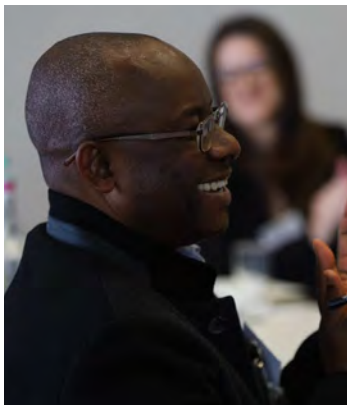


PREPARED

RAPID. EFFECTIVE. ETHICAL.

KICK OFF MEETING

28 - 30TH SEPTEMBER 2022
UNITED NATIONS UNIVERSITY
BONN

Co-funded by
the European Union

PREPARED KICK OFF MEETING REPORT

NADIA KORNIOTI AND DORIS SCHROEDER

5 DECEMBER 2022

We would like to thank Karen Hattenbach and Alina Dobra from the UN University in Bonn for being our generous hosts.

Citing suggestion:
Nadia Kornioti and Doris Schroeder (2022) Prepared Kick-off Meeting Report, available at: https://prepared-project.eu/.

PREPARED is co-funded by the European Union as grant agreement: 101058094.

EXECUTIVE SUMMARY

11 OF THE 16 TEAM LEADERS

PREPARED stands for 'Pro-active Pandemic Crisis Ethics and Integrity Frame-work', and the project's objective is to develop an ethics and integrity framework to support rapid and effective research during global crises.

Project out-puts include:

- an interdisciplinary, accessible, and jargon-free code of conduct for research during global crises,
- 'how to' guidelines to support the needs of research teams, and
- engaging training and capacity building materials, to be disseminated across the Globe.

This will be achieved through the project's extensive network of 16 teams and 14 advisors from five contInents.

This report provides a summary of the kick-off meeting held at the United Nations University in Bonn from 28-30.9.2022.

DAY 1 28TH SEPTEMBER 2022
13:30 WELCOME AND MISSION

Dirk Lanzerath, EUREC and **Karen Hattenbach, UNU** welcomed delegates to Bonn.

Dorian Karatzas greeted the audience on behalf of the main funder, the European Commission.

Doris Schroeder introduced a Draft Mission ...

- We enable fast-paced research to address global crises.
- We focus on research ethics and integrity embedded in global equity.
- We include the voices of vulnerable populations in our work.
- We deliver engaging, concise output for optimal training and impact.

Dirk Lanzerath

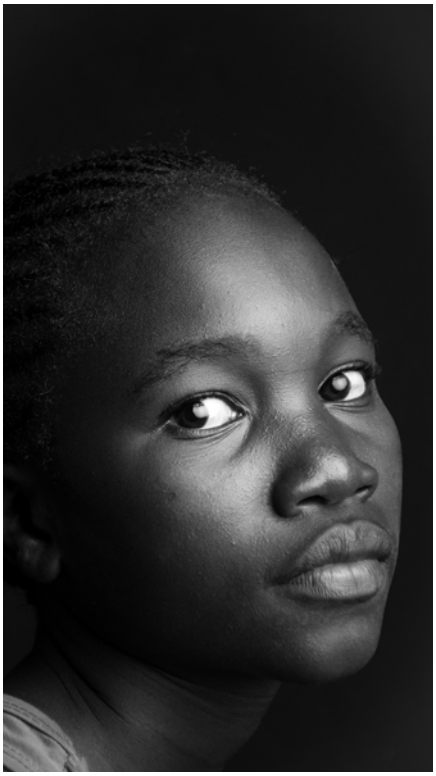
Karen Hattenbach

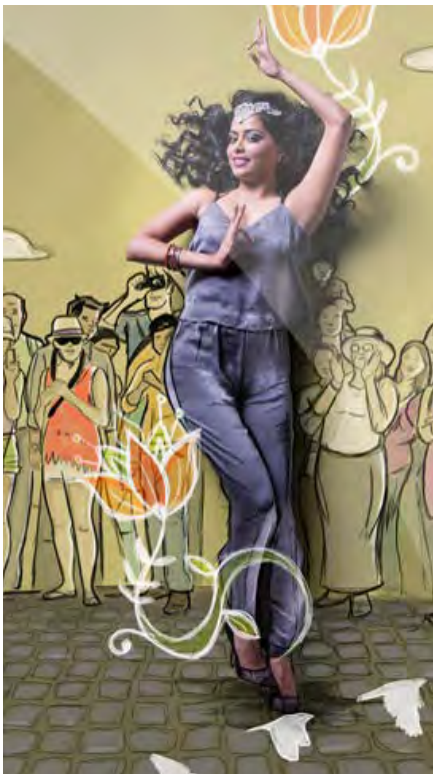
Dorian Karatzas

Doris Schroeder

DAY 1 28TH SEPTEMBER 2022 (CONT)
13:30 WELCOME AND MISSION

... and examples of the work of the project photographer and designer.





DAY 1 28TH SEPTEMBER 2022
14.00 WHAT TEAMS WILL DO FOR PREPARED

Nadia Kornioti

Michelle Singh

Joshua Kimani

Lisa Tambornino

Francois Bompart

Fritz Schmuhl

UCLan Cyprus (Nadia Kornioti) is the Co-ordinator of the project and will lead the development of the ethics and integrity framework for global crisis.

European and Developing Countries Clinical Trials Partnership (Michelle Singh) lead the eight engagement platforms and - as a large-scale funder of health research - the task of ascertaining the learning needs of stakeholders.

Partners for Health and Development in Africa (Joshua Kimani) bring the perspective of vulnerable populations, representing 40,000 sex workers in Nairobi, to the project.

EUREC (Lisa Tambornino) provide access to all **ENERI** https://eneri.eu/ tools, lead the training work package as well as the tasks ascertaining synergies with other projects, stakeholder needs and the development of operational guidelines.

Advisor Francois Bompart, DnDI, provides expertise on access to medicines in lower income settings and is responsible for a scoping review in French.

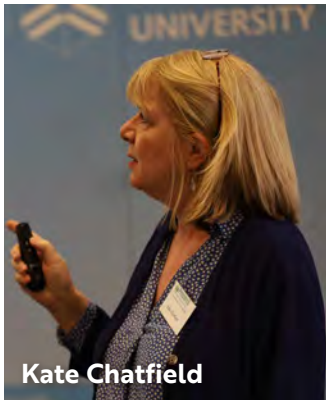
Advisor Fritz Schmuhl links the project to the publishing world, as a senior editor of NATURE Springer.

DAY 1 28TH SEPTEMBER 2022
14.40 TRUST - OUR SISTER PROJECT

Kate and Pam summarized the main lessons learned from the TRUST project as:

- Extensive stakeholder engagement and co-creation
- In-depth research identifying exploitation risks
- Rooted in moral values that resonate internationally
- Avoidance of jargon and focus on conciseness
- Mission driven

https://www.youtube.com/watch?v=POBoER-gO1xY


Kate Chatfield

Pamela Andanda

Hazel Partington

Klaus Leisinger

Pamela Andanda

EnyaO'Connell-Hussey & Orla Drummond

Carleigh Krubiner

Johannes Rath

15.30 WHAT TEAMS WILL DO FOR PREPARED

UCLan UK (Hazel Partington) lead the case studies, the overlapping consensus analysis and are responsible for a special issue in SAGE Research Ethics.

Foundation Global Values Alliance (Klaus Leisinger) lead the industry platform of the project and have a major role in dissemination.

University of the Witwatersrand (Pamela Andanda) lead the fact finding mission with scoping reviews in 7 languages and input from vulnerable populations.

Trilateral (Enya O'Connell-Hussey & Orla Drummond) lead the Dissemination work package and the legal analysis of the challenges of undertaking research during crisis.

Advisor Carleigh Krubiner, Wellcome Trust, provides expertise from one of the biggest health research funders in the world to the project.

Advisor Johannes Rath will provide a report on good biorisk management in global crises.

THE VIEW FROM THE CONFERENCE ROOM

DAY 2 29TH SEPTEMBER 2022
10:00 RISKS FOR RESEARCH DURING GLOBAL CRISES

Michael Makanga

Michael Makanga

Funders' Perspective during COVID19 pandemic

Risks to research

- Lengthy approval process and strained oversight of ongoing research
- Disruption of clinical research activities and enrollment
- Disruption of laboratory activities
- 'Covidization' of research

The pandemic experience helped in the formation of the 'Seven Funder Principles for research in epidemics & pandemics' https://www.ukcdr.org.uk/re-source/funder-principles-for-re-search-in-epidemics/ to inform future funding.

Now is the time to refocus and course-correct.

Eugenijus Gefenas

Eugenijus Gefenas

Research and Russian invasion of Ukraine

Russian invasion of Ukraine bring Research Ethics and Integrity challenges of a different scale; largest refugee crisis in Europe since WWII.

For example, attack on Karazin National University, destruction of equipment, some equipment now in Russian-occupied territory. Some professors and students have been displaced. 'Brain-drain' of female researchers who are amongst refugees.
His research team lost contact with Russian researchers.

Recommended reading: NATURE Seven ways the war in Ukraine is changing global science (2022) https://www.nature.com/ar-ticles/d41586-022-01960-0

DAY 2 29TH SEPTEMBER 2022
10:00 RISKS FOR RESEARCH DURING GLOBAL CRISES (CONT)

Sanna Kaisa Spoof

Sanna Kaisa Spoof
Risks for Research during Global Crises

Research Integrity (RI) is more important during a pandemic. Need for different kind of guidelines at different levels (national, continental, international etc). National guidelines are especially important as they can address misconduct well. Efforts to offer misconduct guidelines at European level have not been successful to date.

There are several different national approaches in Europe at present and some countries have not yet developed their own RI national framework. **ENRIO** – European Network of Research Integrity Offices; one of its activities is to issue guidance statements, including on the pandemic.

Angus Dawson

Angus Dawson
Vaccine Development

Important questions: should research and research governance be done differently during a pandemic? Should we 'skip' or combine established steps in research development processes? Should we use different methods (e.g human challenge trials)? Do we need a 'special' ethics for emergencies, etc?

It is recommended that existing procedures and methods be retained taking into account a need for adaptations. Changes may impact adversely on public trust in a new vaccine, or other routine vaccines, as well as public health in general. Moving away from established systems, there is also a danger that communication with the public is affected.

The discussion after this session was highly engaged focusing on the tension between speed and rigour and potential impacts on trust in science.
Ethics implications in the dissemination of research, e.g. through social media, needs attention when working on trust in science.

We may need a definition of 'crisis' as a project.

Could some research governance convergence be achieved in Europe to stream-line and accelerate processes?

DAY 2 29TH SEPTEMBER 2022
11:00 WHAT TEAMS WILL DO FOR PREPARED

Nearchos Paspallis

Vilma Lukasevicience

Irakli Khodeli

Natalie Evans

Angus Dawson

Shunzo Majima

ICLAIM (Nearchos Paspallis) lead the WP on guidelines, supplements and policy tools. They will also deliver an interactive, highly engaging ethics training app.

Vilnius University (Vilma Lukaseviciene) leads the deductive gap analysis to establish the values on which the moral framework will be based.

UNESCO (Irakli Khodeli) co-lead the policy platform and are the Spanish language partner to obtain insights not published in English.

VUMC (Natalie Evans) lead the engagement WP, including all dialogue events with stakeholders and the evaluation of all training materials.

Advisor Angus Dawson provides academic expertise as a vaccine ethics and public health ethics expert.

Advisor Shunzo Majima provides the Japanese perspective on global crises, including the impact on research after the tsunami.

DAY 2 29TH SEPTEMBER 2022
12:00 CASES - RESEARCH DURING GLOBAL CRISES

Kate Chatfield

Stephanie Laulhe-Shaelou

Kate Chatfield (Chair)

Why are case studies important?

- Help identify challenges in real life context.
- Help identify gaps in government processes.

Case studies are fantastic for teaching, bringing research ethics and integrity to life for students. Excellent learning tools to see what to apply or not.

Stephanie Laulhe-Shaelou

Crisis research in divided societies

Frozen conflict in Cyprus (as a case study). Particular challenges for policy, particularly for the EU, with cross-border implications.

Large research and ethics challenges in times of crisis. Divided societies are ill-equipped to face crisis situations, because their responses are inadequate. Lack proper check and balances. Divided societies react mechanically, with tendency to use the same mechanisms to tackle whatever crises come up. E.g Cyprus used the colonial law to tackle the COVID19 pandemic.
This derives from a focus not to upset existing balances.

What lessons can we learn from divided societies?

Important to be able to work on the ground.

Each crisis is a blow to the democratic process and disengages people. Covid19 brought a physical barrier to Cyprus between the communities of the island, with the crossing points being closed for 18 months. There was a need to find alternative ways of communications.

Impossibility to work at the global level another challenge.
Solutions – Empowering civil society. Advocacy, strategic litigation, policy work. Such work has to benefit local populations and communities.

DAY 2 29TH SEPTEMBER 2022
12:00 CASES - RESEARCH DURING GLOBAL CRISES

Joshua Kimani

Joyce Adhiambo
Perspective as a sex worker and HIV+

The restrictions to movement had a direct impact, due to people's inability to access health services, but also other needs such as food.

Livelihoods were impacted. Some people lost their lives due to lack of access to services and medicines. Also violence increased, since people had to move into enclosed areas. People engaged with people of uncertain Covid status, further spreading the virus.

COVID19 vaccines came fast, whereas people did not have access to an HIV vaccine for the last 20 years. Increase of lack of trust among them.

Death threats and mental health issues are other phenomena observed.

Need for better access to information in pandemics like this one.

The audience highly appreciated the input from this session. The perspective of Joyce and Joshua showed the impact of crises on poorer populations, which have different needs. Further clarifications included: COVID19 created an environment where there was not enough time to engage with communities ahead of research studies. There was a lot of suspicion. Some people had no access to mobile phones, so it was challenging to share information even that way.
Stephanie concluded on need to combine academic and civil society work to engage communities during major crisis.

Joshua Kimani
Lived experience with COVID19 as front-line worker

Numerous ethical challenges for Nairobi clinics when lockdown was into effect. Patients could not access the research clinics. No access to medicine. No access to services. Employees had to work from home. Sex workers could not work. What about the rights of the clinicians?

If there was a Covid case in the clinic, the clinic had to close down.

Ethical challenges in detecting COVID19 and issues of confidentiality. If somebody came to the clinic, should that person be reported to the authorities as breaking the lockdown even for access to medicines?

Controversy of suggestion for clinical trials on COVID to take place in Africa. Not enough time to look at risk assessments for the programme, to read protocols and prepare.

Loss of medical research funding, due to changes in priorities. Community had to be educated before they participated in the new studies. A very confusing time. Dealing with multiple donors and protocols was an addi-ional challenge under very tight time constraints.

Joyce Adhiamho

DAY 2 29TH SEPTEMBER 2022
14:30 RESEARCH DURING GLOBAL CRISES WEBINAR

PREPARED and **SAGE** MethodSpace combined forces to engage with the world beyond the kick-off meeting. Thanks to our very knowledge, high-profile panel, who made the webinar such a success for online and in-room audiences.

Dr Katherine Littler (WHO) and Prof. Charles Weijer completed the panel of experts by joining remotely.

The Webinar can be watched here, where a transcript is also available.

https://www.methodspace.com/blog/save-the-date-for-a-webinar-research-in-global-crisis

DAY 2 29TH SEPTEMBER 2022

16:00 WHAT TEAMS WILL DO FOR PREPARED

Fudan University Team

Ock-Joo Kim and Young Su Park

Vasantha Muthuswamy

Kalle Videnoja

Raffaella Ravinetto

Tom Lindemann

Fudan University (Team of four led by Wei Zhu - video)

provide the Chinese perspective on all PREPARED work including a scoping review in Mandarin.

Seoul National University (Ock-Joo Kim and Young Su Park)

provide the South Korean perspective on all PREPARED work.

RIS (Vasantha Muthuswamy and Nandini Kumar - video)

lead the development of the Code of Conduct and provide the Indian perspective on all PREPARED work, including a scoping review in Hindi.

TENK (Kalle Videnoja)

lead all work around research integrity and linking PREPARED to ENRIO, the European Network of Research Integrity Offices.

Advisor Raffaella Ravinetto

provides expertise on ethics review processes during crisis in lower income settings.

16.40 CLOSE OF DAY 2

Tom Lindemann wrapped up Day 2 of the conference.

DAY 3 30TH SEPTEMBER 2022

Day 3 was devoted to our obligations under the **PREPARED** grant agreement, including an online presentation by the project officer Roberta Monachello.

In addition, several logo designs by **Dave Robinson** were introduced.

Conference photos by **Iddah Akinyi** from the PHDA team in Nairobi.

LOOKING FORWARD TO WORKING TOGETHER FOR THE NEXT THREE YEARS!

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