision about whether to accept funding from a particular source, the following questions are important[26] :

- Have the funds been gained from sources that cause potential harm to others? (Such as funding from Tobacco, Alcohol, or Pharmaceutical companies)
- Is the right question being asked, given the evidence we know to date?
- Is the study designed to get a meaningful answer? (e.g. is it fatally underpowered so as to miss a key health risk? Or is it overpowered to find a statistically significant difference of little clinical or public health importance?)
- Could accepting this funding discredit the institution?
- Could accepting this funding negatively affect existing relationships within the institution?
- Could the outputs or results from this funding be used to promote or market the sponsor?
- Could the research findings influence policies intended to protect health?
- Will the funder be in a position to prevent full publication?
- Will the funder play an active role in the implementation of the study, its analysis and write up?
- Will the researchers have protected autonomy to analyse and publish?
- Will the data be publicly available so that others can do the same analyses to check the results?
- Will potential participants be informed who is funding the study and what their relationship is to the researcher?

Answers to these questions help you to evaluate the risk-benefit of the study.

The following case studies[27, 28] provide examples of some of the complexities of COIs with industry-related research.

CASE STUDY: FORMULA RESEARCH ON BABIES

A study was randomly allocating infant formula to exclusively breastfed low-birth-weight babies in Uganda and Guinea-Bissau assuming that this might prevent wasting and stunting. The trial in Uganda used a brand of powdered formula that was being recalled in the USA and New Zealand. The study overlooked the major health protection provided by exclusive breastfeeding and the serious risks associated with formula feeding of premature and low birth weight babies. These risks include life threatening Necrotizing Enterocolitis (NEC) and the formula's negative impact on the microbiome. The formula company faces lawsuits over the deaths of children from NEC and its failure to adequately warn of the risks of formula feeding. Exclusive breastfeeding from the mother, or breastmilk from a wet-nurse, or donated, is now universally recommended.

A recent review of formula trials found an almost universal lack of transparency, biased, selective reporting, increasing use of formula at sensitive periods of development and a lack of scientific rigour.

COI: The industry uses a humanitarian cover to expand the baby food market.

CASE STUDY: TOBACCO INDUSTRY FUNDING FOR AIDS RESPONSE

Research on the tactics of transnational tobacco companies has documented how they used various charitable causes to subvert tobacco control efforts and influence public health policy. In both Latin America and sub-Saharan Africa, tobacco companies championed the AIDS response in order to delegitimize efforts to develop the World Health Organization's Framework Convention on Tobacco Control.

COI:** The Tobacco Industry aimed to exploit competition between health issues, and **used the high-profile AIDS response to improve their reputation and market access.

CASE STUDY: GOVERNMENT PRESSURE TO EXPEDITE STUDY APPROVAL

During the COVID-19 outbreak, researchers from the Ministry of Health in an African country submitted a protocol to evaluate a COVID-19 vaccine and asked for expedited review from the National Ethics Committee. The researchers were linked to the National Regulatory Authority in the country, which falls under the Ministry of Health. Despite concerns raised by the NEC and some of its members, the protocol was approved. Upon learning this, some members of the NEC released a statement pointing out that they did not approve the protocol and could not be held liable for any negative consequences resulting from the study. They also asked to be excused from reviewing future protocols of this nature.

COI: *Conflict of interest can **involve external relationships** which are not just financial or commercial interests. Here, it seemed political interests influenced the decision-making in the Committee. Finding a vaccine for COVID-19 was a strong pressure and was not obviously for private benefit. However, it should not come at the expense of scientific integrity if the study was not ethical and/or scientifically rigorous.*

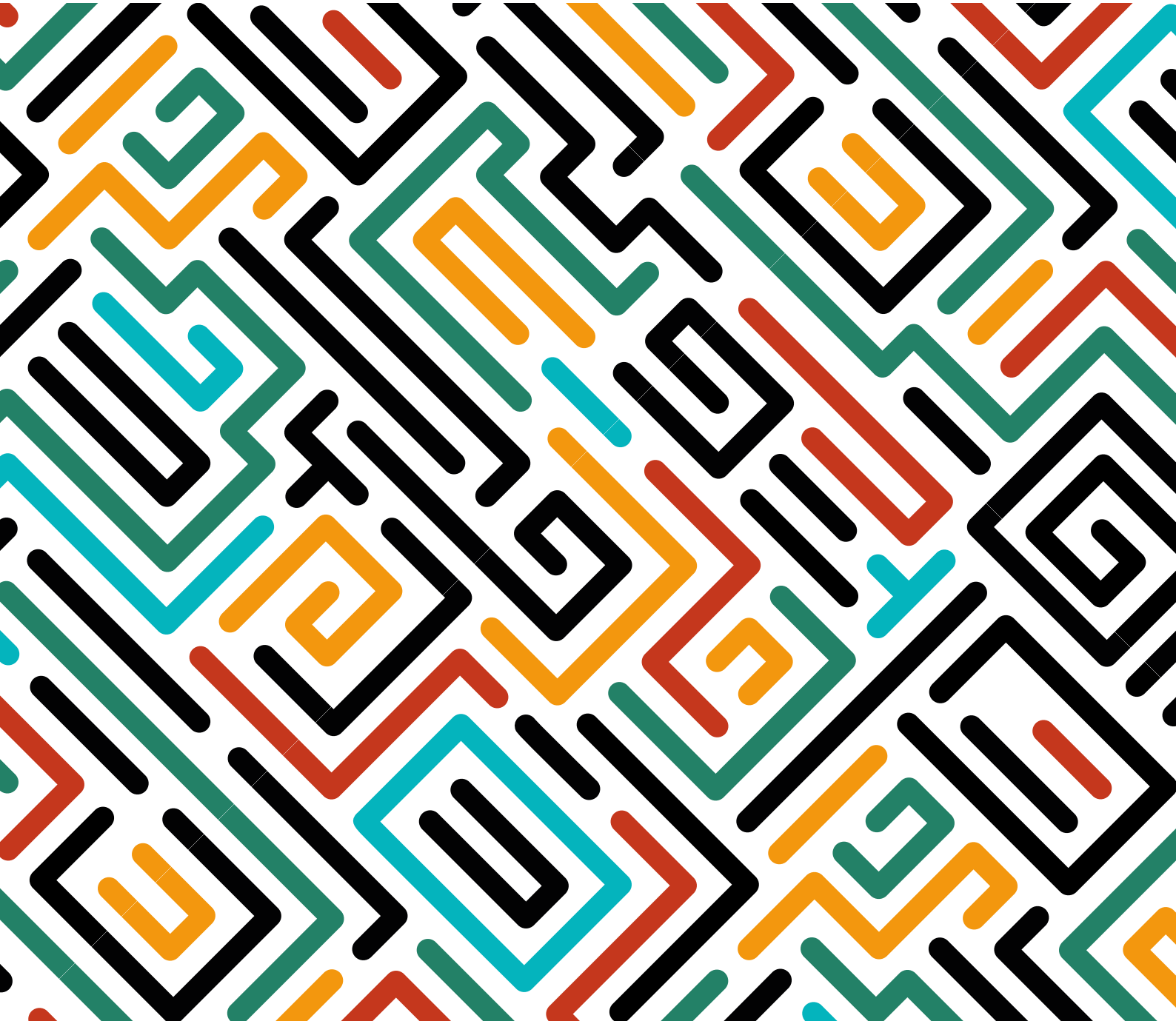
The table below indicates guidelines for managing funding sources.

Table 1: Funding management

MANAGEMENT GUIDELINE	STRATEGY TO MANAGE FUNDING SOURCE
 **Prohibit**	Review boards should not approve research for which sources of funding stem from (a) organisations whose products or commodities have the potential for harm and (b) organisations that have an interest in the outcome of the research. For example, many institutions do not accept tobacco industry funding, or funding from the Foundation for a Smoke-Free World, which is linked to the tobacco industry. Here, there is 'moral certainty' that the research should not proceed.
 **Disclose and manage**	Review boards should screen all funding sources for proposed research. Here, there is 'moral uncertainty' whether the research should proceed. One has to assess on a case-by-case basis.
 **Resolve / Mitigate**	Institutions should establish policies that qualify acceptable funding sources where (a) the funder has no interest in the study outcome and (b) is not involved in producing commodities harmful to health. Here, there is 'moral certainty' that the research could proceed.

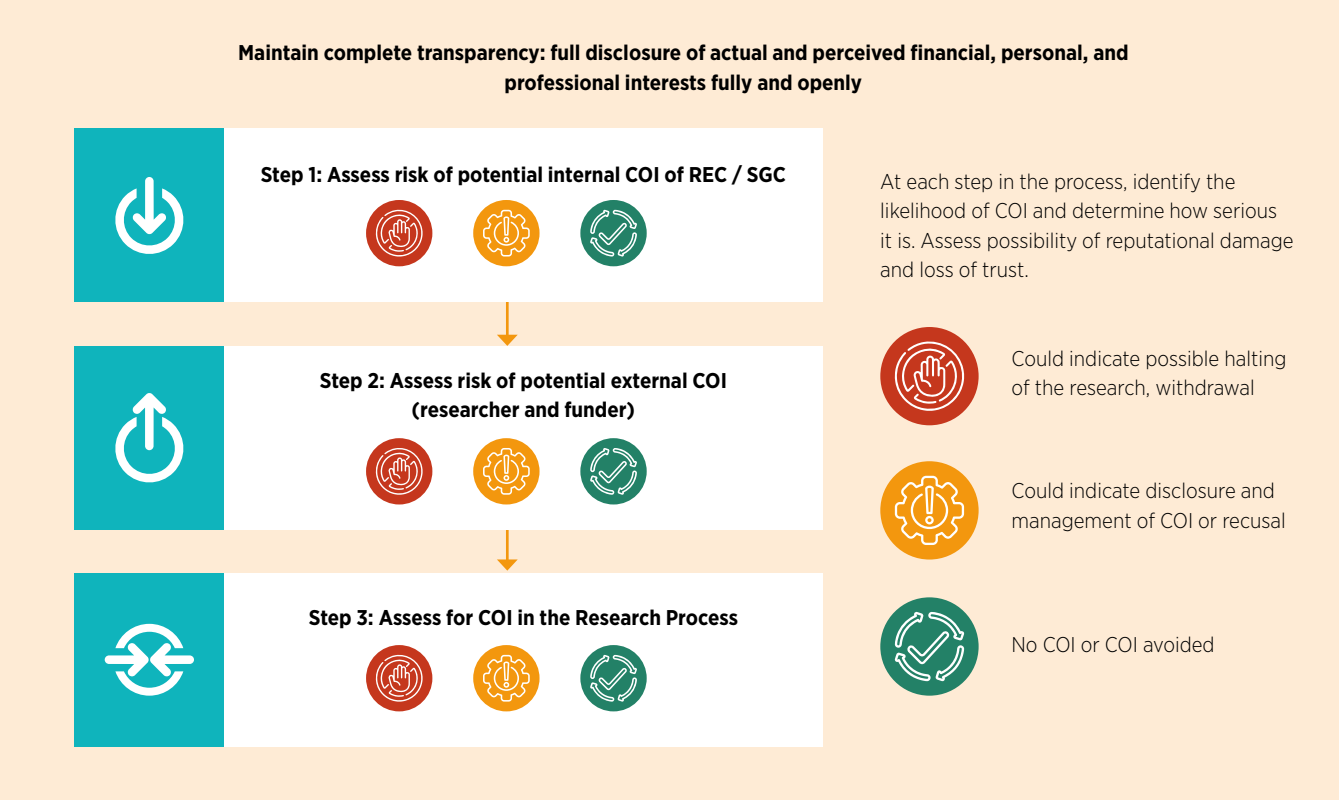
Assessment Process

Assessing conflicts of interest over the entire research process can be complex. We have divided this section into steps to assess internal COI (within REC / SGC), external COI between the researcher and potential funder, and additional COI that need to be managed during the research process.



WHAT IS THE PROCESS FOR IDENTIFYING AND MANAGING CONFLICTS OF INTERESTS?

We have subdivided the identification and management process into three steps. The diagram below summarizes the possible process for both RECs and SGCs.



We start by looking at how COI manifests internally to the organisation (i.e. in how the staff or members of the Council or Committee may have a COI when fulfilling their institutional duties).

STEP 1: ASSESS RISK OF POTENTIAL INTERNAL COI

This section helps to identify COI that could occur in either Research Ethics Committee or Science Grant Council settings. It provides checklists and study examples as well as a table for managing potential internal COIs.

HOW CAN YOU IDENTIFY CONFLICTS OF INTEREST?

There are several domains of interest that need to be assessed. Interests could be primary or secondary.

WHAT ARE PRIMARY AND SECONDARY INTERESTS?

*Primary interests might include **promoting and protecting** research integrity or the welfare of research participants or patients.*

*Secondary interests might include **financial interests, professional advancement and recognition**, or the desire to favour family or friends*[9].

CHECKLIST FOR IDENTIFYING COI

- *Will anyone on the REC / SGC **benefit financially** from the research?*
- *Will anyone on the REC / SGC benefit financially or otherwise from having the research protocol approved or rejected?*
- *Will anyone on the REC / SGC **avoid a financial loss** because of the research?*
- *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?***

The following is an example of a COI relating to a REC / SGC.

STUDY EXAMPLE:

An investigator on a multi-site clinical trial sits on the Ethics review committee of another institution where the trial is submitted for review.

COI: The investigator has a primary interest in the outcome of the Ethics review. *They need to recuse themselves from participating in the review.*

HOW DO YOU MANAGE INTERNAL CONFLICTS OF INTEREST FOR A REC / SGC?

As shown in the example above, the individual had a COI. Other individual COIs might be evident when:

- A REC / SGC member is an investigator on research under review.
- A REC / SGC member of staff holds significant financial interests in the entity that is sponsoring the research study under review by the REC / SGC.
- Loyalty to colleagues submitting research protocols for review.
- REC / SGC members are closely linked to the area of research under review and may be biased and therefore too lenient or too critical.
- There is the possibility of impact of REC / SGC decisions on a REC / SGC member's own work, such as policy change.
- An REC / SGC member has a personal agenda or deeply held religious, cultural or ideological beliefs.

COIs may also be shown at an institutional level. These might be demonstrated through:

- Pressure or desire to protect the institution.
- Concern for institutional reputation or prestige or interest.
- Promoting research rather than protecting research participants.
- Undervaluation of the REC / SGC service.
- The institution seeking to avoid risk and / or liability.
- Conflicting institutional or community values.
- Pressure for speedy reviews.
- Institutional ownership.

The following is an example of a COI in SGC.

STUDY EXAMPLE:

The Director of a Health Research Institute is responsible for public / private research agreements. They have been asked to sit on the Scientific Grant Committee.

COI: *They would have an* ***interest in the outcomes of approvals*** *made by the SGC as this could favour their institute.* ***They should not sit on the Scientific Grant Committee as they would not be impartial.***

STUDY EXAMPLE:

A clinical research protocol was presented for review at the National Research Ethics Board of a West African country. The protocol was funded by the National Institute of Health in the US and also had sponsorship from a for-profit pharmaceutical company. One of the research study team members on this study was an active member of the Ethics Review Board. The Ethics Board secretariat had a meeting scheduled to review several protocols, one of which included this clinical study. The protocol was circulated weeks prior to the meeting. At the meeting, the Chair asked members present to declare any conflict of interest. This conflicted member did not volunteer any Conflict of Interest. Instead, his COI was mentioned by another Board member. The researcher indicated he was aware that he should not be in the meeting, but because he had no financial interest in the study he did not believe he had a conflict of interest.

COI: *The researcher* ***cannot adjudicate a study in which he is a team member.*** *He should have* ***recused himself*** *from the discussion.*

The potential for conflicts of interest can be addressed by instituting **proactive regulations** that would stop certain individuals from holding particular positions and would provide clear guidelines for management if these regulations were broken[29].

Institutions can **employ the services of a dedicated agent / agency / commissioner to identify and manage conflicts of interest**, to refer to institutional policies on conflicts of interest, take action for disciplinary or criminal proceedings if necessary, and effect dismissal.

The response to incidents of conflicts of interest, thus, requires that institutions have clear, unambiguous, informed and regularly-communicated operating procedures and **codes of conduct** for all their employees and officials, both future and current.

The table on page 19 provides some guidelines for managing internal conflicts of interest for REC / SGCs.

Table 2: Management of COI for RECs / SGCs

MANAGEMENT GUIDELINE	STRATEGY TO MANAGE INTERNAL COI FOR REC / SGC
 **Prohibit**	Individuals should be screened for eligibility to participate on REC / SGC. For example, members should be required to have at least some training in research ethics and should not have a history of academic/research compromise. Members cannot have interests in companies that engage in partnership with the university or review board institution. REC / SGC employees cannot hold a position in more than one REC / SGC department or be simultaneously involved in the government legislature. REC / SGC officials/employees cannot be simultaneously employed in the private sector in any position, including that of a consultant. REC / SGC employees cannot own or have shares in private or other government entities that conduct business with the REC / SGC. After leaving the REC / SGC, the employee cannot accept a government position that has links with the former REC / SGC or any REC / SGC for a period agreed in policy (e.g. 5 years). Conversely, after leaving the employ of government, government employees cannot be employed in an SGC department with which the former employer engages, for a period agreed in policy (e.g. 5 years). Employees with a compromised record on integrity or history of malfeasance cannot serve in any decision-making role. SGC employees should be prohibited from secondment to other entities (including research institutions) that might subsequently be unfairly advantaged by the SGC.
 **Disclose and manage**	Members should be required to disclose their financial assets regularly, including other sources of income, and business interests (including board memberships), and declare any past sources of income and business associations that could compromise their REC or SGC position/perspective or influence their decisions on research proposals that involve these companies. Prior to, or at the beninning of each meeting, committee members must declare any COI relating to the agenda at hand. Such declaration should be made in writing. Members should recuse themselves (withdraw from participating) or be required to abstain from discussions and decisions where their personal interests might influence or compromise their views and decisions on research proposals submitted for review. If other members are aware of a member's COI, there should be a procedure to bring that to the Committee's attention, if necessary, through a safe whistleblowing process. In certain cases where it is agreed by the REC / SGC that their judgment could potentially be biased (e.g., where the principal investigator is the chair of the committee), transfer of ethics review application and protocol to another research ethics committee. In certain instances, members may remain in the meeting to address certain questions that the REC / SGC might have, but under no circumstance are they allowed to vote during the meeting. Public disclosure of REC membership, participation in meetings, COI procedures and their implementation.
 **Resolve / Mitigate**	Members should, as a condition of membership, dissociate from or liquidate any private interests that might influence or compromise their roles and decisions. Members with interests that can / do conflict with those of the REC / SGC decisions, should be restricted from access to information that might advantage those outside interests. Compromised individuals, or those with the potential for conflict of interest, can be transferred to another department or alternative roles, where such compromise would be neutralized, or the conflict of interest eliminated. Officials with identified conflicts of interest can be forced to resign, or be dismissed from the position, if the conflict of interest cannot be eliminated or the individual chooses not to dissociate from the conflicting private circumstances or interests. Bribery and fraud committed by any REC / SGC member, are regarded as corruption and pose a conflict of interest. These should be dealt with within the framework of criminal law. Policies at national and local level should be instituted to protect independence of RECs / SGCs from influence. The implementation of policies and procedures to limit COI should be monitored and summary information reported publicly.

COI also exists in the engagements that the REC / SGC may have with parties external to the organisation. We now turn to examine how best to manage these external COIs.

STEP 2: ASSESS RISK FOR POTENTIAL EXTERNAL COIs

This section provides definitions of both financial and non-financial COIs and provides checklists to identify potential COIs between researchers and funders. It looks at assessing severity of COIs and provides a table with strategies for managing external COIs. Examples and case studies are used to illustrate external COIs.

Conflicts of Interest can be financial or non-financial[30] and involve reputation or ideology.

WHAT IS A FINANCIAL / TANGIBLE CONFLICT OF INTEREST?

The most common conflict of interest in research is financial ties, such as sources of funds / grants for the research conducted, receipt of a consulting fee from a company manufacturing the drugs / equipment used in the research, stocks in such a company, or other financial connections that might influence an individual's thinking and affect the research outcome.

WHAT IS A NON- FINANCIAL / NON-TANGIBLE CONFLICT OF INTEREST?

The most common non-financial conflicts of interest in research are personal relationships or professional affiliations. For example, a conflict of interest would exist if an author is the spouse / sibling / child of the editor of the journal to which they submit a manuscript or if the editor is, or was until recently, a supervisor who the author reported to. Some of the more complicated conflicts of interest in research are private or publicly held beliefs and ideologies that can give rise to potential biases in a researcher's work.

There are several factors that make evaluating partnerships complex. Different people or organisations / institutions might have **different perceptions of what constitutes a COI within the same context**[31]. If a partnership has the possibility of a COI, you will need to decide whether to engage with the partner, whether to eliminate, avoid or manage the COI.

HOW CAN YOU IDENTIFY EXTERNAL CONFLICTS OF INTEREST?

The checklist on the right is an aid for assessing potential conflicts of interest. It looks at the domains of finance, material, opportunity and outcomes.

CHECKLIST TO IDENTIFY POTENTIAL EXTERNAL COIs

Financial:

- *Will anyone benefit financially from the research or research contract?*
- *Will anyone avoid a financial loss as a result of the contract?*
- *In whose best interest is the research and research contract?*
- *Does a third party stand to benefit financially from the research or contract?*

Material:

- *Has research quality been compromised in favour of a specific partner / funder / provider?*
- *Has a fair process been followed to select the preferred product provider?*
- *Are the research funder's products / commodities known to produce harm?*

Opportunity:

- *Why has a particular community been selected for the research?*
- *How were the collaborating partners / funders / providers / participants selected for the research?*
- *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 of the research?*

Here are some examples[32] that illustrate conflicts of interest in the partner relationship:

- A researcher has a financial interest in a company sponsoring the research. This conflict of interest is accentuated if the outcome of the research has the potential to increase the financial value of the researcher's investment..
- A researcher is an inventor on a patent(s) or a creator of other intellectual property. This conflict of interest is accentuated if the outcome of the research has the potential to increase the financial value of the researcher's investment.
- A researcher takes part in the negotiation of a contract between the University and a company, where the researcher or his or her family or a close personal friend has a financial or non-financial interest (e.g. a directorship) in that company.
- A researcher conducts a clinical trial which is sponsored by any person or organisation with a financial interest in the results of the trial.
- Industry sponsors prizes for best conference presentations, and provides gifts samples for staff assisting at conferences. Industry gains credibility under the guise of CSR while hiding economic interests.
- A billionaire, whose wealth comes primarily from telecommunications but who also has investments in tobacco companies, proposes funding a university family health centre to support innovative programs in maternal and child health. This could cause reputational damage to the university while clouding the threats to health with mother and child health promotion.

WHAT CRITERIA ASSESS THE SEVERITY OF CONFLICTS OF INTEREST?

CHECKLIST TO ASSESS SEVERITY[9]

Likelihood of undue influence

- *What is the extent of the secondary interest? (This refers not only to monetary value of a grant or consultancy fee, but also to the influence that a relationship might have in creating a conflict of interests.)*
- *What is the scope of the relationship? (How long has it been going on, and how likely is it to influence professional judgement?)*
- *What is the extent of discretion? (How much oversight does a review board have over a research process, and how much freedom does the researcher have to make their own decisions?)*

Seriousness of possible harm

- *What is the extent of the primary interest? (What is the primary goal and what is potentially at risk?)*
- *What is the scope of the consequence? (What are the possible consequences for the research participants, the reputation of the researcher, and the institution?)*
- *What is the extent of the accountability? (What are the consequences for a breach in ethical conduct? Are policies and practices in place to apply sanctions if unethical conduct is disclosed?)*

The following case study[33, 34] provides an example of an external COI.

CASE STUDY: JESSE GELSINGER EXPERIMENTAL GENE THERAPY TRIAL

The adverse effects of an experimental gene therapy were withheld by the lead investigator who had financial interests in the biotech company that was responsible for the development of the gene therapy. An 18 year old trial participant, Jesse Gelsinger, died.

COI: Bias in favour of the pharmaceutical company and financial gain.

HOW CAN YOU MANAGE EXTERNAL CONFLICTS OF INTEREST?

The table below provides a summary of possible strategies for managing researcher – funder COIs.

Table 3: Management for Researcher - Funder COIs

MANAGEMENT GUIDELINE	STRATEGY
Prohibit	Sever or **disallow any relationship between a researcher and a research sponsor** which may create actual or potential conflicts of interest. Disqualify any researcher from participating in all, or a portion, of any sponsored research if their COI will limit their capacity to provide unbiased, independent research. Prohibit any veto clauses by which a funder can delay or stop publication of research findings.
Disclose and manage	**Researcher's financial interest in any research** sponsorship or the commercial success of any strategy, product or service that is the subject of any research results being reported, should be disclosed. Researchers who seek approval for research protocols should disclose their sources of income and business interests, and declare former sources of income and business interests (including those of family members) that might compromise their positions on research projects, and that could potentially influence their reporting of findings. They should rather disclose than assume that because something is unrelated it does not need to be disclosed. Applications for funding should disclose any associations, both current and former, between the applicants and the REC / SGC and its members. A whistleblower process that provides safe mechanisms for third parties to alert the committee to undeclared COI should be established.
Resolve / Mitigate	Establish **independent committees** to review research proposals. Institutions should provide training for researchers to avoid acceptance of funding with possible COI.

STEP 3: ASSESS COI IN THE RESEARCH PROCESS

This section looks at points to consider when evaluating the research process. It provides case studies to demonstrate COIs and summarises how COIs can influence research design, conduct and results. It also outlines strategies for managing COIs in the research process.

HOW CAN CONFLICTS OF INTEREST INFLUENCE THE RESEARCH PROCESS?

Conflicts of interest do not only relate to conflicting interests within a partnership, but may also influence the way the research is designed, conducted or the results produced. Examples of this can be seen in:

- Choice of inferior comparator
- Manipulation of the randomization process
- Prematurely stopping a trial
- Fabrication of data
- Blocking access to data
- Providing an overly favourable interpretation of results (spin)

A **table** that summarizes inappropriate use/misuse of epidemiological methods can be found at: **https://ehjournal.biomedcentral.com/articles/10.1186/s12940-021-00771-6/tables/1**. This serves as a useful checklist for institutions to identify and guard against COI at the levels of research design and interpretation of findings. It helps to recognise the agendas that drive the needs for certainty at the expense of at-risk groups, and to identify the role of vested interests and influence in suppressing specific research and research topics.

The following example[35] demonstrates COI in the research process.

CASE STUDY: WITHHOLDING RESEARCH RESULTS IN ACADEMIC LIFE SCIENCE. EVIDENCE FROM A NATIONAL SURVEY.

The objective of the study was to identify the prevalence and determinants of data-withholding behaviour among academic life scientists. Over 3 000 academics from 50 universities were asked to complete a survey to indicate if they had delayed publication of their results for more than 6 months and whether they had refused to share research results with other university scientists in the last 3 years. Almost 20% reported delayed publication results to allow for patent application, to protect their scientific lead, to slow the dissemination of undesired results, to allow time to negotiate a patent, or to resolve disputes over the ownership of intellectual property. Approximately 9% refused to share results with other university scientists.

COI: They aimed to withhold results in order to secure lucrative patent deals.

Here are additional examples[32] that illustrate conflicts of interest in the research process.

- The researcher holds a position in an enterprise (e.g. as director) that may wish to restrict or otherwise manage adverse research findings for commercial reasons, or not wish to publish the results of the research.
- A postgraduate research student conducts research on a project that receives support from a company in which their supervisor has a financial interest or significant position.
- A researcher who has a senior editorial position with a commercial journal is also on a University library committee that recommends journal subscriptions.
- A researcher chairs a University committee which is to consider the allocation of funds to be shared between a number of Divisions / Schools, including their own.
- A company that manufactures fertilizers and pesticides wants to sponsor a research study on farmers' protective clothing. The company might want to emphasise the role of protective clothing and ignore the harmful effects of its products to farm produce and the environment. The university researcher might be influenced to focus on the protective gear and minimise investigation of the potentially harmful effects of the company's products or more appropriate ways to limit exposure (e.g. product substitution or use of non-chemical pest control methods).

WHAT ELSE NEEDS TO BE CONSIDERED FOR ETHICAL HEALTH RESEARCH?

Risk is a complex concept. There is always uncertainty around the potential benefits of health research. The World Health Organization puts forward some key issues that RECs / SGCs need to consider[36]:

- Risk/benefit assessment does not stop at the individual in a study; it must also consider communities and health systems.
- The risks of research are not limited to potential physical harms, but can also include psychological, social, legal, health system and economic ramifications.
- Evaluation of the benefits of research must distinguish between direct benefits for the individuals who participate in the study, expected benefits for the community in which the study will take place and potential benefits to science and the world at large.
- Identifying and evaluating risks and benefits is not purely scientific endeavour. They require the involvement of all stakeholders in research, including investigators, community and civil society representatives, lawyers, and health authorities.

WHAT STRATEGIES CAN HELP TO MANAGE EXTERNAL COI IN THE RESEARCH PROCESS?

The table below outlines some strategies[30, 37, 38, 39]. for managing COI within the research process.

Table 4: Management for the research process

MANAGEMENT GUIDELINE	STRATEGY
 **Prohibit**	**Exclude the funder** from participating in the research design, data analysis and the reporting of findings. Researchers who do not sign a COI undertaking or follow REC procedures should be **excluded from research activities**. Researchers who **falsify information** about COI should be subject to appropriate disciplinary action. The way a study is conducted should not be done in way to give the funder **unreasonable marketing benefit**. Funders should **not have direct involvement** in implementation, analysis or write up of research. **Peer Reviewers** for academic publications should recuse themselves from reviewing articles of any rival research group so as not to influence the outcome of the publication.
 **Disclose and manage**	**Institutions** should establish disclosure procedures. **Researchers' financial interests** with a sponsor should be fully disclosed to any human research participant. **Researchers' financial relationship** with the sponsor should be included in all written and oral presentations, publications and abstracts. **Funders** should report funding details to the researcher's organisation and disclose the information publicly. **Reporting** to the REC on COI could be implemented more frequently than is done routinely. **Adherence** to conditions of research imposed by an REC or SGC should be monitored. Failure to adhere to conditions of approval should be subject to policy-informed disciplinary action. **Publishers:** To protect authors' and reviewers' rights, publishers are responsible for: • selecting reviewers who do not have a conflict of interest with the authors • protecting reviewers' identities • maintaining a neutral and objective stand in the peer review process. Open peer review can pose a major challenge to these requirements. There should be public reporting on the maintenance of study integrity, without compromising participant confidentiality.
 **Resolve / Mitigate**	The REC may recommend an independent oversight board/committee be appointed to monitor the study closely to ensure that vested interests do not influence the science of the study. Ensure that **contracts ensure complete access to data** and that after the study, public availability of the data is ensured to enable other researchers to replicate findings. Establish **mentoring practices** so that experienced researchers can help junior colleagues and students recognize, avoid, and manage conflicts of interest.

Governance Process

This section highlights COIs to consider when establishing governance processes. It outlines criteria to evaluate COI policies, provides a checklist for identifying and declaring COIs and strategies for establishing governance processes. Finally, this section includes policy enforcement and reporting.

There are potential conflicts of interest within health systems that might influence policies. It is important to consider these when establishing governance processes. Table 5[40] summarises some COIs and the potential effect for policy.

Table 5: Competing interests and their effects on health policy

	COMPETING INTEREST	EXAMPLE OF EFFECT ON POLICIES
Policy makers or regulators are expected to formulate and implement policies that ensure appropriate care delivery by private health-care providers.	A secondary relationship that results in financial, social, or familial connection with the institutions they are responsible for regulating, such that the policy actor or regulator may prefer weaker controls.	**Weakening of policies:** policy formulation influenced such that weaker rules are introduced. Or, policy implementing bodies (eg, drug inspection agencies) are under-resourced to enforce rules.
Formal health-care providers have a responsibility to provide and support the provision of health care in accordance with local regulations and professional ethics standards.	Financial flows from informal (illegal) providers or practice create additional sources of income for formal providers.	**Covert opposition to change:** formal providers publicly support stronger regulation of informal practice, but covertly influence the policy-making process to enable it to continue and thrive.
Policy decisions should reflect public health evidence and best practice.	Policy makers do not want to introduce or enforce rules to curtail the private sector as they know these will be unpopular with large segments of the population and could potentially expose gaps in roles of the public sector.	**Regulatory impasse:** stronger regulations to restrict inappropriate private sector activities, which are good from a public health perspective, are avoided as they might make policy makers unpopular and affect personal career growth.

WHAT CRITERIA CAN BE USED TO EVALUATE CONFLICT OF INTEREST POLICIES?

The checklist below proposes some criteria for evaluating policy[9].

CHECKLIST FOR EVALUATING POLICY

Proportionality:

- *Is the policy effective, efficient, and directed at the most important and most common conflicts?*

Conflict of interest policies and procedures may create harms or burdens as well as benefits.

- *Does the policy and its implementation unnecessarily interfere with the conduct of legitimate research, teaching, and clinical practice?*

Transparency:

- *Is the policy comprehensible and accessible to the individuals and institutions that it may affect?*

Transparency is essential to determine if conflict of interest policies are reasonable and are being implemented fairly. Transparency can also help institutions learn from each other about more and less successful ways of handling particular situations.

Accountability:

- *Does the conflict of interest policy indicate who is responsible for monitoring, enforcing, and revising it?*

Leaders of accountable institutions need to explain institutional policies and monitor and accept responsibility for the consequences, both beneficial and harmful.

Fairness:

- *Does the policy apply equally to all relevant groups within an institution and in different institutions?*

In an academic health care centre, the relevant groups would include faculty, health professionals, students, registrars, fellows, members of institutional committees (e.g., Research Ethics Committees, formulary committees, panels developing practice guidelines, and device purchasing committees), and senior institutional officials.

- *Does the policy identify where powerful interests can get preferential attention to the detriment of other research applications?*

Justice:

- *Are the interests of the most vulnerable served optimally by the policy by balancing or controlling different interests?*

Effectiveness:

- *Does the policy succeed in preventing COI influencing the ethical integrity of the research process?*
- *Is enforcement of the policy done with the requisite resources to be effective?*
- *Do researchers and funders game the system and turn it into a tickbox exercise?*

HOW DO YOU IDENTIFY AND DECLARE CONFLICTS OF INTEREST?

The following checklist[30] will help to establish a process for identifying and declaring COIs.

- ***List all sources of financial support*** *you and your co-authors receive that may be considered as posing a conflict to your research objectives. These need not be just the support you receive for the research you are trying to publish now, but any other grants / funds that you receive for other projects.*
- ***List any social or personal activities*** */ interests that may be considered to influence how you conduct your research.*
- ***Review any institutional ties*** *you may have in the present or have had in the recent past (where you worked / volunteered, etc.) that can be said to affect your objectivity in your work.*
- *Potential for conflicts and ways to deal with them are constantly evolving.* ***Keep yourself updated*** *and seek out new information.*

WHAT SHOULD AN ETHICS POLICY ADDRESS?

An ethics policy needs to provide guidelines for expected conduct, consequences for not following codes, and processes for reporting breaches in conduct. Some important issues[42] to consider are:

- **Confidentiality** – Members are required to protect the confidentiality of all privileged information relating to organisational business or prospects.
- **Conflict of Interest** - Members will proactively disclose financial, personal, professional, and other conflicts of interest that could compromise the trustworthiness of their work on behalf of the organisation.
- **Intellectual Property** - Members should not knowingly infringe the intellectual property rights of other parties.
- **Professional Misrepresentation** – Members are expected to recognise and honestly represent individual boundaries of professional competence.
- **Harassment, Discrimination, Bullying and the Abuse of Power**– The organisation should provide a clear statement on impacts and its intolerance for harassment, discrimination and bullying.
- **Reporting Ethical Violation of Others** – Members are asked to take responsibility to act or intervene where possible to prevent misconduct and report such misconduct when it occurs.
- **False accusations / Improper complaints** – Penalties are outlined for making false or improper complaints and such accusations are noted as an ethical violation.

WHAT STRATEGIES CAN HELP TO ESTABLISH GOVERNANCE PROCESSES?

The following table outlines some strategies for establishing governance processes.

Table 6: Strategies[9, 41] for Governance processes

Management guideline	Strategy
 **Prohibit**	Institutions should establish policies that **restrict participation** of researchers, REC members or SGC staff with COI – either on temporary basis (recusal) or long-term basis (relocation, redeployment or removal).
 **Disclose and manage**	Institutions should **establish disclosure policies** and provide for an agreed course of action should a researcher fail to declare their COI. Institutions should strengthen disclosure procedures and **standardise disclosure content and formats.** Institutions should provide templates which may be used by anyone to **evaluate and disclose potential conflicting interests at any stage of the research process**. These stages include the problem definition / proposal stage, hypothesis formulation, stakeholder oversight / community engagement phase, research design, execution, analysis, interpretation, pre-publication conference presentation, peer-review, dissemination of results, statements made to media or policy-makers, serving on board and advisory committees, data- sharing, and data archival. Policies and forms should be **regularly updated**. Members nominating candidates for election onto a review panel (i.e., nominators) **should be required to submit, along with their nominee details, a disclosure statement** revealing any actual or perceived COI.
 **Resolve / Mitigate**	Institutions should **provide education** on COI. Institutions should **adopt and implement COI policies**, if possible, through consensus involving stakeholders, and supported by training of staff and researcher on the policy. Advocate for **independent research financing.** Create a **national programme for monitoring and reporting** on corporate payments to researchers or institutions that constitute a COI. Lobby a range of supporting organisations, including accrediting groups and public and private health insurers, **to promote the adoption and implementation of conflict of interest policies**, and promote a culture of accountability that sustains professional norms and public confidence in health research. **Research** on conflicts of interest and conflict of interest policies can provide a stronger evidence base for policy design and implementation.

HOW DO YOU INSTITUTE AND ENFORCE COI REGULATIONS AND POLICIES?

It may be difficult to eliminate completely conflicts of interest through withdrawing participation. While disclosure of COI is important, by itself, disclosure has no effect on the actual conflict of interest and its potential consequences[43]. In fact, some have argued that reliance on disclosure of COI to prevent unethical behaviour by researchers may lead to a perverse exacerbation of biased and unethical research practices[44].

However, there is value in the **transparency of disclosure** as it is recognised as a necessary part of identifying the potential for research bias[45]. In addition, the negative effects of concealed academic entrepreneurship needs to be recognised[46]. Disclosure is thus a necessary but insufficient requirement to manage COI. For that reason, existing COI management policies must be accompanied by additional and complementary mechanisms. If not, COI declaration becomes a pointless tickbox that is ineffective or, worse, may aggravate the problem by creating a false sense of oversight and thereby obscuring unethical practice.

One strategy is for members of institutional ethics bodies to be **included in the drafting and review of the regulations**. This would enable inclusivity, engagement of stakeholders, opportunities for feedback and clarification, and would be more likely to achieve buy-in from employees than if the regulations were simply imposed[29].

Another strategy is for institutions to have a **dedicated agency or commissioner to provide institutional oversight** with specific reference to the protection and guidance of employees in navigating the potential for conflicts of interest. Independent ethics committees could provide guidance for patient advocacy organisations in their financial engagements with industry players[47].

Others have suggested that COI declarations move away from generic statements (which obfuscate through clouding the relationships with noise) and rather focus on interests that are clearly relevant to the study in question, so as to enable true evaluation of the risk of bias arising from COI[48]. Public disclosure through publicly accessible databases have also been suggested as a mechanism to ensure accountability by maintaining a structured and comprehensive list of disclosures.

HOW DO YOU REPORT COIs?

By legal definition, **conflict of interest is usually considered to be an issue of ethical conduct**. It is seen as a conflict between professional and private interests. Corruption (commonly defined as a subset of conflicts of interest, where the private interests of the individual are mainly financial), is commonly regarded as an **incident of criminality**[49]. However, in this toolkit, we recognise that "a fine line" marks the difference between conflicts of interest and corruption, particularly as some forms of conflict of interest might be sufficiently harmful to be regarded as criminal, even when the conflict of interest does not necessarily constitute fraud or corruption.

Usually, COIs that are not considered to be legally criminal are dealt with internally within the organisations involved. An intervention is escalated to legal proceedings outside of organisations only when considered to be sufficiently harmful to the organisations.

The disclosure of knowledge about, and evidence for, the occurrence of a conflict of interest can be reported by the person directly involved in the COI (self-disclosure), or could be reported by another person and constitute an act of **whistleblowing**.

WHAT IS A WHISTLEBLOWER?

A whistleblower is someone who discloses illegal, immoral, or illegitimate practices under the control of their employers, to persons or organisations that may be able to effect action[50].

Globally, State institutions are characterised by bureaucratic procedures that potentially discourage a culture of whistleblowing and fail to protect whistleblowers. In developing countries, there are further challenges for whistleblowers.

In these settings, institutions are often characterised by

> ***personalised loyalty, loosely regulated institutional environments, fluid policy-ownership, extreme disorganisation, institutionalisation deficits (limited statehood conditions), dishonesty, haphazardness, amateurism, and autocratic and self-serving leadership traditions. Under such conditions, conflict of interest is elusive, corruption is less punitive, whistleblowers are despised,...***[51]

Whistleblowers are often regarded simultaneously as heroes for disclosing wrongdoing, and as traitors for disclosing institutional practices. In addition, there has been movement globally towards a recognition of the need for whistleblower protection to foster good governance[52].

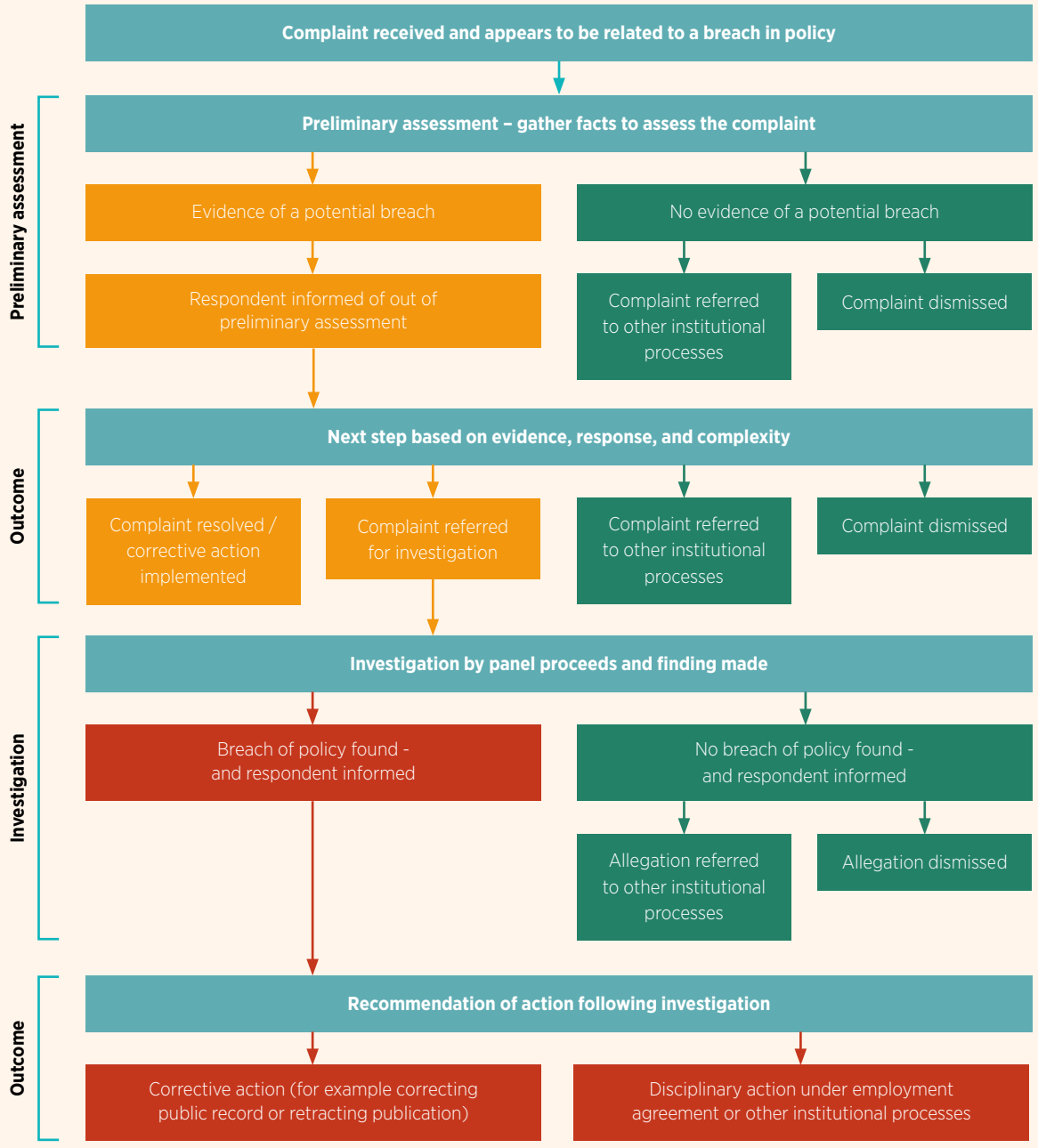
Whistleblowing needs to be seen within a framework of anti-corruption as opposed to an act of freedom of expression or human rights[53] and to counter "whistleblower protection legislation (being) implemented in a reactionary manner"[51]. Employees of institutions usually first try to report a perceived COI within their organisation. However, evidence indicates that, even when there are mechanisms in place for whistleblowing to be addressed, and when whistleblowers are assured of protection, these mechanisms do not translate into a culture of increased whistleblowing, with, thus, no reduction in whistleblowing, and with no decrease in unethical behaviour within the institution[54].

WHAT IS THE PROCESS FOR INVESTIGATING A COI?

When a failure to meet the principles and responsibilities of a policy regarding COI is reported, it is important to investigate the complaint and have a process for following this through.

The policy needs to indicate who should report a possible conflict – and to whom they should report it. In addition, the policy should include the repercussions of undisclosed conflicts[42].

The flow diagram[55] below provides a suggested process for investigating a complaint.




LAGOS
FOOD

Conclusions

RECs and SGCs have a responsibility to respond to incidents of conflicts of interest. This requires that institutions have ways to assess risk and identify COI, as well as clear, unambiguous, informed and regularly-communicated codes of conduct, procedures and policies for all their employees and officials which are regularly updated with the latest information. We hope that this toolkit has provided you with tools and guidance to identify, address, manage and mitigate conflicts of interest.

Important summary points from this toolkit include:

- **Avoid and minimise conflict of interest**

  Although it is not possible to avoid all sources of COI, it is in the best interests of the scientific community and of individual researchers to recognise conflicts of interest, and to take steps to cancel or limit those conflicts.

- **Disclose interests**

  If COIs cannot be avoided, then those conflicts should be disclosed. At minimum, the institution and any other parties with a significant interest should be made aware of the extent and nature of the conflict.

- **Manage conflicts**

  Disclosure is often not enough. For every step of the research process, attempts should be made to keep individuals with COIs away from all decision-making functions.

  However, some COIs cannot be adequately managed by disclosure or procedures alone – bear in mind that there may be some COI that should be **completely prevented**.

- **Keep learning**

  Both the potential for conflicts of interest and the strategies for dealing with those conflicts are evolving. Look for information so that you can keep up with current regulations.

Additional resources

Conflicts of interest: A good practice guide. Northern Ireland Audit Office, 2015.

https://www.niauditoffice.gov.uk/files/niauditoffice/media-files/conflicts_of_interest_good_practice_guide.pdf

This guide seeks to provide clear and simple advice relevant throughout the public sector to help organisations draft and implement conflict of interest policies. It also aims to help board members and staff in key positions to recognise when they have a conflict of interest and how they should act when such a situation arises. The guide includes examples of good practice as well as case illustrations of all types of conflicts of interests with the associated problems and possible solutions. Usefully, the guide provides a typology of conflicts of interest and specifies what to do when the policy is breached. Several appendices offer good practice examples and sample declaration of interest forms.

Conflict of interest: Legislators, ministers and public officials. Carney, G., 1999.

https://gsdrc.org/document-library/conflict-of-interest-legislators-ministers-and-public-officials/

This document assists legislators, ministers and public officials to identify exactly what constitutes a conflict of interest and how conflict of interests pose ethical dilemmas in the performance of an official's duties and responsibilities, and to suggest various mechanisms either to prevent such a conflict of interest arising, or to resolve the conflict when it does arise. These include disqualification from office, disclosure of personal interests, codes of conduct, ethics training and enforcement mechanisms.

Conflicts of Interest and Commitment for Faculty and Investigators Policy. George Washington University

https://compliance.gwu.edu/conflicts-interest-and-commitment-faculty-and-investigators-policy

An example COI policy

Conflict of interest and monitoring financial assets. Organisation for Security and Co-operation in Europe (OSCE), 2004.

http://www.osce.org/eea/13738?download=true

Chapter three of the OSCE report Best Practices in Combating Corruption (pp.28-41) provides two checklists: (1) to help individual public servants identify situations where a conflict of interest is likely to arise and (2) to assess whether a disclosed conflict of interest might require other public officials to ask the person in question to stand aside. It also examines in detail how to avoid nepotism and cronyism in public sector appointments, suggests methods to monitor public officials' income and provides best practice examples of post-public sector employment restrictions for government ministers.

Conflict of interest and public life: Cross-national perspective. Trost, C., and Gash, A., (eds), 2008.

http://www.cambridge.org/gb/academic/subjects/philosophy/political-philosophy/conflict-interest-and-public-life-cross-national-perspectives

This document provides a comparative account of conflict of interest regulations across four Western democracies: the United States, the United Kingdom, Canada and Italy. The study situates conflict of interest regulations within a broader governance discourse, identifies the structural, political, economic and cultural factors that have contributed to the development of conflict of interest regulations, and assesses the extent to which these efforts have succeeded or failed across and within different branches and systems of government.

Conflict of interest in global, public and corporate governance. Peters, A., and Handschin, L. (eds), 2012.

http://www.cambridge.org/gb/academic/subjects/law/comparative-law/conflict-interest-global-public-and-corporate-governance

This interdisciplinary handbook provides insight into thinking on conflicts of interest at a global level, in both the public and corporate sectors.

Frequently asked questions: Johns Hopkins University Policy on Conflicts of Interest and Conflict of Commitment

https://jhura.jhu.edu/wp-content/uploads/2020/12/COI_COC-Policy-FAQs12.21.2020.pdf

This document provides frequently asked questions about the COI policy with examples to clarify when COI might occur.

Johns Hopkins University Policy on Conflicts of Interest and Conflict of Commitment

https://policies.jhu.edu/doc/fetch.cfm/DqwggusL

An example policy on COI

Managing conflicts of interest in the public sector: A toolkit. OECD, 2005.

http://www.oecd.org/gov/ethics/49107986.pdf

Experience shows that identifying and resolving conflicts of interest can be difficult to achieve in practice. To overcome this barrier, in 2005, the OECD developed a practical toolkit focusing on specific techniques, resources and strategies for the identification, management and prevention of conflict of interest situations. It provides non-technical, practical help to enable officials to recognise problematic situations. The tools are based on examples of sound conflict of interest policies and practices drawn from OECD member and non-member countries.

Managing conflicts of interest in the public service: OECD guidelines and country experiences. OECD, 2004.

http://www.oecd.org/gov/ethics/48994419.pdf

Essential reading for those who want to gain a comprehensive grounding in conflict of interest mitigation strategies, the OECD guidelines have three core objectives. Firstly, to provide a practical framework of reference to help governance and public organisations review and modernise existing policy solutions in line with good practice. Secondly, to promote a public service culture in which conflicts of interest are properly identified and resolved. Thirdly, to support partnerships between the public, private and non-profit sectors in identifying and managing conflict of interest situations. The guidelines set out four core principles for public officials to follow when dealing with conflict of interest situations in order to maintain trust in public institutions: (1) serving the public interest, (2) supporting transparency, (3) promoting individual responsibility and (4) creating an organisational culture that does not tolerate conflict of interest.

NCD Alliance Organisational Conflict of Interest Policy

https://ncdalliance.org/sites/default/files/NCDA_Organisational_COI_Policy_April_2020_FINAL.pdf

An example COI policy document

Post-public employment: Good practices for preventing conflict of interest. OECD, 2010.

http://www.keepeek.com/Digital-Asset-Management/oecd/governance/post-public-employment_9789264056701-en#page1

This OECD report from 2010 reviews the measures taken in OECD countries to avoid conflicts of interest when officials leave public office. It provides guidance to policy makers and managers on how to review and modernise rules, policies and practices to prevent and manage conflicts of interest.

Recommendation of the Council on OECD Guidelines for Managing Conflict of Interest in the Public Service. OECD. 2022

https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0316

This document provides guidelines for public employees, both pre- and post- employment to address gaps between the implementation and enforcement of policies, particularly as these relate to State-private partnerships.

Regulating the revolving door. Transparency International Working Paper, 2010.

http://www.transparency.org/whatwedo/publication/working_paper_06_2010_regulating_the_revolving_door

This short working paper offers an introduction to the problem of the revolving door and the associated conflicts of interest which can arise. It goes on to examine the nature of corruption risks and possible remedies.

Sitting on the fence: Conflicts of interest and how to regulate them. Reed, Q., 2008.

http://www.cmi.no/publications/publication/?3160=sitting-on-the-fence

This paper describes the problem of conflict of interest for public officials and the main ways in which it can be tackled, with particular focus on the regulation of elected officials. The paper describes three main types of regulation – prohibitions on activities, declarations of interests and exclusion from decision-making processes – and how these may be best implemented in practice.

Summary table on Institutional guidelines from RECs and SGCs in Sub-Sahara African countries on how to identify and manage common conflict of interest situations in health research

https://health.uct.ac.za/sites/default/files/media/documents/health_uct_ac_za/253/table_coi_ssa_institutional_guidelines.pdf

This table provides an overview of potential COIs, and the institutional strategies in place to manage the COI. It summarises policies from Nigeria, Uganda, South Africa, Rwanda, Sudan, Ghana and Kenya.

The open government guide to asset disclosure and conflicts of interest. Open Government Partnership, 2014.

https://www.transparency.org/en/publications/recommendations-on-asset-and-interest-declarations-for-ogp-action-plans

This document provides ethical guidelines for public officials to avoid, minimise or address conflicts of interest.

World Health Organization Research ethics committees: basic concepts for capacity building, 2009.

https://apps.who.int/iris/handle/10665/44108

This booklet provides a glossary of useful definitions to clarify terms used in research ethics. A framework for evaluating problems and determining the appropriate course of action is outlined.

World Medical Association Manual on Ethics, 3rd edition, 2015

https://www.wma.net/what-we-do/education/medical-ethics-manual/ethics_manual_3rd_nov2015_en/

This document provides a basic introduction to medical ethics and some of its central issues. It is intended to give an appreciation of the need for continual reflection on the ethical dimension of medicine, and especially on how to deal with the ethical issues in clinical practice. A list of resources is provided in the Appendix.

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