Research in global health emergencies:

the Nuffield Council ethical compass and good participatory practice

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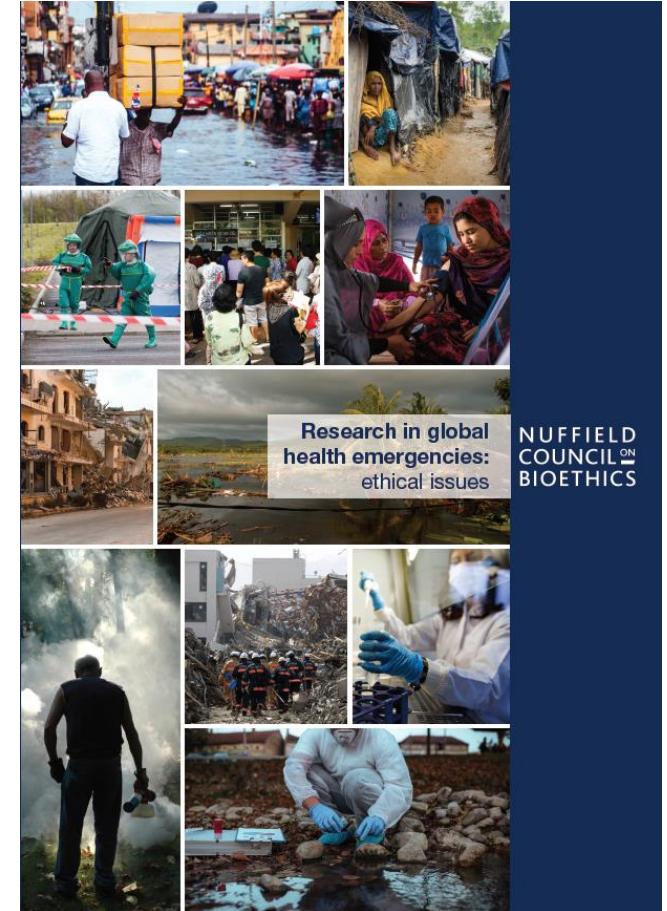

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Who are we? – a bit of background

- **Nuffield Council on Bioethics**
  - UK-based independent body, established in 1991
  - Funded by Nuffield Foundation, Wellcome, and Medical Research Council
- Remit to **inform policy and public debate** about the ethical questions raised by biological and medical research
  - Occupy a similar space to a 'National Ethics Commission' but not government-sponsored
  - Work on a project basis (1-2 years)
  - Role extends, where appropriate, to issues of international concern

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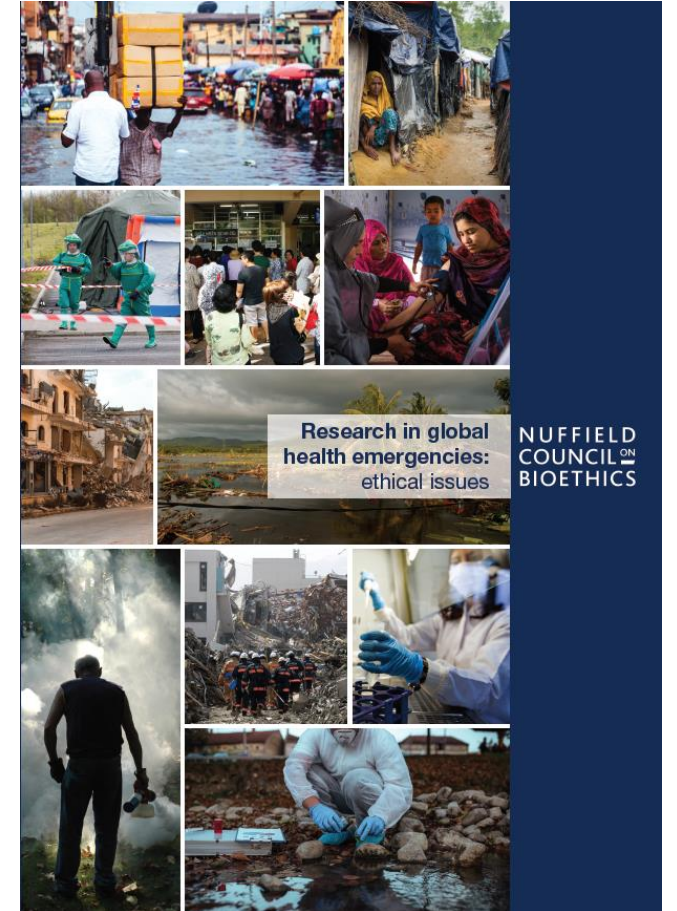
Rethinking ethical research in emergencies

- Aim to identify ways in which research can be conducted ethically in emergencies – recognising that

  - Good quality evidence is essential for effective current and future response – but …
  - … emergencies are highly non-ideal circumstances in which to conduct research

- Two-year project (2018-20), supported by international interdisciplinary working group and global evidence-gathering
  - Contributions from more than 30 countries
  - Detailed report, with policy recommendations

- Very broad scope: from pandemics to natural and human-made disasters
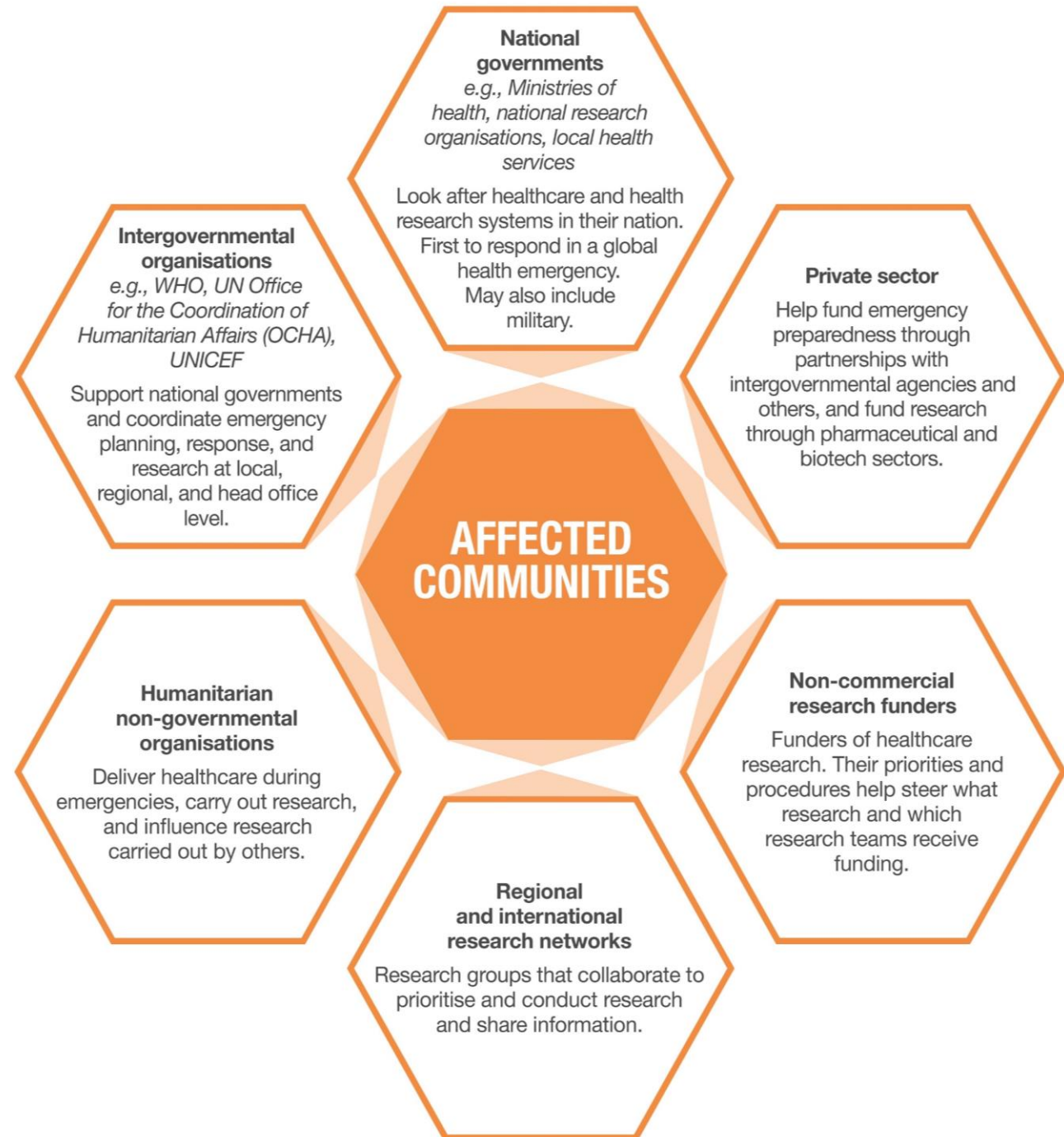
  - Many different kinds of research

Contributions to our inquiry

Preliminary questions

What's different about an emergency?

What counts as an 'ethical' issue?

What's different about an emergency?

- 'Global health emergencies' / 'humanitarian crises' / 'complex emergencies' including (sometimes in combination):
  - Infectious disease outbreaks (Ebola, Lassa fever, Zika… and, of course, COVID-19)
  - Natural disasters (earthquakes, tsunamis, floods…)
  - Human-made disasters (industrial accidents, conflict, mass displacement of peoples)
- Characterised by disruption, great health need, time pressure to act, uncertainty, distress
- Where these transcend country borders, they bring additional ethical challenges in the scope for tensions between different parties over control, responsibility, and legitimacy

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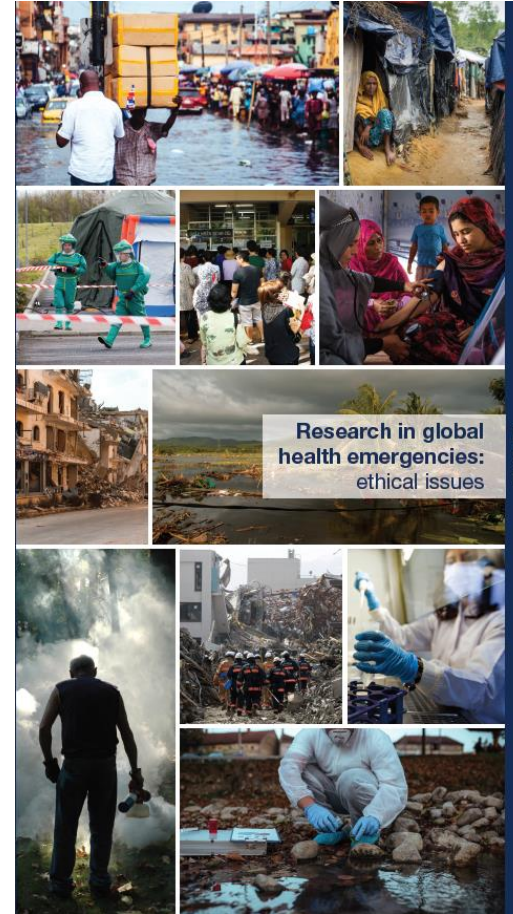
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Key stakeholders

Implications for accountability between researchers and …

- affected communities

- national governments and others with legitimate authority in the jurisdiction (eg national ethics bodies)

- other parts of the research sector

- other key elements in the emergency response, including intergovernmental agencies, the humanitarian sector, and private sector actors

- their own employers and funders

Looking beyond traditional 'research ethics'

- Context of historic inequities and ongoing imbalances of power
  - Neglect can be root cause of some emergencies
  - Most vulnerable / marginalized most impacted
- Yet these groups least likely to have any influence on what research gets done / where / how
- Strong claim for thinking about 'macro' ethical questions, in particular about who has power and influence – and how this should be exercised
  - as well as the traditional 'micro' questions of trial design, review, recruitment, and consent
- Implications for community engagement (GPP); for fairness in international research collaborations; for better support for front-line workers …

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Ethical considerations
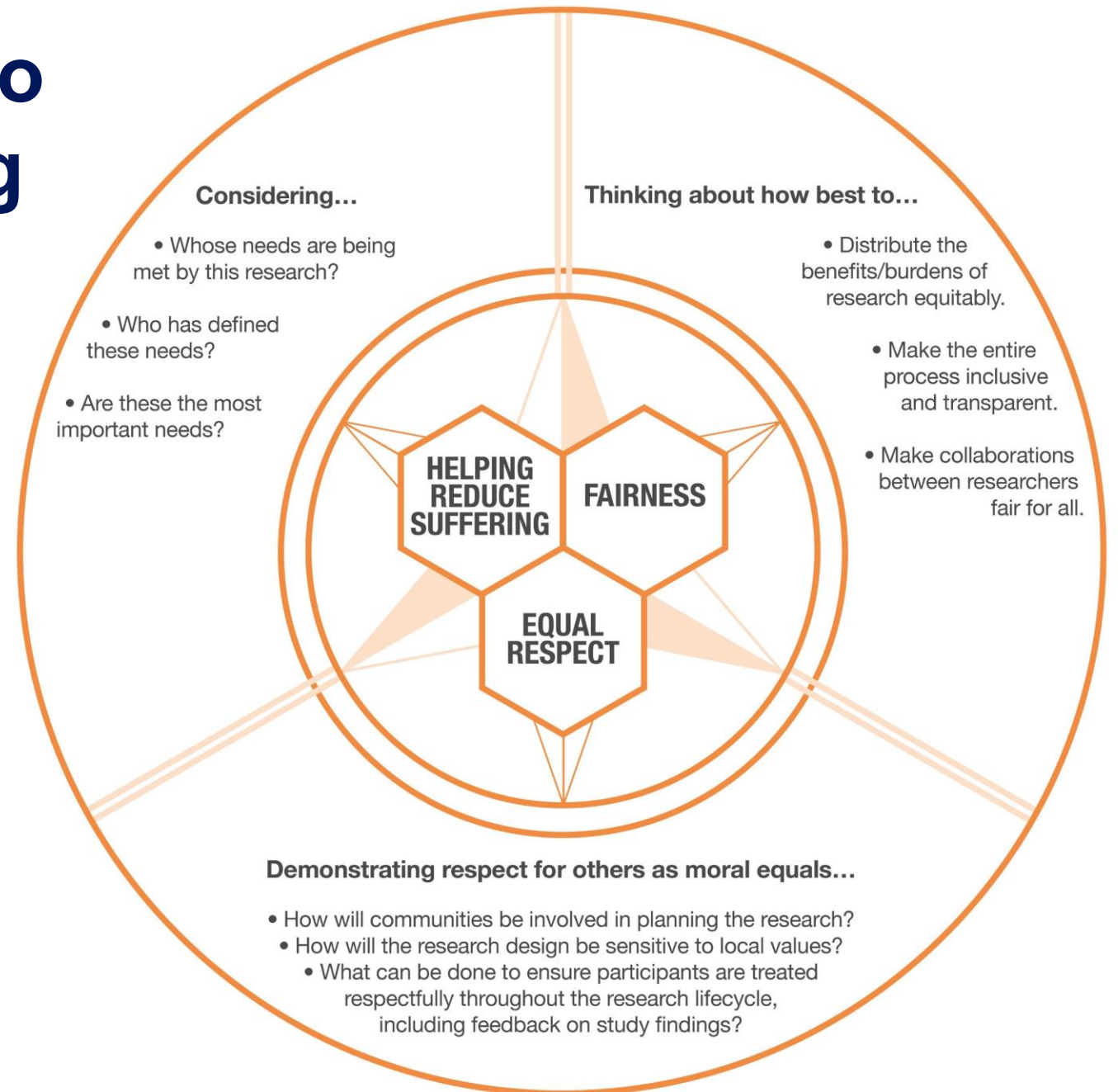
Developing an 'ethical compass'

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An 'ethical compass' to guide decision-making

- No simple answers
- Three core values to guide conduct (at policy level and on the ground)
- Recognition that these values can be in tension – but none can simply be overridden
- Recognition of opportunity costs / harms of *not* doing research

Considering…

• Whose needs are being met by this research?

• Who has defined these needs?

• Are these the most important needs?

Thinking about how best to…

• Distribute the benefits/burdens of research equitably.

• Make the entire process inclusive and transparent.

• Make collaborations between researchers fair for all.

HELPING REDUCE SUFFERING

FAIRNESS

EQUAL RESPECT

Demonstrating respect for others as moral equals…

• How will communities be involved in planning the research?
• How will the research design be sensitive to local values?
• What can be done to ensure participants are treated respectfully throughout the research lifecycle, including feedback on study findings?

Policy implications across six broad aspects of research

- More inclusive approach to influencing research agenda and priorities
- More inclusive approach to study design and review
- Consent – and the wider 'ethics ecosystem'
- Equitable collaborations and partnerships
- Respectful and equitable sharing of data and samples
- Better support for front-line workers

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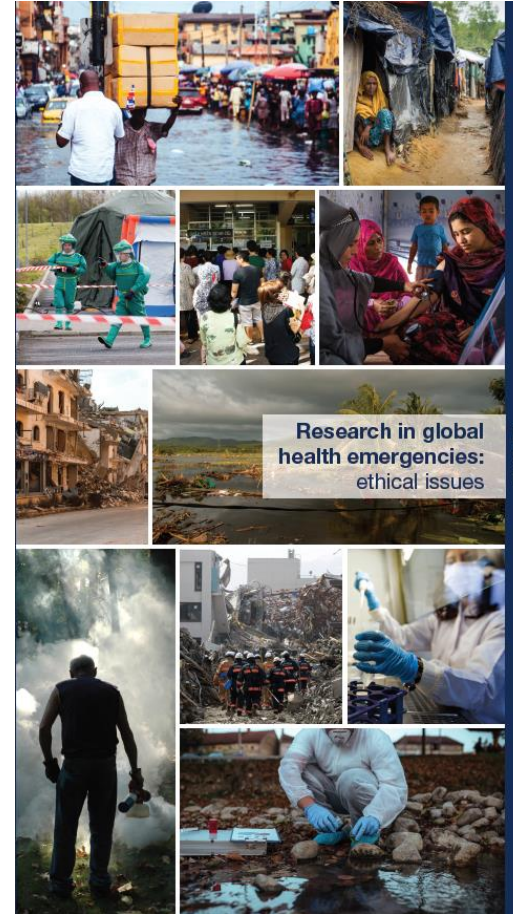
Implications for researchers & ethics committees(1)

- Central importance of meaningful community engagement
  - Local communities should be involved from as early as possible in the research process
  - We recommend that ethics committees, as a minimum, should expect researchers to engage with communities in the development of appropriate communication tools and consent procedures (recommendation 6)

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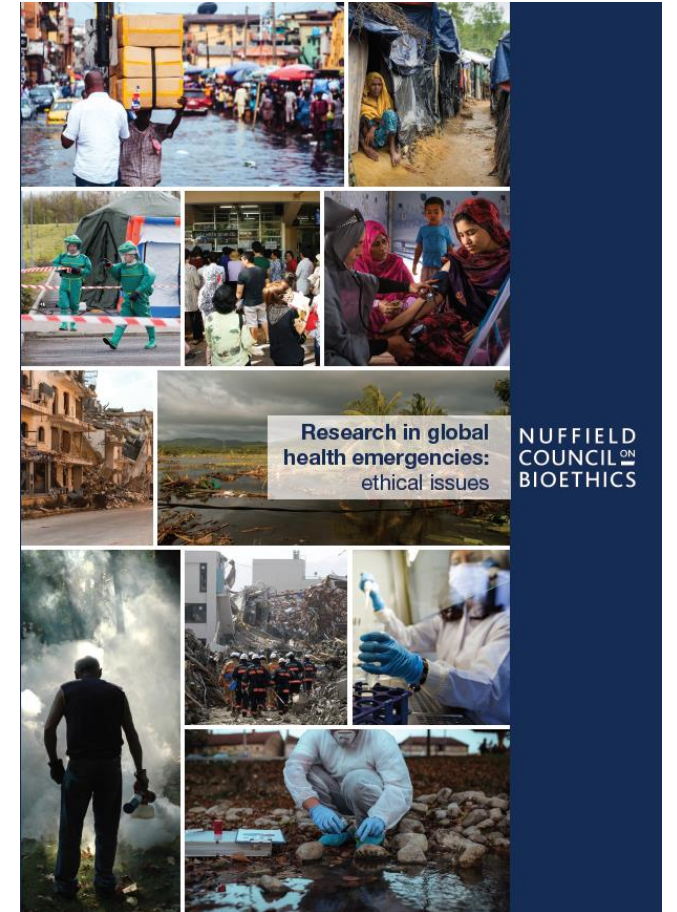
Implications for researchers & ethics committees(2)

- Need to look closely at inclusion and exclusion criteria:
  - In setting criteria, important to think of risks of both inclusion and exclusion
  - 'Vulnerable groups' should not be automatically excluded without further consideration (draw on local knowledge)
  - Ethics committees should expect clear justifications for any exclusion criteria that are set (recommendation 7)

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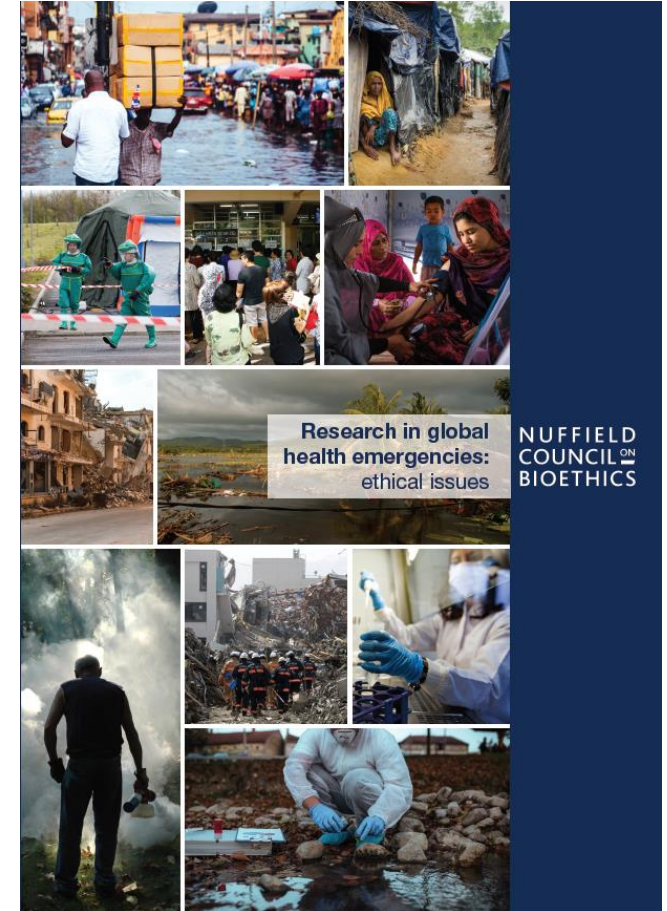
Implications for researchers and ethics committees (3)

- Getting consent right – but also recognising limitations of consent
  - Are proposed consent processes the best and most sensitive that are possible to achieve in the circumstances?
  - Are other requirements are needed to ensure respect for participants as moral equals?
  - Can what is being asked of participants be justified as fair? (recommendation 9)

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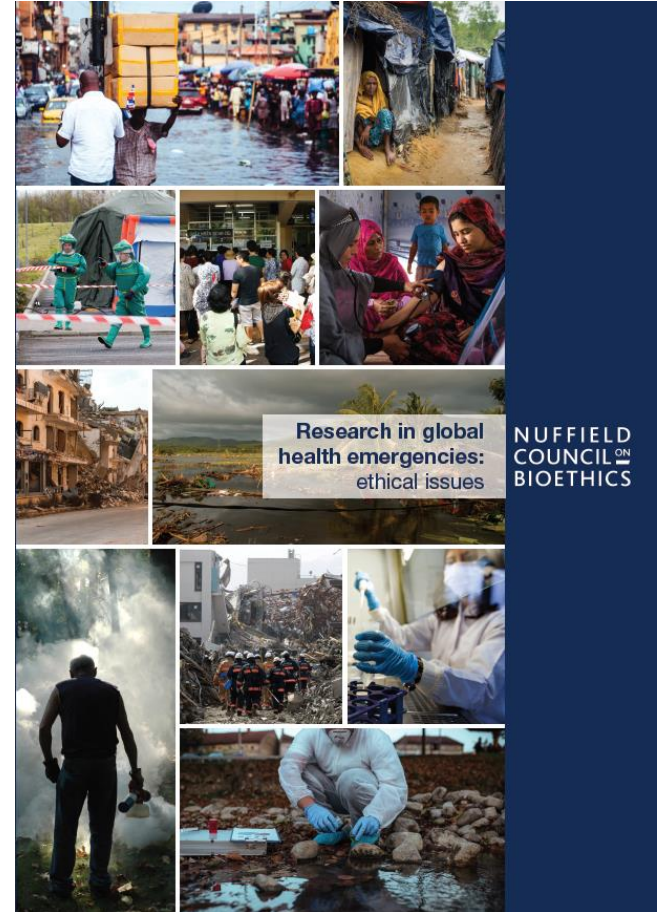
Implications for researchers and ethics committees (4)

- Communicating well throughout the full length of the research process – essential part of respectful relationship with participants
  - Ethics committees should expect to see communication plans across the lifetime of the research when asked to authorise studies (recommendation 10).
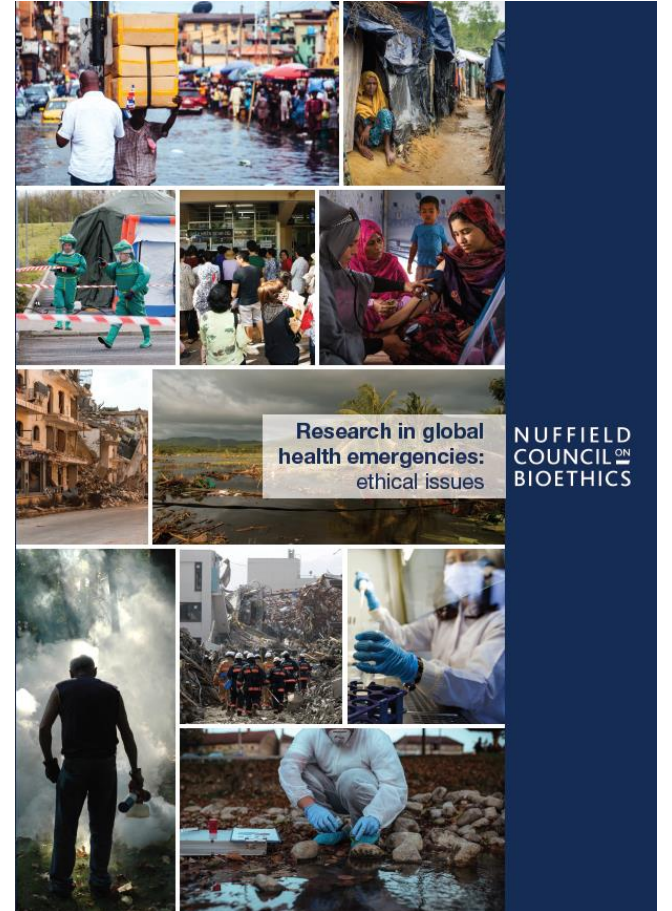
Who are the 'duty bearers': who has a duty to take action?

- Those with the greatest ability to act (for example research funders and governments)

- Those who have a particular relationship with others (eg employers)

- Those whose actions or failings mean they have a degree of culpability in connection with the emergency (eg negligent failure to prevent it, or mitigate effects)

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"Call for action" published (to funders, governments, and others with influence)

- Funders to work in partnership with govts and others to ensure that participants' basic health needs being addressed through response effort – minimum requirement for research to be ethical

- Invest in community engagement mechanisms for the long-term

- Promote equitable collaborations – particularly between research partners in low and high income settings

- Support emergency planning – including robust health and research systems

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Thank you!

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