THE GLOBAL HEALTH NETWORK

TGHN COVID-19 Hub

Workshop Report

"Ethics review preparedness during COVID-19: challenges and lessons learned."

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Introduction

On 10th and 13th of November, 2020 The Global Health Network (TGHN) supported the virtual open workshop, "Ethics review preparedness during COVID-19: challenges and lessons learned." This workshop contributed to the workshop series on the COVID-19 response from various regions across the globe that are being organized by TGHN at the University of Oxford, UK.

This workshop aimed to examine the ethics review process, identifying the variations and challenges that were present across LMICs. This session seeked to provide an opportunity for ethics review bodies or institutional review boards to share and discuss the problems and potential solutions afforded by experience so far, in an effort to ensure a more coordinated and efficient review system.

The workshop was chaired by ***Dr Farah Asif*** from Shaukat Khanum Memorial Cancer Hospital and Research Centre in Pakistan and was also organised in partnership with

i. ***Dr Jackeline Alger*** from the Parasitology Service, Clinical Laboratory Department, at the Tegucigalpa University Hospital, from the Facultad de Ciencias Médicas, Universidad Nacional Autónoma de Honduras (UNAH), in Honduras
ii. ***Roxana Lescano*** who is the past Coordinator of the Peruvian IRB Network and current member of the Peru National COVID-19 IRB
iii. ***Julio Canario*** the Managing Director of Ethikos and the President and Executive Director of the Institute of Mental health and Telepsicology, in Dominican Republic; and last but not least,
iv. ***Sadia Zia,*** lecturer at the faculty of Life Sciences from the University of Central Punjab in Pakistan.

More than 400 people registered for the workshop on zoom. On the day of the workshop 171 participants joined from 46 countries (as shown on the map below).

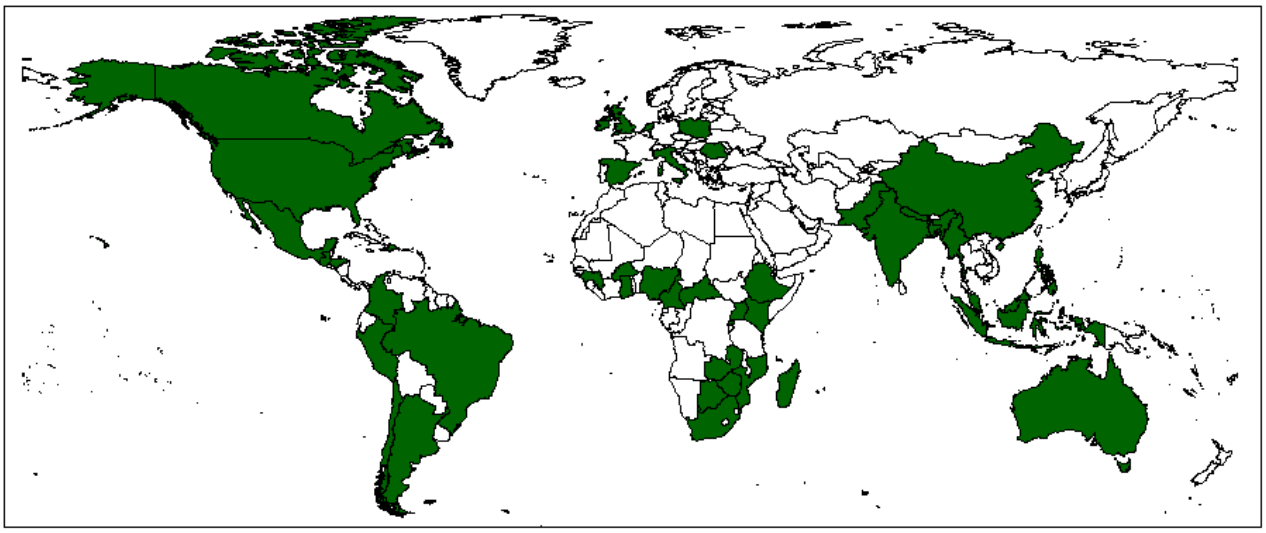

Figure 1 Location of attendees. Participants attended the workshop from the 45 countries shaded in dark green.

Day 1:

Case studies presentations

COVID-19 Challenges from the perspective of the Research Review Processes in India.

Professor Vina Vaswani
Director at the Centre for Ethics. Department of Forensic. Program Director of the Masters in Research Ethics. Yenepoya University. India

"COVID took priority over everything. Planning had to be done immediately at the University level on how best to treat COVID-19 research. Prioritise just COVID related research, or prioritise other types of research. Proposals increased, as did the regular meetings to such an extent they were often happening three times a week.

Let's focus on the research review process. Face to face meetings were not possible, so we had to use the Google meet option – some people didn't want to use it due to questions of privacy/ confidentiality. Also, a lot of apprehensions about the members.

Challenges:

- *Reluctance for online platforms*
  - some people didn't put their video on, and then you don't know if they're engaged.
  - scared of losing connectivity too.
  - people think these online ECs 'lack the punch' – people much prefer to meet face to face.
- *Depersonalisation of the meetings* – not enough social interaction. Primary reviewers do most of the talking. There is much less discussion compared with real life.

- *Time and delays* - clinical trials involving covid-19 took a long time to complete. If documentation was incomplete it took a long time to complete.
- *Consent forms and SOPS* – it is more difficult to coordinate when everything is online. to manage a digital consent form, one has to go back to the SOPs and have them accepted – lots of back and forth.
- *The fear component* cannot be underestimated – people were confused about the focus on research. Some institutions that didn't have ECs.
- *Task Shifting-* Another important thing is that many EC members were chained to other parts of healthcare. This meant that they were not fully focused on EC meetings (phones going off etc).

Responses:

- The institution decided in the second week that everyone on the Ethics committee were to be trained to use online platforms. Trained 6 ethics committees for this process. This included online etiquette - the dos and don'ts.
- COVID-19 related research SOP was changed to have emergency online review processes. Sometimes groups of ¾ would discuss it and then google forms were used, but it took some time because initial response of people was 'do we have to do this'.

Conclusion: Everyone wants to meet face to face, but those who are not from the institution are reluctant to go back to face to face soon. This means hybrid meetings will continue. Those who are on campus drop by and those who are not join online. Resilience is the only tool and ability to adapt helps – and should be developed by everyone."

Solidarity Trial review process in Pakistan

Dr Farah Asif
Clinical research administrator and Secretary to the institutional IRB
Shaukat Khanum Memorial Cancer Hospital and Research Centre in Pakistan

"Pakistan National Bioethics Committee (NBC) is the main official body to uphold the bioethical principles in all sectors of healthcare research. All research studies require prior approval by Local Research Ethics Committees or Institutional Review Boards (IRBs) at their own institutes. Then NBC approval and regulatory approval by the Pakistan Drug Regulatory Authority (DRAP) is necessary.

How did it evolve:

During the current COVID-19 pandemic, the national bioethics review of Pakistan developed new research technique. NBC has devised a mechanism to complete the first review in 72 hours to meet the needs of an accelerated review which is needed in current times. We see this evolution globally too. However, there are certain inherent factors of a framework in a country about how effectively they can adapt to a public health review framework. I would like to go these factors.

Challenges unique to the ethics framework of Pakistan:

- National level guidelines, regulations and training resources are severely limited on key aspects related to research in both pandemic and non-pandemic situations.
- institutional-based local IRBs are not registered or accredited – we do not know about the competency of these IRBs.

- The problem that we face is that there is not much sharing and therefore learning from each other. No mechanisms to interact among IRBs, community and the NBC.

Solidarity trial ethics review:

We started to receive COVID-19 research when we had maximum number of cases. We were living in fear and there was misinformation– we didn't know how large it would be, etc. This caused mistrust among the public, and even among healthcare officials. We didn't know what to give to our critical patients and our researchers were being disposed (societal good vs individual patient well-being). IRBs were also facing pressure to provide accelerated review.

The path that we followed concluded that all participating centres secured a review from their local IRBs which was reviewed by National Bioethics Committee and also Drug Committee in Pakistan. Its good news that local IRBs are slightly relieved – as national ethics committee are better to make big decisions.

Way forward: sets the need for a coordinated, efficient and comprehensive ethical review process to
1. Improve quality and efficiency of health research by decreasing costs and approval time
2. Standardise the implementation of safety regulations"

Saima Iqbal
Chair of the Pakistan national research committee

"We have learned from this experience – realised we need to improve ourselves – need to keep up to date with info. Concern you highlighted with local IRBs still stands – many IRBs are not trained – they are rubber stamp committees. We have been able to pick up things in protocol that IRBs have not. I hope robustness is repeated in all IRBs in Pakistan."

Discussion exercise

GROUP 1: The need for toolkit and guidance to be created for future PHEs

Representatives from Africa, Latin America, India, and the UK.

experiences – any toolkits/ checklist/ SOPs specifically in countries.

- One participant was involved in developing guidelines for IRBs and Ethics Committees for COVID-19 clinical trials. In the preliminary level they started by writing the recommendation for EC members, specifically public health members. Also focusing on what happens after the trial/ if the vaccine gets approved.
- Zimbabwe has developed COVID specific guidelines but they have been asked to add more input in general and come up with more ethical guidelines.
- Uganda there are no specific guidelines – they had a meeting with various issues that they face, these issues were addressed to a certain extent and now the research review has been standardised.
- Chile had the vaccine trials (4 or 5) to be reviewed – very time consuming. Decided with the ministry of health that all trials will be locally reviewed then nationally. In the local reviews, the main problems identified were that there will be a problem with the selection of subjects, informed consent and pregnancies. Clinical trials were being developed in very small offices. Can be very difficult to work with people from different committees – conflict of interests.

ideas

- focused on local IRBS and national IRBS - local committee chair to join the national irb and suggest the guidelines to be implemented at the local level.
- data development checklist.
- all the resources should be available online and in one place – a centralised platform would decrease worktime and resources.

GROUP 2: The Need for a rapid response panel of IRB members

Members from all over the world, including Asia, Africa, Latin America and Europe, different level of maturity.

General consensus was that a toolkit would be of great use especially for countries that are not as mature/ without rapid response mechanisms in place.

Challenges identified:

- lack of standardised review- lack of early standardised protocol. This is quite pertinent in many developing countries. Many members also shared concerns about standardised protocols. A toolkit would be very useful/ desirable and could be shared in many different settings.
- adapting submission response time – there are concerns about the mistakes from peer reviewers due to a short period of time.

Toolkit that would:

- be not just for research but reviewers
- be shared between lots of ethics committees – centralised.
- strengthen the IRB processes.
- guide the process in terms of structural vulnerability. A very important issue for researchers that are new to this field as many researchers are coming into new fields because of COVID-19.
- Strengthen stakeholder engagement- Any response/ rapid response to IRB process must ensure that stakeholders/ research participants interests are paramount.

GROUP 3: The need for Special training for Ethics committee members addressing how to review studies during PHE

There was definitely a lack of preparedness for the pandemic which left people without the appropriate time to train people: overlap between research and practice that needed work.

There was a consensus that training was required for IB members – this was seen as essential. In depth training should ensure all members have relevant knowledge and ability to conduct reviews and be prepared for this and future pandemics.

Content:

- Their role and responsibility and to understand their socio-cultural norms.
- differentiate between public health activities that are not research focused and research activities. Are we talking about research ethics or clinical ethics – the training would be very different for both of these.
- Data sharing
- ECs should understand vulnerability and protecting individuals.
- the issue of confidentiality came up.
    - continuous, ongoing training rather than special training dealing with emergencies.

- specialist training internationally so we can share on an international level.
- train up members very quickly to deal with the surge in applications.

GROUP 4: Identifying successful innovations/ adequations to facilitate sharing and implementation adequate responses to PHE

Online meetings through zoom then sending soft copies.

BENEFITS	CHALENGES
Google forms improved efficiency. Reviewers are usually more available	Software is not available everywhere
Shortens discussion time and decision time.	Online consent forms (google forms for consent process). How ethical this is? – sharing forms – you don't know who signed the form. Need guidelines how are going to improve this.
Electronic submission system became more centralised	
Worked out a better way to secure the data.	

Bottom line – going forward we cannot avoid online system – make things faster, more efficient etc. ***A hybrid model of online and face to face meetings might be the way forward.***

GROUP 5: Engaging communities effectively at early stages

Challenges - failure of communication with community - no strategies for community engagement.

- fear and stigmatisation complicated CE
- public health measures on social distancing → hindered the usual comm engagement strategies/ initiatives.
- no way to change the informed consents/ other material to target the local communities.
- CE is not in the researchers mind by default, it seems optional. Advocacy and CE are thought of as an after-thought, once everything is in place they contact them. That's not how it should work – should really engage the community from the beginning. If it's not it creates mistrust. It's not specific to COVID.
- Large trials don't realise that they need to change to the communities they're in.
- The pace at which things happen during a pandemic create a situation where even the smallest mistakes can be blown up because everything is happening so quickly.

solutions

- Involve social and behavioural researchers
- Extend community engagement to modify and provide feedback to research
- Consider what changes to the communities' research participation could represent.

- Be aware that there are impacts that go beyond health, which are very evident in the case of COVID: freedom of movement, economic hardship, etc.

Comments on the chat on CE (Community Engagement)
CE can help to reduce the mistrust and misinformation, but needs to be built in advance and be considered paramount
I fully agree. Sometimes, it may be claimed that there is no time for CE because of the emergency; but community engagement is particularly needed during PHE, when both fears and vulnerabilities are magnified
And this irrespectively of whether in high or LMICs
It's critical especially during times of crisis.
Agree with that. We should take Info. to community, how to deal the situation.
I agree there is still need for CE even in emergencies otherwise the gains may be reversed
I agree. And the Solidarity trial didn't have any kind if CE strategy
The research and medical community in Mexico also got overwhelmed by trying to keep up with misinformation about treatments: there were disagreements between countries about approved treatments and emotions ran high. I can imagine it would have been worse if any of our countries were involved in the large global clinical trials that faced the dramatic retractions!
Usually, CE is seen as an accessory, not mandatory. Thus, we need to continuously defend our position.
during emergency there may be less participation of communities but it is essentially important to take care of CE
"Usually, CE is seen as an accessory, not mandatory. Thus, we need to continuously defend our position": very true. In our IRB, we put a standard question in the ethics review template, to encourage researchers to reflect on it, and - when it is the case- to explicitly justify the lack of CE
the challenges of CE are considerable but for ethics and preparedness there is a essential need to the community
"In our IRB, we put a standard question in the ethics review template, to encourage researchers to reflect on it, and - when it is the case- to explicitly justify the lack of CE " I've done similar things, but unfortunately the item itself becomes a checkbox and often submissions will all have a copied and pasted answer...
How can we better evaluate whether real CE efforts have been attempted or successful, so CE doesn't turn into a checkbox with a copy/paste answer?

Day 1 summary of chat open discussion and comments

Chat while debrief of the breakout rooms
Toolkit should also include reaching the indigenous and migrant populations...I have been working with these groups recently.
India ICMR came with standardised proposal submission form and special guidelines during COVID pandemic
We get Social Researchers as the big Players, through this research, the community shares its feeling, perceptions and ideas about the situation. The outcome helps to design or re-design the protocol so that we can achieve Clinical Research´s goals.
Issues of Rapid response to IRB approval especially in terms of COVID is a critical issue that should be addressed as approval processes takes so much time. I'm part of A team to conduct COVID-19 Clinical trial. A project that should have started last month but because there no response from Local IRB, we have not started the trial. This should be addressed for future research and pandemic
Apart from stigma, mistrust and misinformation in community engagement, the COVID pandemic has added challenge due its economic impact. In addressing some of these challenges, having a well thought through community entry is vital. Researchers also need to appreciate that the research activities entail change in the eyes of the community and therefore we need to manage this change. We also need to manage their fears and expectations through change agents in the respective communities.
Here are some of the points that I wanted to share but ran out of time CE cannot be limited to informing communities but the scope of it goes way beyond informing. CE is not a recruitment and retention tool. Need for CE should not be stemming from the space of fear (that communities won't support/ we will be in legal trouble if we don't inform) but needs to be looked at from the lens of empowerment both for community/end users and

the researchers. While a lot of focus is on behaviour change of communities, significant amount of work is yet to be done to change the behaviour of researchers and donors with regards to making research more people centred. We need to learn a lot from behavioural sciences and understand intersectionality's when we talk of CE. There is an urgent need to innovate and COVID has further deepened the need. Within the EC people need to be trained/ better understand CE and ask the researchers tough questions around how they wish to engage community. Sadly, mere IEC or informed consent is not sufficient. Many a times even with the best interest and intent in mind researchers are under tremendous pressure to reduce CE to recruitment and retention and that it needs trained EC which can guide the researchers.
In India the ICMR also released Standard submission forms for different types of review for uniformity of submissions. These can be had from the same site as the National guidelines as well as sops for Covid 19 review indicated by dr. Roli earlier.
Agreed Reviewing should not only be done as a tradition. So, the reviewers must have good mastery of what specific things to look for and ask questions when relevant
Electronic EC functioning is well adapted by many Institutions now.
Ethics review processes can facilitate strong stakeholder and community engagement, even during COVID-19 where rapid response is required. Good Participatory Practice (or GPP) guidelines address some of these issues.
Google to be used in case to case basis depending on the proposal and to be reviewed by IEC
Additionally in the context of COVID … many researchers see a distinction in CE need between community based recruitment and clinic based recruitment. This can reduce the engagement at clinic to mere informed consent being signed which is not "engagement"
A hybrid model
Capacity building of irbs and its' members - Training, updating IRB members, Electronic submission and review of proposals:1. We need to exploit the cyber platform more effectively to make things to happen on urgent basis. Another pertinent point is the importance of downsizing the RRP with at least one experienced sufficiently qualified expert on the proposed project
Patients that are in the ICU cannot sign documents. In some hospitals there is no allowed to use paper or pens because of the virus, and the contact with doctors or researchers is very reduced. It is necessary to use electronical devices for IC and/or ask relatives to support IC.
Community Engage. The researchers are the one, who have to bring answers to the community, we are the one who have to participate actively by advocating, Policies, Guidelines. Building Focus Group in Community and discuss with them.
Sharing with other experienced irbs
But we must see that the respondents are not exploited when using short verbal forms for IC/or ask relatives to support IC
It's the fear of the pandemic itself. Which has been a major speed breaker to involve the community who were involved more in coming to grips with the situation. And provide relief
In Peru, we asked investigators to ratify consent of subjects who were initially enrolled with the consent of the legally authorized representative, when subjects recover from COVID-19 and are able to provide consent.
In Latin-American is the availability of the online platform called proethos. In this time proethos should become a very valuable tool
Need to have toolkit thereby to have appropriately designed tools from expert on the subject.
We have to adapt according to the sites conditions so long the objectives are kept, and GCP Guidelines and other international norms are complying.
Above all the IRB members, ethicist and researcher as well need to have optimum commitment and urgency in response in reality.
The CE is a very important in all health improvement strategy. But unfortunately, much misinformation has created a great reluctance in the Guinean rural Community though we just got out of Ebola Epidemic in 2016.

Day 2:

Case studies presentations

Constitution of emergency review panel to review COVID-19 research in Peru

Roxana Lescano
Attorney. Past Coordinator of the Peruvian IRB Network. Current member of the Peru National COVID-19 IRB. Member of the Program Committee for the World Conferences of Research Integrity, May 2022, South Africa
rlescanoquevara58@gmail.com

The Peru national transitory COVID-19 IRB

In early April 2020, a national transitory COVID-19 IRB was created to promote COVID-19 clinical trials by allowing for rigorous timely and compliant review. The national transitory COVID-19 IRB was created by a supreme resolution – highest party in government – mandating all the trials went through this national IRB, which would be then dissolve once this emergency ends. All the duties will be distributed among existing IRBs.

The Peruvian government issued a supreme decree (the highest form of regulatory guidance), mandating that all COVID-19 clinical trials must go through this national transitory COVID-19 IRB. Local IRBs that existed and were accredited were not to review the COVID-19 clinical trials – they all go directly to this national IRB which was set up.

Between March and April 2020, the Pan-American Health Organisation (PAHO) launched a series of documents to provide guidance and operational paths towards improving the quality of review and in order to meet the very difficult timelines. The essential elements were time, rigor, and ethics. The PAHO documents provided clear guidelines on how to achieve these essential elements.

- We followed the guidelines and they recommended alternative and flexible mechanisms for REC review - everything had to be done virtually, with efficient communication and harmonization.
- Collaboration: Worked very closely with the Peruvian regulatory agency and the Ministry of Health. Worked out procedures, we were provided with a list of procedures by a regulatory party - which we updated and adapted to make sure they were adequate.
- Coordination between the national COVID-19 IRB and the regulatory bodies. One of the big reasons this national IRB could become operational very quickly was due the presence of the Peruvian Regulation for Clinical Trials. Peru has had one since 2006, and was updated in 2017. Because of this, we have a list of registered and accredited IRBs, trial sites that have been opened and visited, a list of CROs, and a list of sponsors.
- The regulatory body in Peru called for registration of COVID non-clinical trial research. In addition to having clinical trials registered, we also have a registry of COVID non-clinical trials. This helped the national COVID IRB to fill its duties.

COVID-19 IRB constitution:

The constitution is critical. They did not select the members – the existing IRBs provided a list of interested members who were willing to participate in the national transitory COVID-19 IRB. The national transitory

COVID-19 IRB was provided with a list and the national transitory agency chose from people on this list – that meant they could choose a very diverse selection of members. In addition, they could make sure that all members had a ministry of health hospital experience, which was very important. So they could tell us what was happening in our hospital due to COVID. In addition, we have a wonderful administrative secretary who is very well rehearsed in clinical trial procedures and also ethics, research, and guidelines. 9 members with diverse backgrounds, experience, and training, who were committed joined.

Streamlining the review: making the requirements more flexible to submission.

start the review with some of the documents while the other documents were still being completed. It proved to be a lot more work for the IRB, but it was worth it and allowed us to meet the deadlines. In streamlining the review, we had 1 day to send to reviewers, 3 days for the review, 3 days to schedule the meetings, and 1 day to communicate with investigators right after the meeting.

What did these guidelines mean for IRB members?

- Pro-bono work. They have full time jobs – not getting paid for this.
- long reading hours: took 8-12 hours to be ready for an IRB meeting. It didn't stop with the approval of the protocol – that's just the beginning.
- Training time, meeting time, review of REC actions

Challenges:

- How sustainable is this? How sustainable can this type of efficiency be. Choosing IRB members was by existing IRB members.
- It was v difficult to ensure the 8-12 hours weekly when members were already engaged in their job – many working on the front line against COVID-19 or working virtually.

Detailed ethical oversight to verify

We established monthly reports for every study we approved – we needed to see if the study was being conducted as planned, or if there were changes to the proposal.

- Study is conducted as approved by the REC
- Follow up of new evidence that renders trials futile
- Follow up of new evidence that may affect participants' decision to remain in trial
- Responsibility for oversight: transfer to another REC when emergency is over

Challenges:

- Need a very experienced member who is already trained in human subject protections and IRB procedures.
- Need highly specialised training, particularly when the vaccine trial(s) started.
- Understanding of the science was a challenge too.
- Time - had a huge issue reading the papers and seeing that the society was very confused about research and public health concepts.
- Social media and the press made it come across as if some trials weren't research.

9 months after we have IRB member burn out.

Where we are:

- *300+ Peruvian researchers currently GCP trained and trained in human subject protection.*

- *Learned and adapted to electronic consents/ consents done by telephone.*
- *Storage of consents for future use and MTAs.*
- *Monthly reports for REC to keep track of wellbeing and safety of participants.*

Summary and recommendations: Cannot emphasise enough institutional support and professional administrative support – that are essential for RECs to perform. REC review must be rigorous and ensure compliance with ethical participants. REC members must be experienced, trained, and committed or else you will have the chair doing everything.

Q&A

How did the IRB deal with the challenges of reviewing the risk ratio in evidence on rapidly emerging and at times conflicting information?

You identify the risk based on the safety profile of the drug being investigated: you can look at the risk is looking at literature on same drug/ product used before. Lots of trials were used before and then used for COVID trials – so very detailed look at the safety profile of the drug first step. Our physician members were crucial in identifying and describing the risk. Peru had a v high rate of mortality due to no standard of care. Compare the safety profile with the potential of the participant not dying. The % of individuals who went into ICUs and died were v high because of our poor infrastructure. A very thorough analysis on the safety profile of the drug was the most important thing to analyse the risk.

How did you handle the consent process? The recruitment etc. How was effective consent ensured?

Another very important issue of discussion. You can never tell how effective consent is – can only ensure it is as thorough as possible. Have to be properly trained. Even if electronic, need written consent confirmed and approved by the IRB. Had many discussions about the legally authorized. Many of the participants were hospitalised and not capable to provide/ sign the consent – we needed the participation of the legally authorized representative. As an IRB we required that once the consent was confirmed by the legally authorized representative, once the participant woke up and could confirm, we went straight back to them and ensured that they will still participate in the study. Most of these trials involve 7 days of drug treatment. By the time the participant woke up the drug had already been administered. Therefore, when they woke up it was v important to get their consent again (not stay by family member consent).

Guidelines and experiences of Indian National Ethics Committee reviews

Dr Roli Mathur
Scientist 'F' & Head. ICMR Bioethics Unit. National Centre for Disease Informatics and Research (NCDIR). Indian Council of Medical Research
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The Indian Council of Medical Research (ICMR)houses the central ethics committee on Human Research, acts as the National Ethics Committee for India. ICMR have been very active from 1981 in building the ethical guidance for the country. The latest document is the 2017 National Ethical Guidelines for biomedical research dealing with participants. There is a requirement that every ethics committee has to be registered with a national registry. ICMR National Ethical Guidelines have now become part of regulations, and Ethics Committee registration is mandatory. However, when this guideline was made in 2017, we obviously didn't know something like COVID-19 would happen. But this guideline did give a framework for dealing with emergencies and outbreaks.

Central ethics committee on human research (CECHR)

- Undertakes high-priority quality ethics review of biomedical research led by ICMR.
- addresses emerging ethical challenges
- recommends national guidelines/ policy.

Appointed by DG ICMR, it serves as the national level committee, but there are Ethics Committees at institutional level. Therefore, everything gets reviewed at not just the national level, but also a more local level:

During the COVID-19 pandemic, CECHR had 19 meetings plus expedited reviews and looked over 23 research proposals. The average turn-around time was between 2 and 3 days (48-72 hours), which meant we had to work very hard.

CECHR Action: Rapid, Responsive, Robust. Reconstitution of CECHR to facilitate fast track review:

- New committee was appointed with alternate members to ensure there was not a burn out of members, and it meant that even if a meeting had a short turn-around time, we would always have enough members.
- Independent experts/ Subject experts with no voting rights.
- Good science/ science approvals.
- High priority quality ethics review.
- Site/ investigator/ engagement
- Digitally literate/ Virtual Platforms
- Turn-around time 24-72 hours upon complete submission
- Importance of Local Ethics Review and Monitoring. For a large multi-centric study, once the national Ethics Committee gave approval the Local Ethics Committees would also be asked to review.

All ECs encouraged to review rapidly, but we did not want shortcuts/ compromises on quality.

Benefits of virtual meetings:

- Easy to fix a meeting in a short time
- No travel. Shortened time lines.
- Experts from all over the country
- Easy to record/ take minutes.
- All very smooth and as good as a face-to-face interaction and saved a lot of money.

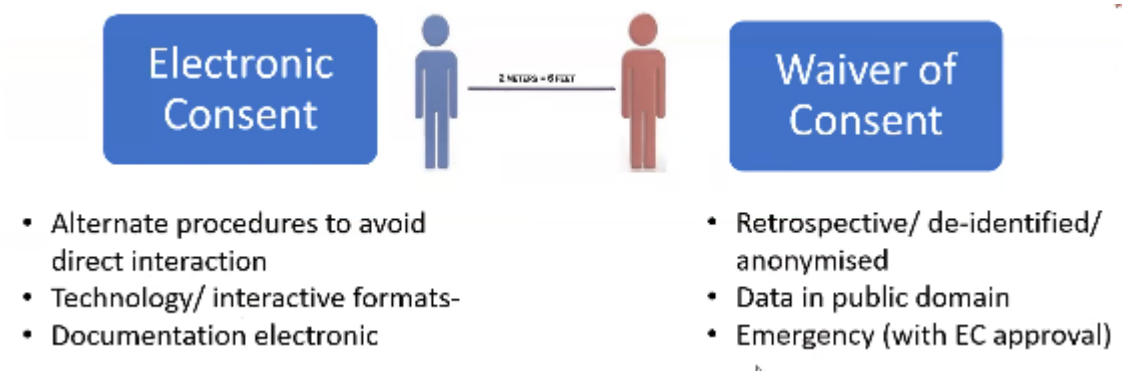
We developed National Guidelines for Ethics Committees during COVID-19. Dealt with COVID and non-COVID related research.

- Talked about virtual meetings (expedited/ unscheduled) – before this, ethics committees did not meet virtually.
- Emphasis on participatory practices – employing innovative methods, dealing with stigma, psychosocial well-being, violence, preventing the problems with infodemic.
- One of the earliest guidelines that came out.

Role of ECs:

- Ensure scientific and ethical review, facilitate expedited review. If local ECs unavailable, any other EC may review.
- Ensure timely review. Be registered (DHR/ CD).

- Virtual unscheduled full committee meetings.
- Ensure Clinical trial Registry of India (CTRI) registration.
- All COVID-19 trials should be registered on this platform.
- EC meetings – timelines, video face-to-face, shorter agendas, frequency and availability, subject expert/ and consultants. Prevention of stigma/ discrimination. Balance between privacy & mandatory disclosure. Oral & Electronic Methods.
- Informed Consent: Electronic Consent – Waiver of Consent.



Challenging, practical difficulties – isolation, quarantine, COVID ward. Decisional capacity low, moderate or critical illness. Inability to differentiate between relief, care and research.

COVID-19 EC guidelines:

- Trust Community Engagement
- Safety of HCW
- Vulnerable persons
- Stigma/ Discrimination
- Psycho-social well being

Beside the main guideline document, we also developed a *SOP template for ECs*, because most ECs said they didn't have an SOP available to carry out emergency meetings.

- Common Forms & Checklists: Facilitates protocol submission as per EC. Improved quality of review. Saves time/ checks/ completeness/ checklist. Especially useful for multicentric studies.

- Common Review of Multicentre Research: One designated EC for full review, local EC to expedite and focus on site-specific socio-cultural issues, informed consent, translations, implementations, and monitoring. Review by other ECs if local is unavailable. Our guidelines were downloaded by more than 30 countries worldwide. International recognition of ICMR Ethical Guidelines.

Q&A

Can you elaborate one thing for us: you have mentioned that you use common review by a designated EC, and then the local EC/ diff institutions will just review the local issues. What was the criteria for the selection of designated IRB that could complete a common review. How did you assess and determine that?

When we had done the piloting for the common review this was the biggest challenge – to know which EC should be the lead/designated EC. Generally, within a multi-centric study there is a main site coordinating a study – for us it was the ICMR headquarters. Let me give the example of the plasma trial that was conducted in 16 institutions. For that, the Central Ethics Committee had done a common review, but after that the local

site was to be conducted which also has to register with the C…, but then there has to be a local review done at the site too. For the non-ICMR research, some other institutions have followed the guideline and acted as the designated EC. It has to be a mutual decision if there are more than one IRB. One challenge is that the ECs don't block each other. We need to invest in ECs and build them up.

Regulatory Authorities and Research Ethics Boards in Central Africa

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What does preparedness mean? Sub-Saharan Africa: 54 countries, 1.3 billion people, and over 2000 languages.

The first key value to achieve preparedness in SSA is *Harmonization in ethics and regulatory environment.*

The African Vaccine Regulatory Forum (AVAREF) is a Pan African network of National Regulatory Authorities (NRA) and ECs. It was established by WHO in 2006 to promote harmonization of ethics and regulatory processes. The Initial scope of AVAREF was extended to medical and medical devices. Under its umbrella the African countries are domesticating common tools for research protocols review, approval, and oversight.

For the COVID-19 pandemic, the National Regulatory Authorities and National Ethics Committees across Africa have agreed to combine their expertise under AVAREF platform to expedite clinical trials review and approvals for new multinational preventive, diagnostic and therapeutic interventions for this pandemic.

Measures taken by Member states of AVAREF to address challenges and establish a COVID-19 expedited clinical trial review:

- An online platform (SharePoint) for joint reviews
- The Secretariat of the AVAREF will convene and coordinate virtual meetings for Participating countries to conduct join reviews
- Virtual meetings will be used to discuss pertinent issues on how regulators and ethics committees can better prepare and respond to the COVID-19 pandemic.
- Regulatory Authorities and Ethics Committees can use a separate platform (MedNet) to share info on planned or ongoing clinical trials in their countries.

In 1990 it was highlighted that only 10% of the worlds research expenditures were spent on 90% of the mortality. Despite progress, several changes are still needed to reduce this gap. Africa hosts 3% of the global clinical studies despite hosting 18% of the world's population. Moreover, within Africa, clinical research is distributed unevenly – most trials in South Africa and Egypt.

Second key value of preparedness is SUSTAINABILITY:

To increase sustainability of the response to remerging and emerging infectious diseases – ALERRT and PANDORA networks stepped forwards, together with WHO to increase preparedness.

Ethics and regulatory institutions are still facing some issues: Insufficient and varying ethical guidelines, lack of or outdated SOPs etc. In 2018, these networks and WHO reviewed guidelines to increase preparedness. In 2019 the Ethics review preparedness was issues. However, ethics and regulatory institutions are still facing some issues:

- Insufficient and varying ethical guidelines
- Lack of or outdated SOPs
- Inharmonious ethics and regulatory procedures leading often to a sequential rather in parallel ethics/ regulatory review/ approvals
- Lack of specific training and procedures for review during PHEs
- Unclear instructions to follow by sponsors/ applicants for their submissions
- Insufficient legislative reassurances for the safety of study participants, scientific integrity and data protection.

The African ethics and regulatory capacities are often compromised by the lack of trained personnel, human resources capacity and financial resources. Consequently, delays in clinical trial application approval and lack of oversight in the conduction of trials are common. Some countries do not have formal national Ethics Committees of Standard Operating Procedures (SOPs) for evaluating clinical trial proposals yet.

In a context of weak logistics and infrastructures, the lack of electronic platforms for ethics and regulatory submission and review is an issue hampering the review and approval capacities. However, ***the rapid increase and complexity of inter-disciplinary, multi-partner, cross-border/ multi-countries health research currently taking place requires the urgency for Research Ethics Committees and Regulatory institutions capacities for timeliness responsiveness.***

Looking at past outbreaks we observed a significant rapid increase of clinical research applications to be quickly reviewed by the relevant ethics and regulatory institutions. Ebola outbreaks have an average recurring rate of 1.5 years since the first outbreak in 1976 – let alone the other. This highlights the importance of having a system capable of managing the emerging and re-emerging infectious diseases.

<u>The third key value is: RESILIENCE.</u>

Around the three key values aforementioned, programs aimed at strengthening the capacity of ethics and regulatory systems to adapt their cooperativeness before, during and following a public health emergency, so that it can continue the necessary operations under both foreseen and unforeseen conditions, have been developed in collaboration with NECs, IRBs, and NRAs in 15 SSA countries.

At the moment, we are testing a new ground-breaking collaborative model – involving a variety of ethics, regulatory and research communities and stakeholders, so to establish a virtuous circle of synergies improving ethics and regulatory environment and ensure long-term impact and sustainability.

CANTAM. Eastern African Consortium for Clinical Research. LiberHetica, Africlinqiue, AfriHetique, Search, and some more programs: Strength, Must, Super.

COVID-19 pandemic, despite its graveness, represents for the African ethics and regulatory bodies ***the potential opportunity to exchange globally on common ethics and regulatory challenges***. COVID-19 differs from past outbreaks as it its global – not just located in Africa.

<u>Q&A</u>

It is amazing to see the variety of the initiatives. Who are the Research stakeholders? Secondly, where is the community in this cycle?

This is one of the main values of our programs. I would like to refer to them as programs instead of projects – projects have a start and end. These programs are focused on the improvement of ethics – the first stages are based on an assessment of weaknesses and strengths of ethics and the committees. After this stage the

programs develop synergies with other communities e.g. Research communities in order to strengthen research procedures. For example, for some of the mentioned programs like Africlinique we have the coordinator of CANTAM – one of the four regional networks of excellence for research funded by the EU. By putting together, the excellence of regulatory research, we can create knowledge and expertise, which is very helpful during public health emergencies. Another example is the program SEARCH, in which we have a coordinator who is also the coordinator of ESA.

Panel discussion

Farah Asif - Chair
Clinical research administrator. Secretary to the institutional IRB.
Shaukat Khanum Memorial Cancer Hospital and Research Centre (SKMCH&RC).

Panellists:
Katherine Littler
Co-Lead, Global Health Ethics & Governance Unit, Research for Health Department, World Health Organization.

Caesar Atuire
Senior Lecturer (University of Ghana), Visiting Fellow (All Souls College), Institutions: Department of Philosophy and Classics, University of Ghana; All Souls College, University of Oxford.

Roxana Lescano
Past Coordinator of the Peruvian IRB Network, current member of the Peru National COVID-19 IRB and member of the Program Committee for the World Conferences of Research Integrity, May 2022, South Africa.

Roli Mathur
Scientist 'F' & Head, ICMR Bioethics Unit, National Centre for Disease Informatics and Research (NCDIR) Indian Council of Medical Research.

Dario Scaramuzzi
Partnership & Capacity Development Manager, R-Evolution Worldwide.

Francis P. Crawley
Coordinator, European Fellowship in Research Ethics (EFRE)
Executive Director, Good Clinical Practice Alliance - Europe (GCPA)
Strategic Initiative for Developing Capacity in Ethical Review (SIDCER)

We have seen that most ECs have adopted many adaptations due to COVID-19. We have seen that all around the world have prepared themselves with the challenges. How should we assess that ethics committees are sufficiently qualified and prepared and qualified to review the research related to deal with public health emergencies. Who is accountable here? Is a self-assessment by ECs or the institutions sufficient?

Caesar Atuire: Thanks for the question, it's very important. It is the classic question: who is the guardian of the guardian. I think that ECs (at least in Sub-Saharan Africa) are not all prepared to meet this emergency. In the previous presentation, Dr Dario Scaramuzzi showed some of the networks that exist and the capacity building that is going on, but this emergency has pushed the demand/ ethics committees. How do we assess the quality/ competence of ECs. There is one consideration I would like to make first: let's not forget that

engaging local ECs is a form of community engagement. The more we engage with local ECs the more we carry out community engagement (especially when talking about international projects). Secondly, when we look at ethics reviews, we need to put them under the microscope. Members of the local ECs may not offer new insights into the scientific quality/ input of the research project, but they can offer a lot of guidance for the local context. Therefore, we need to assess with these two criteria in mind. On the one hand, scientifically we may just be repeating protocol with various scientific committees, but on the other hand, we need to adapt the protocols to the local communities. For assessing, I do not think there is a uniform criterion that one can implement.

It's just been a few months since living in this emergency, we have seen that across the globe there are countries, frameworks and ECs that are lagging behind. Of course, this will depend on their basic competencies etc. Looking at the different levels of preparedness across different countries, could you suggest a way forward for them to pick up the pace/ what initiatives can we take to narrow this gap between countries.

Katherine Littler: Part of the solution is to identify where the gaps in research ethics capacity are. Initiatives can help with building regional capacity – joining together, learning from experiences of other local Ethics Committees. Need to be more effective with online training modules. Pick up on the q you asked Caesar – there is no panaceum – we know most countries have established some kind of ethical system/ oversight, we know there have been standards (WHO) yet little is known how these systems are working. Some Committees will be operating below their best capacity and may not even be aware of it. Need to understand these systems better. Important to look to develop indicators – it doesn't answer everything about ECs but helps measure the quality. Indicators could help to promote appliance, standards, and accountability. Help with benchmarking, and should promote multi-country research by hopefully facilitating deference to other countries ECs – there are many countries currently looking at ethics equivalency, which is v important to avoid duplicative measures on ethics review. Important to understand countries needs more broadly. WHO has been looking at the development indicators – part of the preparedness work we need to focus on. One of the things I really like about the AMREF initiative is that it looks at the ethics AND regulatory oversight. Simple answer: These bottom up regional initiatives, to build core competencies going forward. We have to be better prepared. Better understanding of the needs is critical in going forward.

In the current pandemic we have seen a surge in research – during this we have seen small studies. When these studies are submitted for review, the ECs are charged to review them, but should it come under the mandate of IRBs? What is the role of IRBs in this case, when we see this research surge and the small studies that might waste resources of the IRBs and cause duplication?

Francis P. Crawley: This workshop is in many ways showing us a way forward. If we see what Peru and India have done, we can all learn from that. With regard to preparedness, we can say largely the IRBs and ECs were not prepared. But none of us were (scientists, research centres, hospitals). This is what we need to learn as we go forward – how to be prepared. And this preparedness also includes competence. We also need to learn that it is not just about the disease of the pandemic, but it's also about keeping our institutions running. Weve seen how many diseases have been neglected (shortage of HIV treatment in Africa, for example). Preparedness is not just addressing the therapeutics of the disease of the pandemic, but also how the IRBs work. How to prepare ourselves so we can continue to function well during an epidemic/ pandemic.

Dr Roli Mathur could you please clarify what is the rational for a double review – so first at the national level with the central review committee, and secondly at the local EC. And what do you do if the committees have conflicting views and how do you manage that?

Roli Mathur: We want to avoid repetition. Often, we have seen that a v simple study such as a survey has to go to every ethics committee participating in the research. The ICMR guidelines suggest: in the case of low risk research, one would have a common review. There are various suggestions about common review – one designated EC identified to do the review, but it would not like to take the autonomy of local sites – often site concerns that central EC/ common committee wouldn't be aware of. Want to review it but don't want to overtake the autonomy of the local EC/ sites. Ethics committee review is not a one-time activity, needs to be monitored throughout, even after completion of the study. So, we need to involve the local but also need to reduce the duplication of activity. The scientific review that is done can be taken care of at the central level. But there are specific areas – one EC in Delhi should not be deciding what's done on the other side of the country. Suggestion there is that there could be a joint review, a few members from each committee in order to make an efficient review, have to also be competent. It is not yet resolved. To add to the preparedness issue, in most places, institutions have not invested in ECs, it is time to think of ECs as a job – should be given protective time. Can work around these things. Members appointed in many ECs are the busy people – have to find the right people with enough time to invest in the ECs.

Roxana, what was the experience of consent overt the phone, any lessons learnt, and what practices were adopted for it?

When we think of consent by phone/ electronic consent, we often think of it as a one-time thing. It's not. It requires every single item of a hard copy. The consent is the guideline used when discussing consent process with. 1) is you have a guideline, have requirements to meet regarding meeting, competence etc. Number 2 is you need to have a process. How are you going to do this – when do you call them – any time of the day or do you set up a time so it is more likely they answer properly? Participant also needs to be able to ask questions. This is all part of a section of the protocol called the enrolment process. The consent by phone is not just a consent by phone – it is a lot more, and as the IRB. Varies from protocol to protocol.

How do programs ensure monitoring of all ethical review despite different research settings, and how this will impact Low Income communities in Sub-Saharan Africa?

Dario Scaramuzzi: The monitoring of ethics is very important to manage – also in terms of sustainability. The ethics preparedness of reviewing as said by the other panellists could vary. This is true in Africa of course. We are involving and reviewing this in order to externally monitor the quality of the Ethics review. Based on that we are learning the points on how to implement actions like training. The overall objective of the evaluation we are doing is to monitor the ethics and preparedness in terms of procedures and guidelines.

Caesar Atuire: Before answering your question directly – there is something emerging worth considering. The pandemic has taught us to take another look at what we expect the ethics committees to do/ goals of ethics committees. The dominant mode we have all be employing we make sure research participants are protected but we are now seeing that the challenges go beyond this and the ethical consents are wider. The ethical value of the research project itself, and then the procedures. Lots of the time, ECs sit down and do exactly the same thing, but if we classify the activities and various ethical requirements, then they can be evenly distributed between the committees. For example, if it's a question of community engagement, then local ethics committees are best placed to carry this out – if it's the science then the central bodies are better equipped. So, what we really need to do is structure how ethics reviews work so they're not an appendix to our institutions, we need to have people who are better qualified and who have time. The institutions actually promoting ethics committees also properly invest in ECs. Ensure they're competent, independent:

most of the time institution bodies are creating ethics committee and then the ethics committees cannot operate independently. And finally, be able to identify where we can avoid duplication. These 3 points are important.

Sadia Zia: Thanks, I want to ask a question about capacity building, dedication and the recruitment of dedicated people etc. In LMICs we have different scenarios, my suggestion for WHO and all stakeholders: the bioethics committee/ hub, for the LMICs there must be a dedicated and separate guideline. The people in LMICs are having big misconceptions about clinical trials, ethical issues, and community engagement. They don't have proper information (misinformation). So, we need to positively engage the people and secondly positively identify the vulnerable communities to select them for the trials. Need to build up trust with the organisations, regulatory bodies etc.

In the current pandemic, we have seen that those who are vulnerable have changed. Are we all vulnerable and how ECs can ensure that vulnerable groups are protected? Is it fair to not include them? Can we assume by not including them we are protecting them?

Katherine Littler: It's a tricky question, even outside of COVID the issue of vulnerability is a loaded issue. Are we all vulnerable? It has exposed vulnerability/ weak links in our societies. Should we include vulnerable people in research? Setting specific – also depends on vulnerable definition. Identifying these vulnerable populations in different settings is very important – migrant and refugee populations are a great example. Don't think you should automatically exclude on the premise of vulnerability. How do you define vulnerability: E.g. pregnant women – not sure they should always be classed as vulnerable. Premise is you don't start will exclusion due to vulnerability. COVID has exacerbated some vulnerabilities. Seen more vulnerable groups in different ways e.g. In US lower socio-economic status. 1700 ethics related papers and a good percentage on vulnerability and exclusion. A lot of work to be done in terms of migrants/ refugees: migrants often left out. An addition comment is that its v important in terms of ethics committees is to acknowledge the role of the secretariat – they will have good knowledge of applications and issues that keep coming back to a committee as the actual committee demographics often change. Very important that some sort of accreditation system is given to people devoting time at their Universities. Also look at the structure of the ECs, if all applications is about data and sample sharing – is there someone who has the expertise to deal with this. Not just looking at the seniority, but across the board. Ethics research should be seen as a fundamental part of the research process, not an add-on.

Julio Canario: Thank you Farah. I want to comment on the aspect that Katherine mentioned about who serves at the committee. I have seen in some countries that the exclusion of bioethics experts at the national ethics committee. In Caribbean, there are communities that don't have any guidelines at all regarding research ethics. There are not locally developed guidelines. So, I want to point this out as its one of the issues we need to tackle, when research is not a big priority.

Caesar Atuire: On the last comment made by Julio, and is linked to what Katherine mentioned. We have been discussing with other African countries (other than Ghana) – having a shared database of competencies. Because sometimes there are certain research projects that require a specific competent that existing members of our ethics committee don't have. If we had this shared database with experts in certain fields would help hugely.

Katherine Littler: Very interesting proposal, and builds on some areas where its happing. In Africa in the human genome editing, they have built on regional knowledge of different committees that have gone through genomics to build that expertise in communities. Some of these models already exist, happy to explore how to build on this. One of the models that some people use for ethics review is to have a small core committee, then you get in external experts depending on what you're researching, whether it be data

sharing, adaptive trial design etc. Some have core ethics committee, then bring in people when you get a protocol on that subject – and they advise you on the subject. Different models for doing it, whether you have a regional competency level of people who sit on ECs or draft in external experts who don't sit on ECs.

There are clear differences around the world, but how to harmonize different approaches to face COVID 19 research and ethics. What do you think about a global IRB that would be able to deal with research ethics when they're a common issue. Any comments on this from the panel?

Roxana Lescano: In regards to a global IRB as a body that issues general guidance on ethics, I think it would be very helpful. Couldn't take the role of countries ideas and cultures but many of the local IRBs would benefit from general guidance. The problem with a global IRB would be gathering consensus and opinions, but I see a lot of potential. Another issue is the competence of IRB members – what is an IRB member? / become a competent IRB member. Commitment is probably number 1, But we also have to invest time. Invest in training, as IRB members we look to gain knowledge and platforms like TGHN allow worldwide views on topics such as these. An ad hoc team of experts/ panellists would continue to expand the knowledge of IRB members. IRBs do not float in the air, they need institutional grounding, but as mentioned before many institutions don't think they have an obligation to support IRBs.

Francis P. Crawley: I want to point to the example of Chile and Peru, where they have more or less taken the review of COVID-19 studies up to a national level. The difficulty is the relationship between the national review and local review – because local review is needed as well. I would have some doubts/ hesitate about a global, international IRB, because I would hesitate about the politicising of ethics and ethical review. I would rather see ways of collaborating between ECs within countries and across national borders. That is a more solid foundation on which we can build.

Caesar Atuire: The idea of a global IRB sounds interesting however, there are some bodies that already exist, and there are some ethical committees that advise the WHO are doing something like that – giving guidelines that can be used in numerous countries. I agree with Francis' point – the fact that the constitution/ makeup of the body is very important because it can become an instrument that feeds into existing power mechanisms. If the global IRB becomes too powerful it could undermine/ sway the independence of local IRBs. There is already a concentration of power and we don't want to exacerbate that.

So many people have been violating ethical issues, which are more important because of the current pandemic. This is especially true in zones of conflict. What can the ethical body do about this?

Caesar Atuire: Importance of Local Ethics Committees – who are grounded within the context. Conflict zones sometimes require a different set of rules. The relationship between research and the community is so important – some of these things came out during the most recent Ebola outbreak in DRC – the way the community had to be engaged because of the conflict in the area – the reactions to healthcare and research were conditioned by conflict. We need to increase the capacity of local organisations who understand what is actually at stake in order to be operate within those zones. The normal rules do not apply during periods of conflict. Some work has been done – thinking of a doc prepared by the Nuffield council talking about research emergencies – this document gives some consideration about the local context in being order to operate. Taking into consideration the local context in order to operate. We need to be able to understand that dynamics.

The COVID-19 scientific literature is evolving so rapidly, with a plethora of information. How are the ethics committees dealing with this and can we group research of vaccines with evolving scientific literature emerging on a daily basis?

Francis P. Crawley: We just started a project on looking at recommendations for ECs when reviewing vaccine clinical trials. For the COVID situation, we are starting behind the curve. Found out this week we got WHO funding for that. Never been a more complex time in history for vaccines. We see already now maybe 10 vaccines that are close. A huge q is how we vaccinate, how we roll out these studies/ vaccine programs within particular regions/ countries. Critical issue and the IRBs play a critical role in this. Have to finish this project by 31st of March. The vaccines are almost/ already there, but by the 31st of March, the ECs will be confronted with many more studies and a much more complex field due to number of vaccines - not just whether this vaccine is safe/ effective, but also how it will play out in a country where another vaccine is already in use. Need to figure out specifically what ECs must do to address this v difficult situation.

What is the role of ECs in reviewing the community engagement strategies and how to ensure there is not therapeutic misconception - when we are reaching out to the communities we give them up to date information. We are not fully sure about safety and efficiency of vaccines. Want to ask the panel – have we done a good job in engaging the communities during this pandemic? So, the information for vaccine research for potential participants in the community.

Katherine Littler: A critical question – we have seen the infodemic, people have been overwhelmed by misinformation – lots of work is being done at the moment to correct this mis-information. A lot more clarity is needed in terms of vaccines: need to be clear between whether it is a vaccine trial/ roll out. Still a long way to go. There are some good models are being developed and a good participatory practice guidance developed in 2016 and that has been updated for COVID – I know colleagues are looking into the implementation of this guidance in terms of vaccine trials. However, the bottom line is that we still have a long way to go – it's on us, as the global health and research community – there is the fear we lose trust and faith if we don't get it right.

Dr Roli Mathur: What are the strategies you are following for community engagement?

Roli Mathur: It's tricky to engage with communities – difficult to implement in practice. We suggest that the researchers need to engage with the communities to understand the needs of the community right at the time. Important to have the community as part of the research team to have their needs and desires accounted for. For the EC to invite community into the committee. Also, suggestions to have community advisory boards. Doing the research has to be drafted to the community. Have to work hand in hand – not a one-way system.

Chat during the Discussion Panel
training programs are needed for ethics committee members. online training is better
Equivalency is something that we have been looking at in SIDCER-FERCAP-FERCI since we wrote the WHO 2000 Operational Guidelines for ECs. There are strategies, but they need to be approached with a good understanding of the role and responsibilities of ethics committees. This pressure, rushing of reviews, is not good if we do not first understand what we are doing. When I have evaluated ethics committees in Asia, Africa, and Eastern Europe, we constantly are confronted by ethics committees that are underfunded (if not funded). There are wonderful and dedicated and competent people doing amazing jobs with very little resources.
It is very true that EC members should not systematically selected by seniority, but in such a way that they have reasonable time availability, and personal motivation to engage in ethics review. Indeed, being an EC member also comes with indirect benefits: we learn a lot, by confronting research in different fields
There is also a need for true cooperation. This needs to happen on the ground level, but it also needs to happen at the international level. We miss too much when people working in ethics work in silos. We are all asking people to do open research and share their data. This needs to happen with and between ethics committees and between the organisations working with ethics committees.
Many countries have very good concrete guidelines but the suggestions that coming from the expert panels from this

platform can be in the form of guideline which can shared to everyone. Thank you so much for such enlightening session.
We are seeing in Europe a greater degree of 'professionalism' in ethics committees. 'Competent' is a broad word for ethics committees. The specific competence(s) of ethics committees need to be better defined. Here we are really lacking guidance.
Competence is indeed a broad word, this is the reason why we need to map the various activities of ethics committees and identify the competencies required. Sometimes the competency needed is administrative, other times it's about pure ethics, other times scientific.
Agree. And community. I like your idea of mapping this or 'identifying', as I say, with regard to roles and responsibilities. This is what we did with the European guidelines and then with the WHO guidelines. But it needs a deeper dive, I feel.
All LMICs are facing so much problem but I must congratulate Dr. Roli for such concrete Ethics guideline that ICMR have prepared.
Agree.
Vulnerability is indeed a mobile and constantly evolving concept. Vulnerabilities change in time even within communities.
Competence of members is very wide. it is about science, identifying ethical gaps, knowing the local cultural sensitivities, aware of codes and laws of the land, even the procedures of their own Ecs. etc. That's why training of members is a vital requirement
Secretariat staff of Ethics committees need to trained on ethics principles / research ethics...
Also agree whole heartedly with enhancing capacity of the IRB secretariat. I think developing career tracks for those working in research administration would also contribute to that
Good points from Katherine, vulnerability is not simply a divide between LMICs and HICs - it is not a geographical divide, it is a socio-economic divide. Covid-19 is highlighting this.
But IRB member competence should also include capability to deliberate and justify decisions and positions, in a respectful manner
The key of success seems to be cooperation and taking advantage on some pounds of view and ways that authorities act. some authorities, at all levels, seem to ignore ethics in order to achieve fast success, as they see / need it.
Permanency of Secretarial staff is an important issue. they are the basic pillars of every committee. if you do not have a well-trained IRB administrator and staff, the ECs suffer.
completely agree about education and the local dimensions.
I wonder if people think there should be a minimum stage of career / threshold of expertise of people serving on an ethics committee, and what this would/should be
Very good point Cesar!
great idea Dr Ceaser. This is similar to being asked to review a manuscript by an international Journal.
We need to create awareness on Ethics Career so we may get expert on this issue. Few people are expert on this issue so its overburden who are involved in the matter.
It sounds great, building expertise is very practical way of looking at it, we never know when it comes handy. Secondly if the research agenda is set already, we can harness the expertise existing to build training for EC/IRB members for instance in CHIM studies.
We need more local IRB. Huge burden but not evaluated properly
Huge burden but not evaluated properly
Very important points @ Caesar and Katherine. I also think some level of conversation should be encouraged among the IRBs at various levels, starting from our local IRBs through the National to the regional
Good point Katherine, In Tanzania We have National Ethics Committee with a subcommittee for review of clinical trials plus additional Consultant reviewers that some of them can serve review of topics whose expertise are missing in the committee
Just as we have universal ethical principles in spite of cultural variability, IRB skills for example upto 60 or 70 percent remain same, there could be variation upto say 30 percent, it makes a great Idea to have global IRB. They give the bones and outline, like we have WHO guidelines.
Real and valid concern, Francis. IRB decisions are not political
Ethics would be consumed by politics if the global institution would be established!

From Dr Francis P. Crawley: We already have so much concentration of power (in ethics as well). This is not good.
would a global IRB threaten independent IRBs?
I think we need to separate the IRB process from the process of development of guidance but we need to better facilitate the lines of communication between the local, national and global level
We need to focus on the ground level. We need to be as close to the patient and the communities as possible.
To Pawel....In Science let us focus on positive outcome than start putting politics ahead of our objectives
As a general comment, I appreciate the usefulness of the discussions that have taken place in these two-day workshop. But specially, as a researcher and faculty that teach research methodology and ethics I appreciate very much the positive impact that exerts this networking. We are physically and emotionally exhausted after eight months of pandemic. Working together builds resilience and allows harmonization and sustainability (as Dario pointed in his presentation)
We cannot dilute the authority of local and national committees by having a global IRB.
The guidelines and the guidance need to be built from the ground up. The need to be built, not just with the ethics committees, but from the ethics committees. This is what 'best practices' means.
A conflict (civil, military) is a public health emergency. Epidemics and pandemics lead, almost inevitably, to conflict. When we talk about epidemics & pandemics, public health emergencies, we need to understand that 'conflict' is an ever-present danger.
Dr. Atuire, I completely agree with your points. We should focus on building capacity of local committees who understand the local context.
Very important to have up to date scientific review on any application you receive. Highlights the importance of needing additional expertise and the need for additional guidance on how to handle the complexity of vaccines protocols.
In Poland PL there's the idea of separating people in 4 groups, when vaccine will be available: medics first, then people "vulnerable", then people working in key businesses, then "the rest".
From Dr Francis P. Crawley: Dr. Pawel, the questions of 'populations', for studies, for inoculation, is going to be extraordinarily difficult.
Good point, Dr. Katherine, 'the onus is on all of us'.
you are right @ Katherine, when it comes to vaccine trial especially in Africa, there a lot of myth about vaccine inoculation even before corona virus pandemic, we need to be careful engaging the community to win their trust. in Nigeria community advisory board has helped in vaccine trial
Thank you, Dr. Roli. The relationship between ethics committees / IRBs is complex.
agree with the points of Dr.Roli challeges are there but how to manage the things are real task
The ethics committees and researchers have to come together for improving the ethical aspects of research.

Resources shared during the workshop:

- **WHO**

GPP for COVID-19 trials here: https://www.who.int/publications/m/item/r-d-good-participatory-practice-for-covid-19-clinical-trials-a-toolbox

- **PAHO/OMS for COVID-19**

Research ethics review and oversight:

https://iris.paho.org/bitstream/handle/10665.2/52089/PAHOHSSBIOCovid19200004_eng.pdf?sequence=1&isAllowed=y

https://iris.paho.org/bitstream/handle/10665.2/52086/PAHOHSSBIOCOVID19200007_eng.pdf?sequence=6&isAllowed=y

- **ICMR**

National Guidelines for Ethics Committees reviewing biomedical research during COVID19 pandemic. Can be downloaded from: https://ethics.ncdirindia.org//asset/pdf/EC_Guidance_COVID19.pdf

ICMR SOPs for research in emergency that can be adopted by EC are available at: https://ethics.ncdirindia.org//asset/pdf/SOP_Template_EC_COVID19.pdf

Common forms for Ethical committee submission. These forms help to make the submission complete and to avoid delay and ensure robust review by ethics committee. These can be downloaded and adopted by any institution and will help improve quality of ethics committee functioning. It has checklists as well. Please visit to download https://ethics.ncdirindia.org/Common_forms_for_Ethics_Committee.aspx

- **ProEthos**

A free platform for research ethics review. Https://www.paho.org/en/proethos-platform-ethics-review-human-subjects-research Proethos test site: https://proethos.curso.bvsalud.org/login

- **Software innovation**

www.iecmanager.org

- **GPP guidelines for Emerging Pathogens**

https://www.avac.org/resource/good-participatory-practice-guidelines-trials-emerging-and-re-emerging-pathogens%c2%a0-are

- **Strengthening Stakeholder Engagement Through Ethics Review**

An online, free course looking at engagement in HIV prevention trials for RECs (but also includes resources for COVID) and may be of interest as much of the training remains relevant. You just have to register on the platform, and can access the course at this link: https://engage.avac.org/courses/strengthening-stakeholder-engagement-through-ethics-review-hiv-prevention-trials/

- **Guidance for research in response to humanitarian emergencies by Wellcome Centre for Ethics and Humanities, University of Oxford.**

https://researchsupport.admin.ox.ac.uk/files/guidanceforresearchinresponsetopublichealthorhumanitarianemergenciespdf

- **UK NHS SOP for research ethics committees.**

It's a long document, and this was written pre-covid. Just in case it may be useful! https://www.hra.nhs.uk/media/documents/RES_Standard_Operating_Procedures_Version_7.4_June_2019_lHKuibH.pdf

- **The Lancet**

Use of digital health and data sharing. Use the following link:

https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31978-4/fulltext?dgcid=raven_jbs_etoc_email

Call to action and next steps

If you are involved in COVID-19 research please contact us to share any relevant papers, protocols, associated tools and your experiences. Please send in your comments and feedback on the COVID-19 webinar.

Further virtual workshops are planned, which will be topic-specific and in response to demand. If you would like us to conduct a workshop related to a specific theme of COVID-19 research, please let us know what topics would be most helpful. You can get in touch here info@theglobalhealthnetwork.org