Center for Informed Consent Integrity (a programme of the GE2P2 Global Foundation)

Informed Consent in the Council for International Organizations of Medical Sciences (CIOMS) guidance on Clinical research in resource-limited settings

Webinar, 21 July 2021

https://ge2p2global-centerforinformedconsentintegrity.org/webinar-series/

Speakers

Webinar Host – David Curry, MS; President & CEO, GE2P2 Global Foundation

Paige Fitzsimmons, MA; Associate Director, Center for Informed Consent Integrity, GE2P2 Global Foundation

Dónal O'Mathúna, PhD; Senior Fellow and Director, GE2P2 Global Foundation; Associate Professor, College of Nursing and Center for Bioethics, The Ohio State University

Getnet Yimer, MD, PhD; Director, Global One Health Eastern Africa Office

Call Summary

Blue: Selected key points of discussion (from the recording, timer readings in brackets)

On July 21st 2021 the GE2P2 Global Foundation's Center for Informed Consent Integrity continued a series of webinars focused on integrity in informed consent. This call focused on the newly released CIOMS Guidance on clinical research in resource-limited settings.

(00:15) Overview

David Curry opened the call with a high-level overview of the guidance and its relationship to the 2016 CIOMS guidance: International Ethical Guidelines for Health-related Research Involving Humans.

The 2021 CIOMS consensus report is complementary to the 2016 CIOMS ethical guidelines, amplifying on certain points. Taken together, they are a powerful complement to other guidelines and norms, and should be used to guide most research.

Foreword points to some real, relevant issues:

- Research in resource-limited settings (RLS) can sometimes be exploitative, with adverse effects for participants or communities.
- Good quality research in RLS is needed.

Content

- Five report chapters; focus of this webinar is on ethics / informed consent

Conclusions, some key points:

- Regulatory systems and oversight in low- and middle-income countries remain fragile
- Current Good Clinical Practice (GCP) guidelines originated in industrialised countries and are challenging to implement in RLS
- Need to build sustainable local research capacity
- Need for cooperation between researchers, funders, industry, regulators

(00:13:00) Informed consent in the 2021 CIOMS consensus report

Paige Fitzsimmons followed with a brief overview of how informed consent is treated in the guidance.

4.2.1, Informed consent

- Possibility to withdraw at any time
- Distinction needed between study participation and being offered a new treatment
- Must be culturally relevant

- Must not be a mere symbolic paper
- Verbal information should also be given
- Language / translations
- Getting true informed consent from illiterate participants
- Family and group consent may be needed

2.2.4, Legal / regulatory issues

Chapter 4, salient recommendation

- Researchers should spend adequate time and resources to obtain true informed consent

Annex 1, Special populations: Children – getting assent

(00:22:00) Field perspectives of the guidance

Getnet Yimer provided observations and reflections on this guidance and associated challenges with implementation from a field research and ethics review board perspective.

Target audience: governments, regulatory authorities, researchers, sponsors, international organizations…

Limitations:

- Consensus report is based on individual personal experience, no in-depth literature review
- More contributors from LMICs would help drive implementation

Bold statements, e.g. calling attention to rampant corruption

Need to make Research Ethics Committees (RECs) aware of this guidance.

Challenges in obtaining informed consent:

- True understanding needed: REC should approve the information given, should "read every word"
- Fear of signing
- Role of impartial witnesses – do they understand what they are being asked to do?
- Family involvement, there can be many problems

Barriers to implementation should be analysed in advance, tailored strategies needed

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(00:37:20) CIOMS guidance: Community engagement

Dónal O'Mathúna closed the discussion by examining how community engagement is treated in the new guidance.

Amplifying on Guideline 7 of the 2016 CIOMS ethical guidelines, showing "how" – this will help, reduce misunderstandings

4.5.1, Methods of community engagement – see the example of the CAGED study:
Community engagement and building trust to resolve ethical challenges during humanitarian crises-experience from the CAGED study

4.5.2 Benefits of community involvement – benefits-sharing negotiation

2.2.5, Public distrust: This is a real concern

Cultural issues need more attention in research, see e.g.:

- Peeters Grietens K, Ribera JM, Erhart A, et al. Doctors and vampires in sub-Saharan Africa: ethical challenges in clinical trial research. Am J Trop Med Hyg. 2014;91(2):213-215. doi:10.4269/ajtmh.13-0630

- Kate Chatfield, Doris Schroeder and Joshua Kimani. Vulnerable Populations in North-South Collaborative Research. Nairobi Plenary 2016

4.4.1 Responsibilities of REC: Includes obtaining true informed consent

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Overall, the 2021 report does a great job of showing how good quality research can be conducted in RLS.

(00:53:30) Open forum

This panel was followed by open discussion amongst all call participants.

Introducing Walter Jaoko (DNDi / University of Nairobi), a contributor to the 2021 CIOMS Working Group report

Research integrity is important – how to safeguard this?

- Value of sponsors' audits to complement ethics review/institutional review board (IRB)
- See the TRUST project, calls for integrity (*Global code of conduct, reference 6 in the CIOMS report)*
- Need the right IRB members
- Shared responsibility: regulators, sponsors …

Local ethics guidelines should be adaptive, living documents.

Communities should be involved from the design stage (but funding often only comes afterwards)

Cultural challenges are multiplied in multi-site trials across cultural settings

In paediatric research, community involvement can drive recruitment of participants

"Next steps" to implement guidance (this one, and others) in LMICs:

- Implementation guideline for countries
- Mechanisms to disseminate (webinars? Training module? Video presentation? Providing printed guidelines works e.g. for HIV, TB, but less well for ethical guidance)
- Monitor uptake and implementation – would make an interesting case study: life cycle of a guidance: uptake, steps, delays …
- Some guidance gets picked up by other organisations such as ICH, and then becomes part of national regulations. Can CIOMS approach WHO to help drive such a process?

Bioethics guidance in general is challenging to implement. A Cochrane review found little scientific evidence that activities to improve research integrity actually change researchers' attitudes, knowledge and behaviour:
Marusic A, Wager E, Utrobicic A, Rothstein HR, Sambunjak D. Interventions to prevent misconduct and promote integrity in research and publication. *Cochrane Database Syst Rev*. 2016;4(4):MR000038. Published 2016 Apr 4. doi:10.1002/14651858.MR000038.pub2

(1:30:40, webinar closed)