

## THE COHRED FAIRNESS INDEX™

## **GLOBAL CONSULTATION DOCUMENT**

(Comprehensive Version)

Printing Date: 22 January 2015

This document is prepared to obtain comments from all stakeholders in international research for health on the establishment of the COHRED Fairness Index (CFI) – intended to create a certification system that promotes fair practices, transparency and accountability in research partnerships for global health.

Feel free to share this document on your website, send it to contacts, or make it wider available in any other manner.

The first global consultation period runs from 21 January – 27 March 2015

For any questions, comments or suggestions please feel free to contact:

Najia Musolino

musolino@cohred.org

### **AKNOWLEDGEMENTS**

COHRED would like to thank the Technical Working Group of the COHRED Fairness Index for the time, valuable input and discussions towards the development of the global consultation document on the COHRED Fairness Index. We thank each member of the Technical Working Group for the successful completion of the report. The responsibility for the contents of this document rests with COHRED. The full list of all members of the TWG is provided on our website: <a href="http://cfi.cohred.org">http://cfi.cohred.org</a>

## COUNCIL ON HEALTH RESEARCH FOR DEVELOPMENT (COHRED)

COHRED, the Council on Health Research for Development, is a global, non-profit organisation whose goal is to maximize the potential of research and innovation to deliver sustainable solutions that promote health, equity and development people living in low and middle-income countries. For more information, please visit our website <a href="http://www.cohred.org">http://www.cohred.org</a>

### THIS REPORT IS PREPARED BY COHRED'S Core Writing Team:

Carel IJsselmuiden, MD, MPH, FFCH (SA) Najia Musolino, PhD Janis Lazdins; MD, PhD Jacintha Toohey, LLB

For more information on the core writing team, please visit <a href="https://www.cohred.org/ourteam">www.cohred.org/ourteam</a>

ISBN N° 978-92-9226-064-4

Contents may be reproduced freely for non-commercial purposes.

### **Council on Health Research for Development (COHRED)**

1 – 5 Route des Morillons PO Box 2100 1211 Geneva 2 Switzerland Tel: +41 22 591 89 00

Fax: +41 22 591 89 10 Email: cohred@cohred.org

http://www.cohred.org http://cfi.cohred.org

## **Executive Summary**

This document is meant to build stakeholder understanding of and engagement with the COHRED Fairness Index (CFI). It constitutes a first public version to elicit substantive comments that will increase the credibility and effectiveness of this Index, which focuses on international health research collaborations. Circulation is global and directed at all parties that have an interest in high quality, responsive and responsible health research collaborations.

The CFI is designed as a certification system based on a best practices guide for all actors in international collaborative research. Its ultimate goal is to improve the alignment of interests of all partners in global health research, and to increase the capacity of low and middle-income countries to optimize the use of research to improve health, reduce inequity and stimulate socio-economic development.

The design of the CFI was steered by a multi-stakeholder Technical Working Group (TWG) who engaged in an interactive, bi-weekly consultation process from September to November 2014.

Guided by the feedback from the Technical Working Group, this report was produced by COHRED's core writing group. It formulates the outcomes of the consultation and is structured to give an overview of the scope of the Index, its operational model as well its potential application and uptake by end users.

The report is now made available for wide global distribution, consultation, comments and contributions for the period: **22 January – 27 March 2015**.

In **April 2015**, the Fourth COHRED Colloquium will bring together 80-100 key representatives of different stakeholder groups during a 2-day meeting at the facilities of the Wellcome Trust in London. The results of the first global consultation will be presented at this meeting. The anticipated outcome is a new version of the CFI and a broad endorsement of its nature and operation.

Over the next 6 months, COHRED's core writing group and Technical Working Group will prepare an update of this document for a second global consultation. Finally, it is expected that the CFI will be inaugurated before the end of 2015.

We are encouraging contributions to improve the alignment of the principles and scope of the Index with the direct needs of all stakeholders of the CFI. These contributions will help us ensure that the CFI will be accountable for the claims the Index makes and that these are backed up by substance.

We also ask you to consider endorsing the need for, and process of establishing the CFI. The more endorsement we have, the easier implementation will become!

Any comments, feedback or questions and endorsement statements are welcome at any time and can be sent to <a href="mailto:musolino@cohred.org">musolino@cohred.org</a> or via the CFI website <a href="http://cfi.cohred.org">http://cfi.cohred.org</a>

## **Table of Contents**

Executive Summary	3
Table of Contents	4
Definitions and Abbreviations	5
Introduction	6
Values Process	10 10
Governance – I – International Standards	12
Governance – II – COHRED Fairness Index	12
Setting Standards – I – Index Systems in general	14
Setting Standards – II – COHRED Fairness Index.  The proposed COHRED Fairness Index – in a nutshell  The Goal Statement for the COHRED Fairness Index  Building Blocks of the COHRED Fairness Index  Objectives and Principles of the COHRED Fairness Index	20 20
Operational Model – I – Index Systems in general	25
Operational Model – II – COHRED Fairness Index	27
Financial Sustainability – I – Index Systems in general	30
Financial Sustainability – II – COHRED Fairness Index	32
Monitoring and Evaluation	36
How to Engage the CFI development	37 37
Further reading	38
APPENDIX	i

### **Definitions and Abbreviations**

#### **Beneficiaries**

The last entity in the value chain that benefits from the impact of the COHRED Fairness Index.

#### **Benefits of Research**

Refers not only to study results, papers and publications, but also the individual, institutional increase in research capacity and research competitiveness, sharing of intellectual property, increased potential for spin-off business and socio-economic activity.

#### **Collaborative Research Partnerships**

Cooperation between researchers and research institutions to address complex problems in research for health. In global health context, such partnerships often imply greatly unequal finance, human resource and contracting capacity that the CFI intends to re-balance. Such 'unequal partnerships' are not limited to research in global health – they can occur anywhere. The CFI will have global appeal to all such situations.

#### **Equity**

In the context of this paper, equity refers to the fair distribution of all the benefits of research for health to all partners engaged in a given partnership.

#### **Fair Research Contracting**

A guidance tool for contractual negotiations developed by COHRED for low middle income country institutions in research for health. See <a href="https://www.cohred.org/frc">www.cohred.org/frc</a>

#### Innovation

In the context of this paper, innovation is used in the sense of new products or services ('technical innovation') and changes in behaviour of individuals or society ('social innovation') that result from research for health being translated into scalable applications and solutions

### Stakeholder in Research

All who are engaged in the research process that impact substantively on health and health equity. A non exhaustive list includes: academia, researchers, international organisations, pharmaceutical companies, other companies involved in research for health – diagnostics, genetics, technology, services, insurance, 'big data' collectors, government institutions, NGOs, donors, philanthropies, research sponsors, concerned citizens.

### **Technical Working Group**

A multi-stakeholder consortium contributing towards the development of the COHRED Fairness Index.

#### Users

The implementer of the guidelines of the COHRED Fairness Index for the purpose of audit and certification in the field of research for health.

### **Abbreviations**

CFI COHRED Fairness Index

COHRED Council on Health Research for Development

FRC Fair Research Contracting

ICDDR,B International Centre for Diarrhoeal Disease Research,

Bangladesh

ISEAL International Social and Environmental Accreditation and

Labeling

LMIC Low and middle income country
M&E Monitoring and Evaluation
TWG Technical Working Group

## Introduction

- Billions of dollars of health research funding
- · Hundreds of thousands research projects
- Tens of thousands researchers
- Thousands of research partnerships
- A thousand and more research Institutions, businesses, universities, nonprofits and public private partnerships
- Close to two hundred governments
- And perhaps 100 major philanthropic funders
- Operate the field of research for health and research for global health
- Without any framework or standards for collaboration, partnerships, benefit sharing, capacity transfer, fairness, transparency and accountability.
- The COHRED Fairness Index is aimed at providing a structure, a tool and an incentive to optimize the impact of research and innovation on health, equity and development around the globe.

---

The purpose of developing the COHRED Fairness Index (CFI) is to establish a costeffective global mechanism to encourage the attainment of the highest standards in global best practices in international collaborative research for health.

Improving health, increasing longevity and deepening well-being requires sustained and growing investments in research for health. <sup>1</sup> This applies as much to high as to low and middle-income countries and populations. While much health gains can be achieved through improving health systems and service delivery, the major gains in longevity, health and well-being – and sustaining these – will require increasing research and innovation. In turn, such research and innovation will have to rely increasingly on effective multi-stakeholder and transnational partnerships to deal adequately with complexity, scale and equitable access.

Low and middle-income countries face an extra hurdle – their system for research [and innovation, *see footnote 1*] are not sufficiently robust to address their own priority health challenges. Years of global support for health research in low and middle income countries have resulted in many products, many improved services, many lives saved but have not substantially improved the systems that countries need to prioritize, conduct, commission, partner or finance research and to translate results into effective policy, practice and products.

<sup>&</sup>lt;sup>1</sup> In first instance, we focus the CFI on 'research for health' rather than 'research and innovation for health'. This is done in the realization that we will have to include 'innovation' in the near future, that it will be complex enough to get started even in the more limited domain of 'research for health', and that it will be eminently possible to expand the CFI in future to include innovation partnerships as well.

The primary rationale for embarking on the creation of the CFI was to measure and incentivize international research partnerships involving researchers, donors, industry, institutions and research sponsors from high-income countries on the one hand, and those of low and middle-income countries on the other hand.

But there is even more at stake. As the differences between 'developing' and 'developed' countries is blurring, imbalances in research relationships are everywhere, even within high-income countries. A mechanism that would improve distribution of all benefits of research and the research enterprise will be instrumental in growing the global capacity to deal with increasingly complex health challenges – when and where they occur.

Imbalanced partnerships put partners at risk of unintended (and, perhaps also, intended) harm to people – through omission or commission, as there may be insufficient checks or regulatory capacity in the system. In addition to individual harm that may result, researchers – research funders – research institutions and business taking part in such partnership may run the risk of serious damage to their reputations in the countries concerned and even globally.

#### An Effective CFI Should Result In:

- Greater health research capacity
  in low and middle income countries,
  and even worldwide, to deal with
  more complex problems and
  provide more comprehensive
  solutions
- 2. **Reduction of harm** of research to people
- Reduction of reputational risk to all partners in the research process and to health research itself

---

As a result of COHRED's traditional focus on building research and innovation system capacity with and in emerging economies, the often flagrant imbalances in the relationship between partners in research for health started our interest in designing a cost-effective mechanism that can improve research partnership balance and a more equal access to the benefits of research. However, as we started work on the CFI and began wide consultations with all types of stakeholders in global research for health, it became clear that there are many other very good reasons why a CFI could be useful. As we heard more opinions, there are at least 7 other major areas where the CFI can have a positive impact each of which may have to find a place within the COHRED Fairness Index.

1. **Research Contracting**: In 2006, the International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR,B) raised the issue of equitable research contracting practice with the World Health Organization's Advisory Committee on Health Research(3). ICDDR conducted a survey that found that more than 70% of the contracts were negotiated by principal investigators rather than by their base-institutions, and that more than 85% of the contracts were identified as unclear or difficult to understand by staff who handled the contracts. One result of this work was the development by COHRED of a Fair Research Contracting (FRC) Initiative – <a href="https://www.cohred.org/frc">www.cohred.org/frc</a>.

- 2. **Equal Partnership is not the same as Equal Financial Contribution**: while there is a general wish to describe research relationship as 'partnerships', this does not imply financial or other equality in power between partners. The same applies to 'co-financing' of research efforts and funding schemes: a million dollar to a high income country Foundation is not the same as a million dollar to a low or middle income country research institution. The CFI will need to find a practical definition of how 'equal' is defined and assessed in fair partnerships.
- 3. **Responsibility for post-research action**: research sponsors, pharmaceutical companies and large research institutions in high income countries would like to have an acceptable standard of what constitues 'best practice' in ensuring that medicines, diagnostics, technologies or biologicals developed as a result of research become available to populations and countries that participated in research. From blank refusal to take any responsibility to attempts to forumulate ad hoc responses the CFI will need to agree on a best practice and on indicators to measure these.
- 4. **Reputational risk**: not having substantive and transparent guidelines with clear mechanisms of implementation puts all actors in the research process especially private sector and research sponsors at risk for reputational harm and demands for financial compensation for real or perceived harm. A CFI should be able to significantly reduce risk of reputational harm.
- 5. <u>Acceleration of contracts, increased accountability, trust</u>: negotiating any contract, including for collaborative research, without competent negotiators on both sides is a recipe for delay, frustration, lack of trust, and even corruption. The CFI should incentivise all sides to invest in growing research partnerships management capacity and transparency leading to quicker and better contracts, increasing trust, and reduction of financial loss or non-implemented contracts.
- 6. Aligning different interests of different partners harmonizing relationships: Most successful research institutions and their staff have world-class expertise and operate in a very competitive environment where excellence and productivity are the only focus. Many researchers in such institutions do not realise that there is an extensive system around them that enables them to become super-focused and highly productive. Countries and institutions on the way to becoming world-class often have other priorities in particular, to also become globally competitive, to be able to attract people and finance, to spin-off companies and create value in their societies. By clarifying different objectives and finding space to meet both output and system goals of all partners, the CFI can be instrumental in changing ad-hoc collaborations that expend lots of energy to create into long-term, productive partnerships that are easier to maintain.
- 7. **Preventing 'collateral damage' of large research programmes**: when one large clinical trial can absorb more than half of the nurses that a country graduated in a year, it is obvious that research can do more harm than good. The CFI could include a measure of balance between costs and benefits of research in relation to the health system.

There are probably many more areas where a CFI can have positive impact – which is exactly what we intend to find out through this consultation. Please do provide comments and insights into other areas where you feel the CFI should play a role.

In response to the above issues, COHRED embarked on the development of a standard that would serve to provide guidelines for best practices in international collaborative partnerships in research for health. Thus, the subject of this document is primarily aimed to serve the stakeholders with an Index that will add value to their own specific areas of operation in research for health.

In short, the COHRED Fairness Index (CFI) as proposed is designed as:

# A facilitation mechanism in international collaborative health research aiming to

- Increase fair distribution of effort and benefits, transparency, accountability and relevance to global health
- Encourage all users to gradually improve collaborative partnerships

The Index will include indicators, a measurement process, and a reporting system that is independent, transparent and that can address the key problems and potentials of collaborative research partnerships.

### **Limitation of Scope of CFI – at inception:**

In principle, the CFI may address fairness in collaborations at national, institutional or project levels. *At this stage, we propose to limit its application to certification at national and institutional level,* because the infrastructure to deal with certification at project level will be too complex. Nevertheless, at a later stage, we may well want to begin including large research programmes, for example.

While we focus on collaborations in research for health in this document, we are aware that, with appropriate modifications, a similar Index system could be of relevance to research collaborations in other sectors. <u>At this time, the CFI focuses</u> on research collaborations focused directly on having a health impact.

In the future, the application may – and probably should – also be expanded to cover innovation partnerships as that is where most translation of research to intended health outcomes happens, and where much of the economic added value of the research enterprise takes place. For purposes of this first round of global consultation, the CFI is designed to focus on the research partnership component only – not on innovation.

## **Consultation and Decision-Making**

#### **Values Process**

While we have given significant importance to stakeholder input for designing the COHRED Fairness Index, great attention has also been given to the major work devoted by the ISEAL Alliance to develop the understanding of building robust index and certification systems that focus on environmental sustainability.<sup>2</sup> Therefore, building the COHRED Fairness Index did not start from scratch: in the preparation of this document we have relied extensively on the ISEAL Credibility Principles<sup>3</sup> and adapted these where appropriate.

#### **Timetable**

The development of the COHRED Fairness Index (CFI) includes a sequential process of multi-stakeholder consultation and reporting. The following flow-chart describes the process from the inception of the CFI until its expected launch in October 2015.



Figure 1. Timelines of the work plan for the development of the COHRED Fairness Index

<sup>&</sup>lt;sup>2</sup> http://www.isealalliance.org

<sup>&</sup>lt;sup>3</sup> Principles for Credible and Effective Sustainability Standards Systems, ISEAL Alliance.

### **Stakeholder Consultation**

An index can only be as good as the added value that it offers to all its stakeholders. To ensure optimal value for all partners in <u>collaborative research</u> <u>for health</u>, we are committed to a very open process of consultation and decision-making.

The development of the CFI is the result of a multi-sector consultation approach involving a Technical Working Group (TWG) with representative key stakeholders from both categories including NGOs, international organizations, philanthropies, donors, the public and private sector as well as academic institutions. Using a rigorous methodology, these key stakeholders in global research and innovation propose CFI as an important tool that highlights new opportunities for fair and equitable partnerships in resource limited settings. With a size of 28 members, the TWG has been built to represent a wide spectrum of constituencies with close attention to balance in gender and geographical representation. The stakeholders were engaged for consultation through 5 rounds of consultation (electronic surveys) as well as interviews (by phone or in person). The stakeholders engaged during the consultation period defined the preliminary features of the CFI. Details on the membership and constitution of the TWG can be found on <a href="https://cfi.cohred.org/technical-working-group/">https://cfi.cohred.org/technical-working-group/</a>.

In addition to the steps outlined in Figure 1 above, we envisage the following steps in global consultation:

- 1. <u>Posting of this document</u> (in downloadable and on-screen, interactive format) to enable a worldwide dissemination and review. Start 22 January 2015.
  - Receive online comments until 27 March 2015
  - Synthesize version 2 of this report by 12 April
  - Consideration of version 2 by high level stakeholder meeting in London, 16-17 April
  - Synthesize comments and production of version 3 by 15 May 2015
  - Global Consultation Phase 2 on the latest version
  - Synthesize inputs from this phase to inform final implementation in October 2015.Ongoing stakeholder consultation and CFI improvement cycles will be started from then.
- 2. <u>Crosslinks to CFI website through interested organisations</u>
- 3. <u>Use of workshops and conferences in which COHRED is involved</u>
- 4. Twitter and Facebook campaigns
- 5. <u>Campaign to get early endorsements of the principle and process (see further in this document)</u>

## Governance – I – International Standards

The three most common types of governance structure for internationally used standards or indexing systems are:

- **Membership based:** Individuals or organisations will have indirect representation in decision-making, e.g. Board of Directors (representation from different sector, interest and geographic scope).
- **Appointed decision-making body:** Members representing the interests of different stakeholders each elected by the 'standard-owner' or by the appointed decision-making body itself.
- **Multiple appointed decision-making body:** A small governance body (strictly operational focusing on 'due diligence' of organisation) and a larger body that is actually responsible for the decisions on the content and features of the Standard/Index System. (Possibly the implementing organisation or a Technical Advisory Board to the implementing organisation).

## Governance – II – COHRED Fairness Index

To advance the global acceptance and use of the COHRED Fairness Index (CFI), a credible and impartial governance structure needs to be put in place.

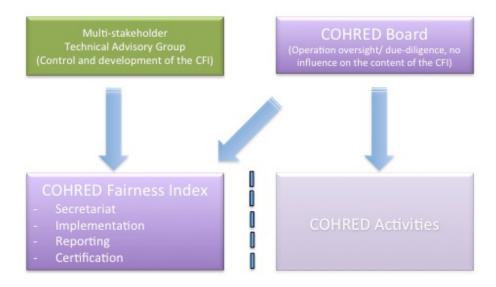


Figure 2. Schematic diagram of the proposed governance structure of the COHRED Fairness Index.

**The following key points** have been considered to be essential in proposing an appropriate governance structure for the CFI:

- 1. **Independence:** the governance structure will probably not differ from other proven governance structures of international standards, but it shall be independent and transparent with an expertise that inspires confidence and confers credibility and legitimacy.
- 2. **Low cost:** A heavy governance structure will be avoided to 'keep costs down and enable agility'.

The real 'standard owner' of the CFI is the multi-stakeholder Technical Advisory Group of which COHRED is a member like any other stakeholder. This group has the mandate to improve, update, and change the standard according to agreed and transparent process. Size, composition and operations will be determined in phase 2.

**The organisational home for the CFI is COHRED** – with two main areas of responsibility:

- 1. <u>COHRED Board:</u> operational oversight and ensuring due diligence in the way COHRED implements the CFI, as it does for all other COHRED work. The Board does not influence the standard or the certification process.
- 2. <u>COHRED CFI staff</u>: ensures implementation of the work of the CFI independent of other COHRED work. It concerns 5 major functions:
  - 2.1. Secretariat to the Technical Advisory Group
  - 2.2. Implementation of CFI activities
  - 2.3. Reporting
  - 2.4. Certification
  - 2.5. Financial sustainability and management

## Setting Standards – I – Index Systems in general

### **ISEAL Principles**

This section has been adapted from work done by the ISEAL Alliance. <sup>4</sup> The ISEAL Alliance, a global membership association for sustainability standards, proposes ten principles of credibility as the nucleus around which standards should be built. The ISEAL Alliance encourages use and adaptation of these principles to suit specific standards, such as the CFI, rather than using them as compliance guidelines for the development of any Standard.

The 10 ISEAL Credibility principles are: <sup>5</sup>

- 1. Sustainability
- 2. Improvement
- 3. Relevance
- 4. Rigour
- 5. Engagement
- 6. Impartiality
- 7. Transparency
- 8. Accessibility
- 9. Truthfulness
- 10. Efficiency

Please see the ISEAL publication on Credibility Principles for details. We found all except the first one to be of direct relevance to the construction of the CFI, and have replaced 'sustainability' with 'fair research partnerships'. In other words, the CFI as presented in this document should satisfy all of these 10 principles. Comments are specifically invited to modify the CFI in ways that make it an even better reflection of these principles. Perhaps there are other, more relevant principles as well.

### **Operating Standards**

### An 'Index' or a 'System'?

An 'Index' can be a tool that is published for use – a type of 'best practice' consensus without the backing of a 'system' of measurement, verification or certification.

The CFI is proposed as a 'system' – including indicator and standard development over time, provision of index tools for self-assessment, followed by a process of verification and certification. Effective implementation will be a process that will take time to develop, and needs a complement of staff and an organisation behind it for improvement, validation, communication and certification.

<sup>&</sup>lt;sup>4</sup> ISEAL Alliance – www.isealalliance.org

<sup>&</sup>lt;sup>5</sup> http://www.isealalliance.org/our-work/defining-credibility/credibility-principles

### Voluntary or externally monitored or both?

Standards can be made available for voluntary use, implementation and reporting. Or a system for measurement, reporting and certification is set up outside the organisations using the index. Or, there is a combination of both.

The CFI is proposed as a mixed model – with a strong component of self-assessment to reduce costs and encourage gradual improvement – complemented by periodic external verification and certification.

## **Setting Standards – II – COHRED Fairness Index**

The primary goal of the CFI is to create a certification system that promotes fair practices, transparency and accountability in research partnerships for health – globally – prioritizing low and middle income countries.

There are currently many international indices for the measurement and evaluation of the social and environmental activities of the private sector. None of these address the specific issues raised by international research collaborations.

To our best knowledge there is no other available standard that seeks to achieve the same goals as the COHRED Fairness Index (CFI). The closest standard available in global health research are the "11 Principles and 7 Questions" printed in the "Guide for Transboundary Research Partnerships" published by The Swiss Commission for Research Partnerships with Developing Countries (KFPE), as a set of principles for voluntary use in science in general. <sup>6</sup> These eleven principles of research partnerships proposed as guidelines for grant applicants and funding agencies are an exemplary effort in fostering balanced partnerships between developing countries and low middle-income countries.

The absence of guiding frameworks does not automatically imply a need to create one. However, COHRED and the CFI Technical Working Group believe that there is an urgent need for such and Index and guiding mechanism to benefit not only low and middle income country (LMICs) related health research partner-ships but also in or between high income countries or in and between LMICs.

In 2006, the International Centre for Diarrhoeal Disease Research in Bangladesh (ICDDR,B) raised the issue of equitable research contracting practice at a meeting of the World Health Organization's Advisory Committee on Health Research. COHRED was asked to pursue this work, and a multi-author, multi-institutional publication on 'improving research contracting' resulted (9). Since its publication, COHRED has pursued the translation of this work into a practical tool under the name of the "Fair Research Contracting (FRC) Initiative" with support from a variety of donors and philanthropies. FRC consists of guidance documents for institutions without trained contracting staff to negotiate fairer research collaboration agreements, connection to intellectual property advisors, webbased support and possible on-site training.

While FRC is useful in for individual projects and institutions, it does not provide a mechanism for global reach. The logical next step became the conceptualisation of a certification mechanism that can include verification of adequate research contracting in addition to many other aspects of fair partnerships in international research. CFI is also more likely to be of use voluntarily, even without COHRED involvement, and be used by high-income country researchers. Above all, achieving improvement in research for health partnerships through certification will be far more cost-effective than a system of individual technical support.

<sup>&</sup>lt;sup>6</sup> http://www.naturalsciences.ch/organisations/kfpe/11\_principles\_7\_questions

<sup>&</sup>lt;sup>7</sup> www.cohred.org/frc

A certification mechanism like the proposed CFI will have stronger global impact at very low cost with minimum infrastructure. Once conceptualised in this context, it became rapidly clear that the terrain of international health research partnerships is vast and largely unstructured, and providing a framework for 'fairness' in several other important components of research partnerships was a high priority for a very different set of stakeholders. Seven such examples were given in the introduction. These demands were not merely voices from governments and research institutions of "the South" but also calls from both private and public research institutions in "the North".

Based on this clear global interest in an Index that can foster trust, accountability and equity in international research partnerships for health – in a cost-effective and efficient manner – COHRED decided to continue with the further development of the CFI.

### The proposed COHRED Fairness Index – in a nutshell

As the name suggests, the COHRED Fairness Index (CFI) is envisaged as an Index System that will be designed <u>to set and measure best practices in collaborative partnerships in research for health</u>.

In principle, the CFI can be designed at multiple levels to address fairness in research collaborations for health at national, institutional or project/programme level. At this stage, for practical and not for principle purposes, we propose to limit its application to <u>certification at national and institutional level</u>.

The financial and operational aspects of the CFI are envisaged to be affordable and cost-effective in order to make the Index <u>accessible to all its stakeholders</u> without exception.

As a result, a combination of self-assessment and external audit is proposed. To increase both global reach and organisational independence, we foresee that external audit is done by accredited individuals or institutions [not by COHRED].

Accreditation of competence, verification of due diligence and compliance with CFI standards for auditors that will be prepared by COHRED's Technical Advisory Group will be done by COHRED, as will be the final certification. COHRED will not have influence on the audit itself – that is the responsibility of accredited assessors or auditors.

### How can the COHRED Fairness Index add value to its stakeholders?

In the construction of the CFI, we have mapped expectations of different potential users of the CFI to understand better how it can create alignment of the objectives of the CFI with the level of assurance that each CFI user will want before engaging with it. The table below gives a summary of this 'map'.

BENEFITS OF USING THE COHRED FAIRNESS INDEX				
If you are a donor	<ol> <li>You will demonstrate respect and value for transparency and openness to public scrutiny of engagements with grant recipients.</li> <li>You are thinking local, respecting the priorities of your beneficiaries.</li> <li>Wide application of the CFI will lead to improved national priority setting, accountability and institutional research management capacity.</li> </ol>			
If you are grant recipient	<ol> <li>Enhance public profile as a proof to research sponsors and the public that the utilisation of grants is executed under the code of conduct of the CFI.</li> <li>Increase your fundability by building and improving longstanding relationships based on reputation and trust with collaborators.</li> <li>Facilitates access to partners and partnerships.</li> <li>Better contracting expertise.</li> </ol>			
If you are a <b>research</b> contract organisation or SME in health in a low middle-income country	<ol> <li>Gain leverage to convince local governments and private sector to invest in priority problems.</li> <li>Easier to establish and gain access to local resources.</li> <li>Access to a practical tool to prove transparency.</li> <li>Higher result rate and lower failure rate.</li> <li>Gain a competitive edge.</li> <li>Provide a proof of books: Proof of fairness, provides validity. Maintain an up-to-date record of practices.</li> </ol>			
If you are a low income R&D institution seeking to improve funding track	<ol> <li>Gain partners sensitive to best practices, for example by using FRC, and focus on priorities.</li> <li>Increase the benefits sharing and ability to negotiate.</li> <li>Provides you with incentives to improve institutional capacity for research management.</li> <li>An investment in the future value of the institution.</li> <li>Provide assurance to partners/collaborators that the figures and activities shown in contracts are true and equitable.</li> </ol>			
If you are a pharmaceutical company	<ol> <li>Decrease reputational risk, increase credibility</li> <li>Have a simple tool to improve the social bottom line of your company.</li> <li>Provides a guideline that defines limits to the extent of engagement needed in good partnerships.</li> <li>Identify and avoid duplication and redundant activities to reduce transaction costs and time wasting.</li> </ol>			
If you are a research sponsor	<ol> <li>Provides a guideline that defines key characteristics of fair and productive partnerships – which you can include in your grant requirements.</li> <li>Results in an increased pool of competent research managers in your partner institutions.</li> <li>Reduce potential conflict of interest in partnership with the private sector in funding research.</li> <li>Demonstrate commitment to transparency.</li> </ol>			

If you are a ministry of health, science and Technology in low middle-income countries or Research Council	Have donors and research sponsors align better with national priorities. Research system building is enhanced. Practical tool to support national research governance. Build institutional partnerships and promote moving from personally driven to strategically institutional driven relationships with collaborators. Demonstrate that the institution has a strong control environment that sufficiently mitigates potential risks. Easier agreement on 'equity' in partnerships.	
If you are an international organisation	<ol> <li>Reduce potential conflict of interest in partnership with the private sector in funding research.</li> <li>Provides a practical and transparent approach to research engagement for global health.</li> <li>Practical tool to exercise global research stewardship.</li> <li>Promote a culture of 'consciousness for equity in partnerships'.</li> </ol>	

Table 1. Advantages of using the COHRED Fairness Index

In brief, the CFI as proposed can be a way forward to establish parameters that will not only assess how solid, equitable and fair research collaborations are, but that can also provide a framework for the alignment of interests in collaborations.

In particular, we see four 'domains' where interests of different stakeholders may be at a variance and where the CFI can have a two-fold effect: the CFI can make the differences in interests between partners explicit, and, secondly, it can stimulate action for alignment by the certification process and by the preference for durable partnership creation.

### Different levels of Expectations of Health Research Collaborations

#### 1) Context

- 1. Political goals
- 2. Ethical goals
- 3. Financial goals

### 2) Capacity and Technical ability

Issues of capacity and technology transfer, overhead costs, training, leadership, research contracting.

### 3) Outcomes of Research

Not just research results, but also expectation on IP sharing, pricing of drugs, coauthorship, decision on publications, data sharing and ownership.

### 4) Economic Benefits

The 'business of research' is a major source of jobs, income tax, social development and careers in some areas but not in all. The CFI can also measure potential economic benefits of international research collaboration, for example, at national level.

### The Goal Statement for the COHRED Fairness Index

### We propose the statement of intended change to be:

The CFI will promote global best practices in research for health by creating a widely accepted and cost-effective mechanism that measures and certifies alignment in health research collaborations at governmental and institutional levels. <sup>8</sup>

### **Building Blocks of the COHRED Fairness Index**

In order to shape the final contents of the COHRED Fairness Index, we have to specify the hierarchy of elements or 'building blocks' in more detail. The figure below provides a generic scheme – applicable to any standard or index – as suggested by the ISEAL Alliance.

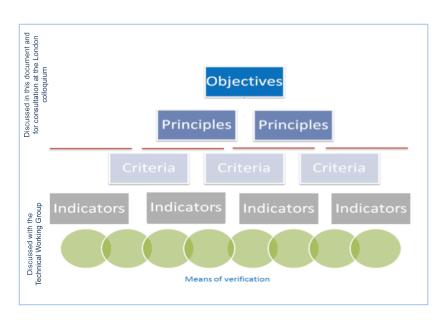


Figure 3. Adapted with permission from ISEAL Emerging Standards - Module 2: Setting Standards9

To clarify this – a very limited set of objectives is derived from the goal statement of a standard/index. The proposed Goal Statement of COHRED is provided on the previous page. In subsequent pages, we have proposed 3 Objectives and a total of 7 Principles that should direct the development of the CFI.

<sup>&</sup>lt;sup>8</sup> The application of the CFI to projects is not part of the current phase of development – this is for pragmatic reasons only. In particular, at the start, including it would add an enormous layer of complexity for implementation while excluding it will not prevent the CFI from including project / programme focused certification later.

 $<sup>^9\,</sup>http://www.isealalliance.org/online-community/resources/module-2-setting-standards-0 \ and \\ http://www.isealalliance.org/sites/default/files/Standard-Setting-Code-v5.0.pdf$ 

We also decided that the more technical work of defining 'criteria', 'indicators' and 'means of verification' is beyond this first Global Consultation. We first want to come to a common understanding and agreement on the Goal Statement and the derived Objectives and Principles. That is the purpose of this first phase, and of the April meeting in London.

From there – the more technical parts of the CFI which will be the subject of the Global Consultation 2 phase involving the Technical Working Group, any other interested parties.

### **Objectives and Principles of the COHRED Fairness Index**

This is the heart of the CFI – and, together with the next section on operating the CFI – it is here where we hope to achieve most feedback, comments and suggestions for improvement. It is also here where we seek broad consensus – this is what the CFI intends to achieve. Please consider this section and the next carefully, and, where possible, comment in detail – providing alternatives, examples, case-studies where it will help to illustrate the need for changing these objectives and principles.

Objective: Common understanding of what the standard seeks to achieve

**Principle:** Provide the details of the objectives

**Criterion:** Conditions required to achieve a principle

**Indicator:** Measurable states whether the criteria are being met

**Means of verification:** Type of information used to demonstrate achievement of an envisioned state

From these definitions<sup>10</sup> it should be clear why this document focuses on the top of the hierarchy first. Nevertheless, we have worked out an example to show how these five building blocks fit together. Should you already wish to comment on 'criteria, indicators or means of verification' at this time – please feel free to do so, but our priority at this time is wide agreement on Objectives and Principles.

### Example of the use of a Standard Hierarchy

Hierarchy of the COHRED Fairness Index - example only				
Objective	Promote Equitable Health Research Partnerships			
Principle 1	Transparency in finance, decision making, protocol development, study execution			
Criteria	Full disclosure on these 4 areas to collaborators (in detail) and to public (in summary format)			
Indicators	<ol> <li>Financial Transparency:</li> <li>Institutions have a policy to make total research budget known to partnership leaders prior to contract and throughout study.</li> <li>Overall research spending information will be made public per country, per disease / health area.</li> <li>Institutions receiving funds will keep records of allocation by investigator, project, focus area</li> </ol>			
Means of verification	<ol> <li>Policy document exists and is available</li> <li>Financial audits (internal, external) are available</li> <li>Annual reports / routine publications contain sufficient information for public to understand allocation</li> </ol>			

Table 2. An example of the building blocks of the COHRED Fairness Index

-

 $<sup>^{10}</sup>$  Adapted from ISEAL Alliance

### Proposed Objectives and Principles of the COHRED Fairness Index

## **OBJECTIVE 1:** Promote equitable health research partnerships

### PRINCIPLES:

- 1. **Transparency** in finance, decision making, protocol development, study execution
- 2. Research contracting is compatible with an existing fairness index or standard (such as FRC, KFPE)
- 3. **Capacity transfer** where needed ('any intervention that will reduce capacity imbalance in scientific, technical, ownership, financial or institutional sense')

OBJECTIVE 2: Increase resources for research for health – prioritizing low and middle income countries and populations – and improve their use

### **PRINCIPLES:**

- 1. **Equitable contributions or resources** from partners in collaboration
- 2. **Improve research management** at institutional level **and research governance** at national level
- 3. Allocation of research resources commensurate to local priorities
- 4. **Post research action** is taken to the limits of agreed responsibilities

OBJECTIVE 3: Include all health research priorities – *local and global* – receive adequate attention

### **PRINCIPLES:**

 Are there credibly set and regularly updated national health research priorities – and are institutions aligned with these

- 2. **Built-in flexibility** to deviate from standard funding and granting protocols to accommodate local priorities
- 3. Links to policy, practice and implementation

## Operational Model – I – Index Systems in general

### **Operational models**

In addition to "what an index measures", it is key to define "how it will do so, and how it will report". There seem to be four operational models in common use:

- **1. Guidelines for voluntary implementation** (such as the KFPE principles<sup>11</sup>)
- **2. Self-assessment only** (*Good Weave International*<sup>12</sup>)
- 3. Self-assessment supplemented by external audit and an accreditation scheme (such as well known index systems like the Forestry Stewardship Council<sup>13</sup>, Better Cotton Initiative<sup>14</sup>, Global Reporting Initiative<sup>15</sup>, etc.)
- 4. External ranking and publishing
  - a) **Comparative ranking** (e.g. for responsible investment e.g. Vigeo <sup>16</sup>, Covalence Ethical Quote <sup>17</sup> or for 'big pharma' contribution to increase access to medicines e.g. the Access to Medicines Index <sup>18</sup>)
  - b) Ranking with 'naming and shaming' (Berne Declaration<sup>19</sup>)

As we indicate below, it is proposed that **the CFI uses general scheme 3**: a combination of self-assessment supplemented with external audit and an accreditation scheme for auditors / assessors.

We note that "self-assessment" has limitations in evaluating partnerships. By definition, it represents only one side of the partnership. As the CFI is focusing on partnership arrangements, we may decide to widen the concept of "self-assessment" to include all partners. This limitation may have special relevance to 'project certification' and possibly less or none at all to the use of the CFI at institutional or national levels.

What the CFI does need to include is a transparent manner to deal with diverging opinions between partners. Perhaps this can take the form of a mechanism to lodge an objection to certification to the certifying body (COHRED) which could then request a renewed self-assessment or a renewed external audit.

<sup>11</sup> http://www.naturalsciences.ch/organisations/kfpe/11\_principles\_7\_questions

<sup>12</sup> http://www.goodweave.org/home.php

<sup>13</sup> https://ic.fsc.org

<sup>14</sup> http://bettercotton.org

<sup>15</sup> https://www.globalreporting.org/Pages/default.aspx

<sup>16</sup> http://www.vigeo.com

<sup>17</sup> http://www.ethicalquote.com

<sup>18</sup> http://www.accesstomedicineindex.org

<sup>&</sup>lt;sup>19</sup> https://www.bernedeclaration.ch

### **Scoring mechanisms**

There are, generally, three scoring types in use:

- **5. Percentage based scoring**: attainment of a percentage threshold defines compliance.
- **6. Pass or fail score**: *Non-compliance is divided into major and minor categories, each with a defined pass / fail level for its indicators.*
- 7. **Stepwise scoring**: such as a "Traffic Light" system with red, yellow, green practices, including an improvement scheme over a period of time. This usually includes the requirement of conformity with minimum scores for indicators in the initial certification phase followed by further improvement over specified periods.

<u>Example:</u> Applicants with advanced level (green) score are awarded the Standard's seal of approval for 5 years. Applicants with intermediate level score (yellow) are awarded the Standard's seal of approval for 3 years. Applicants with unsatisfactory score (red) are awarded the Standard's seal of approval for 1 year followed by an obligatory second round of audit and certification.

### **Reporting and Certification**

Reporting is a key component of most operational models. In the most limited application, reporting remains internal and the guidelines serve as an aspirational goal relying on the goodwill of the individual or the institution. At the other end of the spectrum is full public reporting of key information for the sake of transparency and accountability.

Certification labelling is one example of public reporting. Other forms include newsletters, press release, annual reports, monographs, web-site information, social media use and advertising.

#### **Complexity of Operating an Index**

We have studied well over 75 index systems that we thought appropriate to the construction of the CFI. The organisation of these varies from the very simple to very complex, with clear implications for cost and human resources, and therefore, for financial sustainability.

At its simplest, the certifying organisation ('standard owner') and the auditors are parts of the same organisation that work independently, a regular practice in financial audit companies. At the other end, the 'standard owner' may be different from the certification organisation, which may be different from auditors, which may be different from the organisation accrediting the auditors. In other words, all parts of the process may be outsourced to specialist agencies except the awarding of the "seal of approval" – which remains the domain of the 'standard owner'.

The clear message in relation to designing an effective COHRED Fairness Index is to create a pragmatic solution that can be performed credibly, at minimal costs, and be set up for future expansion.

## Operational Model – II – COHRED Fairness Index

In the case of the COHRED Fairness Index (CFI) – designed, at the start, for implementation at the institutional and national levels - we propose a mechanism similar to the model 3 described in the previous section: a combination of self-assessment supplemented by periodic external audit and accreditation of assessors/auditors. This should provide a relatively simple and cost-effective three-step approach that allows for a separation between assessment/audit and certification. A schematic representation of the proposed process is given in Figure 4.

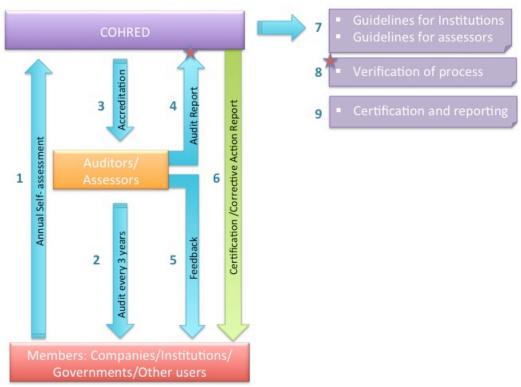


Figure 4. Work Flow design of the operational model of the COHRED Fairness Index

### The Essential Steps Proposed to Operate the CFI are:

- 1. <u>Reporting through self-assessment</u> on a set of indicators developed under the CFI. The reporting is envisaged to be annual.
- 2. <u>A periodic external audit</u> performed by individuals or organisations who are legally and structurally separate from COHRED, who use CFI Standards and Guides developed and maintained in a transparent process managed by Technical Advisory Committee.
- 3. <u>Accreditation of Assessors/Auditors</u> will be done by COHRED using Accreditation Guides prepared by the Technical Advisory Committee in a public and transparent manner.

- 4. <u>External audit reports are sent to COHRED</u> to complete information needed for certification / re-certification. The role of COHRED will be to verify that Assessors/Auditors adhere to CFI process, guidelines and accreditation requirement. COHRED has no influence on audit outcomes.
- 5. <u>Constructive feedback from auditors/assessors</u> to institutions, in addition to the audit report, is expected.

We envisage for the future that there will be a panel of accredited assessors and auditors who are publicly listed. The contracting of the auditors is left to individual institutions or countries. Selection of auditors may include criteria of cost but also feedback or other services – the determination of which is left to the contracting institution or government.

6. <u>Certification and/or Indication of Corrective Action Requirements</u> will be provided by COHRED, based on timely submitted self-assessments, external audits, and verification of due process by auditors/assessors.

To ensure the CFI works, COHRED's responsibilities include:

- 7. <u>Preparing Guides and Standards</u> for self-assessment and external audit through the Technical Advisory Group.
- 8. <u>Preparing Guides and Implementation Mechanism for accreditation of assessors and auditors</u> through the Technical Advisory Group.
- 9. <u>Reporting, Awarding Certification</u> Labels or Logos, and monitoring of effective and correct implementation.

The CFI system is primarily designed to provide a pathway for all stakeholders in health research partnerships to improve partnership arrangements, effectiveness and outcomes over time. The CFI is NOT meant to be a 'comparative ranking' system, and definitely not a 'naming and shaming' version of this. The following tools and reporting are proposed to support this operating principle:

- 9.1. **CFI may decide to use a 'step-wise' scoring system** possibly in the following 'traffic-light' manner:
  - 9.1.1. *Those with a positive score on 75% of indicators or more <u>and</u> do not score negative on any 'major' indicator will be awarded a <u>GREEN certification</u> valid for a period of 3 years subject to annual submission of self-report.*
  - 9.1.2. *Those with a positive score of 50 to <75% of indicators <u>and</u> do not score negative on any 'major' indicator will be awarded an <u>ORANGE certification</u> valid for a period of 2 years subject to annual submission of self-report.*
  - 9.1.3. **Those with a positive score of <50% of indicators** <u>and/or</u> **score negative on any** 'major' indicator will be <u>flagged RED</u> and not awarded the certification. A report with a corrective action needed to achieve the certification is issued by COHRED.

- 9.2. **Dealing with disagreements**: to deal with discrepancies and interim changes in status quo of users, we propose the following:
  - 9.2.1. *In case of substantive changes* (e.g. change in law, merger, change of mission of institution etc.), the institution involved needs to notify COHRED. An assessment will be done to see existing certification needs to be withdrawn, if corrective action needs to be taken, or if renewed self-assessment or external audit is required.
  - 9.2.2. In case of complaints or an expression of disagreement submitted by any legitimate stakeholder involving a particular certified institution or government, COHRED may require a renewed self-assessment and/or audit even before the normal scheduled assessment or audit is due, or withdraw the certification altogether.

### 9.3. Public and Individual Reporting by the COHRED Fairness Index

The CFI will focus both on individual and public reporting – through

### 9.3.1. Individual Reporting

- Certification
- Possible supplements to audit reports
- Comments on self-assessment reports

### 9.3.2. Public Reporting - periodically / annually

- Listing of certified users including Green and Orange label
- · Listing of accredited auditors / assessors
- Guidelines, Indicators, Process descriptions
- Monitoring and Evaluation Reports and Analysis: based on member reports, external audits, and ad hoc investigation
- · Financial reports and external audits of COHRED

### 9.3.3. Public Reporting – on-going

- Web-based information updates and real-time information on most of the above
- Newsletter to users to stimulate continuing improvement

COHRED Fairness Index Self -assessment •CFI Users submit a self-assesment report annually. This will be carried out internally by the applicant to evaluate their performance against the requirements of the CFI Code of Practice

Second party : Externa

- CFI Users engage an accredited auditor of their choice
- CFI Users prepare and implement a corrective action plan for any nonconformance
- Major non-compliance will require remediation before (re-)certification

Thrid party : Verification and Certification

- •COHRED verifies due process concerning external audit
- •COHRED provides the CFI certification

Figure 5. Core of proposed implementation scheme of the COHRED Fairness Index

## Financial Sustainability - I - Index Systems in general

### Financial sustainability

While it is common practice to rely on grants-in-aid for the development and start-up costs of any Index, it is crucial to determine a business model that will allow the Index system to achieve self-sufficiency in the shortest possible time early on in the Index development.

We have found many ways in which existing international standards achieve financial self-sufficiency or even make profit if they are designed to serve that purpose. As is well known, there are many businesses and organisations whose core business is certification and accreditation.

Each method or combination of methods will have its particular advantages, disadvantages and potentials for conflict of interest that need to be countered. A major additional factor to consider is that reduction or elimination of disadvantages and potential conflicts of interest is likely to increase complexity and costs of the system – to the extent that some key stakeholders will no longer be able to be (full) users.

A non-exhaustive list of the most common practices is given to help deliberation on what would be best for use in the CFI:

### **In-cash contributions:**

- **8.** Donations, charitable **grants**
- 9. Individual/institutional/organisational membership
- **10. Subscription** service
- 11. User fees
- 12. Sponsorship and partnerships
- **13. Fourth party funding**: Bodies along the value chain that will benefit from entities having received certification may subsidise the costs of such audit and certification to improve their own inputs
- 14. Assessors/Auditors: Licence fees
- 15. Consultancy services to meet Index standards
- **16. Sales** of Index related material

### **In-kind contributions:**

- 1. **Media sponsorship** program for raising awareness
- 2. **Pro-bono support** from partners to improve awareness and recognition of the CFI label/logo

### "Critical Users and Critical Payers"

To be able to design a sustainable financing system, an Index system will need to have a sharp analysis of who will be the "critical users" and who will be the "critical payers".

User segmentation is necessary, as any Index system will have different values and benefits for different users. A clear understanding of who the users and who the payers are and what their particular interests are in the CFI is crucial to ensure that the content of the Index is responsive. It is also key to determining the business model and in deciding who should be the priority participants in the continued updating of the Index.

The segmentation may include users both from high, middle or low income countries; from Non Governmental Organisations (NGOs) and Civil Society Organizations (CSOs); investors; donors; capacity building organisations; government organizations; international organizations; researchers and academic institutions; patients or healthcare professionals organisations; corporations; Small and Medium-Sized Enterprises (SMEs); Public Private Partnerships (PPPs) and Product Development Partnerships (PDPs), or any other stratification that makes sense – only limited by the need to reduce complexity and costs of implementation.

<u>"Critical Payers" are not necessarily the same as "Critical Users"</u> – especially not in situations like the CFI where an Index Systems is intended to help reduce capacity gaps.

For example, a low income-country institution may not be able to cover the full cost of an audit. In this case, the System should still be able to provide an audit at a loss to this particular institution in question but be able to compensate from other sources.

### **Branding Strategy for Index Systems**

Non-profit organisations often do not think in terms of branding. However, it is clear from successful International Standards that an explicit branding, labelling and also trademarking can be crucial for success and development of the Index even at an early stage.

### **Label and Trademark**

Misuse of certification and labelling – especially of those with global impact – is not uncommon. Different modes of protection are available such as patents, trademark or copyright to assure appropriate use of the Index logo/label.

## Financial Sustainability - II - COHRED Fairness Index

The proposed CFI is designed as a non-profit, financially self-sufficient index system operated within an existing organisational infrastructure to minimize start-up costs.

Achieving financial sustainability for the CFI has been divided into three phases:

### Phase 1: development – up to October 2015

This is our current phase. The costs are carried by COHRED from its core budget, and are supplemented by small contributions from Pfizer, Sanofi and Celgene including an in-kind contribution from the Wellcome Trust. We expect some other sources of funding to become available before October to reach a balance between paying stakeholders.

### Phase 2: Start-up – three years, up to 2018

From October 2015, when the CFI will be activated, we expect a gradual increase in users, including paying users. The exact business model for financial self-sufficiency is being developed currently– but, irrespective of the model, we anticipate it will take 3 years for user derived income to cover costs.

- 1. To implement the start-up phase and create a core operating unit we estimate that EUR 300,000 per year will be needed for 3 years.
- 2. For credibility reasons, it is essential that the sources of funding are balanced, i.e. funding should not represent one group of stakeholders only.

### Phase 3: Implementation, Improvement, Growth - from 2019 onwards

User derived income will cover cost and future growth. The experiences of other successful and sustainable indices show that maturity is often only reached after 10 years or more.

At this time, we envisage a mixed source of income derived from the following (not necessarily in the order of priority). The low range will correspond to users from low middle-income countries. At first sight, the potential for income generation allows the CFI to become self-sufficient and grow gradually after that. We hope and expect that such state can be reached within 3 years.

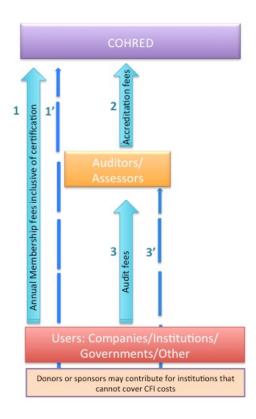
Magnitude of Annual Contributions needed to make the CFI self-sufficient – *indicative*:

- Non-profit institution/organisation membership fees (approximately EUR 2,500-10,000)
- 2. For-profit organisation/corporate/ low middle-income SMEs membership fees (EUR 5,000-20,000)
- 3. National membership fees (EUR 7,000-50,000)
- 4. **Assessors/Auditors Licence fees** (EUR 500-1,500 for individuals and 5,000-10, 000 for corporate)
- 5. **Research sponsors and research funders** (EUR 10,000-30,000)
- 6. **Philanthropy and impact investors** (EUR 10,000-30,000)
- 7. **Fourth party funding** for institutions that cannot afford membership fees
- 8. Additional sources to be developed

At this time, we cannot be very specific as our market survey and understanding is far from complete. Following this Global Consultation (1) and the April High-Level Meeting, we will be able to be far more detailed in building a solid business plan for the CFI.

Until then, we propose that the following funding streams will be at the heart of the financial sustainability of the CFI – see Figure 6 below.

- 1. **Annual membership fees for users** inclusive of the certification.
- 2. Annual auditor accreditation fees.
- 3. **Periodic external audit fees** paid by Users directly to accredited auditors.
- 4. **Donors or sponsors contributions** for institutions that cannot cover CFI costs themselves (for example, as part of grant awarding to institutions, the funder may demand that the grantee institutions are CFI compliant) or pay for specific expansions or applications of the CFI that can not be funded from regular income.
- 5. **Additional sources** may be developed as the system advances.



 $\label{lem:control} \textbf{Figure 6. Schematic representation of money channels in the implementation of the COHRED Fairness Index. } \\$ 

## Critical Users and Critical Payers of the CFI - for consideration and improvement

	Critical User	Category	Critical Payers +/++/+++
1	Research / Academic Organisations in LMICs	Non-profit institution/organisation	+++
2	LMIC Governments Health, STI, Education, Finance	National membership	+++
3	Pharmaceutical Industry (And related industry: CROs, Medical Technology, Health & Beauty producers)	For-profit organisation/corporate/ low middle-income SMES	+++
4	Global non-profits, PPPs, international research collaborators	Non-profit institution/organisation	++
5	Bilateral donors / HIC Governments of Development Cooperation, Foreign Affairs	Research sponsors and research funders	++
6	Philanthropies in this area, including disease specific foundations	Philanthropy and impact investors	++
7	International Research Sponsors	Research sponsors and research funders	+++
8	HIC research institutions, universities	Non-profit institution/organisation	+++
9	International Organisations	Fourth party funding for institutions that cannot afford	+
10	Patient (Safety) Organisations	Non-profit institution/organisation	-
11	Media / scientific and public press etc.	Fourth party funding for institutions that cannot afford	-
12	Research start-ups (non-profit, for profit)	For-profit organisation/corporate/ low middle-income SMEs	+
13	Others	Additional sources	-

Table 3. "Critical Users" and "Critical Payers" of the CFI as potential critical payers

### **Branding Strategy COHRED Fairness Index**

Until there is more clarity about the CFI, its users and payers, we cannot focus on branding of the COHRED Fairness Index (CFI). Following the Global Consultation (1) and the London High-Level Meeting in April, branding and marketing will become a priority.

### Label and Trademark for COHRED Fairness Index

As part of the consultation with the COHRED Board and the COHRED Fairness Index (CFI) Technical Working Group, it was decided to pursue a trademark in Switzerland for the CFI. COHRED Fairness Index was filed for trademark registration in Switzerland (Swiss Trademark n° 664310). This allows CFI to be associated to the annotation, ™ providing it a strong protection at the national level. For further protection at the international level, the Madrid System for international registration of trademarks (Madrid Protocol) is currently under consideration.

## **Monitoring and Evaluation**

To demonstrate the practical impacts of the COHRED Fairness Index (CFI), it is essential to determine what improvements have been achieved within a three-year (short-term) or a 10 year (long-term) span. A monitoring and evaluation (M&E) program will be an important aspect of the CFI to determine the changes in international collaborative research in health that have occurred over time as a result of cumulative behavioural and etiquette changes in the potential users of the CFI.

At this time, we have noted the urgency to develop a comprehensive M&E system, but realise also that the M&E system is intimately linked to decisions about the CFI Goal Statement, Objectives and Principles – i.e. the very topics of this Global Consultation (1). Once these are clear, and we have had time to develop and agree on indicators and means of verification, we anticipate that short-term evaluation would link to the use of the CFI. In the medium- and long-term, a focus on outcomes and impact on practices of stakeholders will be possible. More downstream impact measure may well be possible to create, but we decided not to spend time on this until there is an agreement on Goals, Objectives and Principles.

### Short term M&E

- Number / increase of users
- Number / increase of payers
- Increase of certifications per year
- Number of attendees at CFI consultation events
- Number of citations of the CFI
- Financial results

### Medium and long term

- Number of orange and green certifications awarded and those moving from one to the other
- Quantification of the changes in the indicators that measure the achievement of the objectives and principles of the CFI (See pages 23-24). This is the basic 'outcome' framework for the CFI.
- Work still needs to happen to find suitable long-term impact measures.

## How to Engage the CFI development

### 1. Comment on this Document

It may well take 3-5 years to set and begin operating this Index, and many more years to mature the concept and its implementation but this will not stop us from beginning and advancing the process. A global participation of stakeholders at this early stage is key to ensuring it will serve your purposes as well as those of others – that you are represented as well as others.

**Global Consultation 1** – *i.e. this document* – **will take place between 22 January and 27 March 2015**. After that, we will be preparing a new document based on all the inputs received. Please contact us by mail or phone, or leave a comment on this document on our website using the following contact details:

E-mail: <a href="musolino@cohred.org">musolino@cohred.org</a>
Telephone: + 41 22 591 89 00
Website: <a href="http://cfi.cohred.org">http://cfi.cohred.org</a>

### 2. Endorse the COHRED Fairness Index - now

This development stage is a sensitive period and depends on scarce funding, a small but committed group of people, and – most importantly – on the clear expression of interest of future users.

You can help this effort tremendously by making your support for the CFI known through an endorsement. Endorse <u>the need for</u> and <u>process of development</u> of the CFI, without committing in any way – at this time – to the final product nor to future use.

The CFI needs it, to get CREDIBILITY, LEGITIMACY and RECOGNITION. The CFI website will carry the names (and logo's) of institutions and names and affiliations of individuals on the CFI website – if you agree.

In the Appendix, we have included two Template letters: one for Institutional and one for Individual endorsement of the CFI. You are free to modify these to suit your circumstances.

We provide a possibility of endorsement on the COHRED Fairness Index website as well <a href="http://cfi.cohred.org">http://cfi.cohred.org</a> or by directly contacting <a href="musolino@cohred.org">musolino@cohred.org</a>.

### 3. Support Us

Especially in the first 3 years, we need start-up funding and it needs to come from a multitude of potential Users to enhance its credibility. Even small contributions can help us achieve the targets for getting the CFI off the ground. A budget is provided in the section on "Achieving Financial Sustainability" on Page 32.

If you want to make a financial contribution – please contact Najia Musolino directly on <a href="mailto:musolino@cohred.org">musolino@cohred.org</a>

## **Further reading**

- 1. Afsana, K., Habte, D., Hatfield, J., Murphy, J., & Neufeld, V. (2009). Partnership Assessment Toolkit. Canadian Coalition for Global Health Research.
- 2. Bammer, G. (2008). Enhancing research collaborations: Three key management challenges. Research Policy, 37, 875-887.
- 3. Bates, I., Akoto, A., Ansong, D., Karikari, P., Bedu-Addo, G., Critchley, J., & Agbenyega, T. (2006). Evaluating health research capacity building: An evidence-based tool. PLoS Medicine, 3: e299
- 4. Bradley, M. (2008). On the agenda: North-South research partnerships and agenda-setting processes. Development in Practice, 18, 673-685.
- 5. Buss, P.M., & Ferreira, J.R. (2010). Critical essay on international cooperation in health. RECIIS, 4, 86-97.
- 6. CCGHR (n.d.) Building respectful and collaborative partnerships for global health research. Ottawa: Canadian Coalition for Global Health Research
- 7. CIOMS (2002). International ethical guidelines for biomedical research involving human subjects. Geneva: CIOMS.
- 8. countries. Geneva: COHRED, Global Forum for Health Research and UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR),
- 9. David A Sack VB, Michael Behan, Alejandro Cravioto, Andrew Kennedy, Carel IJsselmuiden & Nelson Sewankambo. Improving international research contracting. Bulletin of the World Health Organization 2009;87:487-487.
- 10. ESSENCE (2011). Planning, monitoring and evaluation framework for capacity strengthening in health research. Geneva: TDR/ESSENCE
- 11. Fowler, A. (Ed.). (2013). Striking a balance: A guide to enhancing the effectiveness of non-governmental organisations in international development. Routledge.
- 12. Ghaffar, A., IJsselmuiden, C., & Zicker, F. (2008). Changing mindsets: Research capacity strengthening in low- and middle- income
- 13. Marais, D., Toohey, J., Edwards, D., & IJsselmuiden, C. (2013). Where there is no lawyer: Guidance for fairer contract negotiation in collaborative research partnerships.
- 14. Migot-Adholla, S., & Warner, M. (2005). North-south research partnerships: A guidance note on the partnering process. London: Overseas Development Institute.
- 15. Migot-Adholla, S., & Warner, M. (2005). North-south research partnerships: A guidance note on the partnering process. London: Overseas Development Institute.
- 16. Miriam Shuchman, Dawit Wondimagegn, Clare Pain & Atalay Alem (2014). Partnering with local scientists should be mandatory. Nature Opinion, 20, 11-11.
- 17. OECD (2006). The challenge of capacity development: Working towards good practice. Paris: OECD.
- 18. OECD Global Science Forum (2009). Investigating research misconduct allegations in international collaborative research
- 19. projects: a practical guide. OECD.

#### **APPFNDIX**

### Endorsement letter on behalf of an institution:

### USE YOUR INSTITUTION'S LETTERHEAD, please

### **TO COHRED**

### **ENDORSEMENT FOR THE COHRED FAIRNESS INDEX (CFI)**

In our capacity as the....., we write to express our support for the development of the COHRED Fairness Index (CFI).

We understand and support the COHRED Fairness Index (for ethical and equitable research collaborations for health), which is being developed through global consultation of all stakeholders – to create a certification system that promotes fair practices, transparency and accountability in research partnerships for global health.

In doing so, the CFI hopes to contribute substantially to global health by improving research partnerships, financing, benefit sharing, institutional and national research management and governance, infrastructure, and more – especially in low and middle income countries and populations.

Accordingly, we are pleased to endorse the need for the COHRED Fairness Index.

We understand that by endorsing the COHRED Fairness Index, we are not committed to approve the final Index nor to become a User. Endorsement also does not commit us to make any financial contribution – even though we may decide to do so to advance or accelerate its development.

We agree that the official logo of ....... can be used as a symbol of endorsement of the CFI on any relevant documentation (advocacy material, web portal, meeting presentations) produced related to the CFI.

Finally, we understand that we can cancel our endorsement at any time by informing COHRED in writing of our decision to do so.

Signature Position Institution Place Date

### Endorsement letter for individual:

### PLEASE USE YOUR ON YOUR PERSONAL LETTERHEAD, if available

### **TO COHRED**

### **ENDORSEMENT FOR THE COHRED FAIRNESS INDEX (CFI)**

In my personal capacity, I want to express my support for the development of the COHRED Fairness Index (CFI).

I understand and support the COHRED Fairness Index (for ethical and equitable research collaborations for health), which is being developed through global consultation of all stakeholders – to create a certification system that promotes fair practices, transparency and accountability in research partnerships for global health.

In doing so, the CFI hopes to contribute substantially to global health by improving research partnerships, financing, benefit sharing, institutional and national research management and governance, infrastructure, and more – especially in low and middle income countries and populations.

Accordingly, I am pleased to endorse the need for the COHRED Fairness Index.

I understand that by endorsing the COHRED Fairness Index, I am not committed to approve the final Index nor to become a User. Endorsement also does not commit me to make any financial contribution – even though I may decide to do so to advance or accelerate its development.

I agree that my name can be used as a symbol of endorsement of the CFI on any relevant documentation (advocacy material, web portal, meeting presentations) produced related to the CFI.

Finally, I understand that I can cancel our endorsement at any time by informing COHRED in writing of our decision to do so.

### Signature :

Position (optional – but preferable) Institution (optional – but preferable) Place Date