Global Forum on Bioethics in Research

Meeting report:
Ethical issues arising in research with people with mental health conditions

30 November - 9 December 2021

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Executive Summary

Grounding: The Global Forum on Bioethics in Research (GFBR) convened online in December 2021, to explore the topic of '**Ethical issues arising in research with people with mental health conditions**'. Case studies and governance papers were presented and used as the basis for stimulating discussion. This report summarises the meeting discussions and the range of views that were expressed. The report does not provide a full account of the cases studies and governance papers. Instead, it provides enough details to give context to the discussion. The full cases studies and governance papers can be found on the GFBR website.[1]

Conceptualisation of mental health conditions

- **Conceptions of mental health and mental health conditions (MHCs) vary across the globe and are often influenced by context and culture**. The biopsychosocial framework used in some countries may not resonate with how mental illness is conceptualised in others which may attribute supernatural and spiritual explanations. Conceptualisations naturally reflect in the language people use to communicate about mental health. If researchers use language that is not understood in the local context, or is perceived to increase stigma, they are unlikely to get meaningful answers to research questions.

- **Long term engagement with communities is required to understand the local context and how mental health is perceived**. Learning should be reciprocal, so researchers learn from the communities and the communities also learn from researchers. This is especially important when there are community views about mental ill-health that result in negative attitudes towards people who have MHCs. Engagement will help researchers to:
  - **Avoid imposing or prioritising their own biomedical views or value systems**
  - **Understand the right kind of research question(s) to ask**
  - **Devise appropriate engagement strategies and research methods**
  - **Communicate in language that is sensitive to – and understandable in – the local context**
  - **Design research that does not create or compound stigma.**

- **There is an ethical imperative for researchers to assess and address mental health stigma through their research and engagement activities, while also ensuring that the research itself does not exacerbate the pre-existing stigma**. Sometimes, researchers need to walk the fine line between avoiding language that might consolidate stigmatisation, and purposefully choosing what is considered stigmatising language to challenge such views.

Maximising impactful, locally-relevant research

- **Limited mental health research capacity and infrastructure in many low- and middle-income countries (LMICs) calls for contextualised and culturally grounded research methodologies that maximise scare resources to produce meaningful and impactful outcomes.** Researchers should articulate what 'impact' looks like for their research and how impact will be achieved and monitored; including how they will promote change in policy and practice to have broader, more sustained impact.

- Tensions and challenges can arise in the processes of maximising impact, notably:
  - **between scientific rigour and social impact** e.g. where methodological issues of research design or procedural ethics requirements limit opportunities for impact

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[1] https://www.gfbr.global/past-meetings/15th-forum-online-30-november-9-december-2021/

- o **balancing community versus researcher priorities**, especially where communities may value physical health over mental health
- o **in understanding the diversity of needs of different communities** (e.g. rural vs urban)
- o **when determining an appropriate approach to ancillary care** (e.g. guiding the community to existing care options, or including care in research design).

- **Meaningful engagement and local partnerships are important to bridge the gaps between researchers and local communities** (e.g. geographical, linguistic, socio-economic and/or related to power), **and to understand local community needs and priorities**. This is important for maximising the impact, local relevance and social value of the research. **Partnerships can be with a range of stakeholders, including local mental health professionals, community-based organisations, Non-Governmental Organisations and People with Lived Experience (PWLE). Collaboration with local government and policy makers is also important to promoting uptake of research recommendations.**

- **Partnerships and bi-directional conversations between researchers are especially important as a foundation for impactful, ethical research. These can ensure the use of language, methods, and measures that are appropriate to the sociocultural context**. Partnerships between high-income countries (HIC) and local LMIC-based researchers should be underpinned by policies that promote equity (e.g. publication policies), and that strike a balance between the objectives and needs of the different partners. This can be challenging where countries lack formal policies or agreements, calling into question how equitable (or tokenistic) the partnership is.

Engagement and co-creation

- Intersecting disadvantages can undermine co-creation and engagement efforts. Equally, co-creation and engagement with a community may exclude or expose PWLE, and even cause harm. **Co-creation processes should aim to raise awareness and empower the community to grasp the nuances and sensitivity of mental ill health to enhance their participation in a productive manner**.

- **PWLE bring a unique perspective and should be a fundamental partner in all mental health research. But ethical processes around co-creation and engagement with PWLE can be complex**. Challenges include:
  - o **Achieving inclusive and equitable participation** (e.g. of people with impaired functioning)
  - o **Maintaining privacy and anonymity**
  - o **Identifying and mitigating unintended harms** (e.g. distress or stigma)
  - o **Promoting the autonomy of PWLE** in close-knit communities and with their caregivers.

- **To promote the inclusion of PWLE in co-creation and research, researchers need to adopt additional strategies or methods to address these challenges**. For example, by:
  - o **Extending engagement activities** to the localities of marginalised groups
  - o **Collaborating with local health and psychosocial workers** to reach the relevant communities, and to help with sensitisation of, and support for, participants and caregivers during the research
  - o **Adapting interview and engagement protocols** so they do not identify PWLE to the broader community, to reduce risk of stigma and discrimination (e.g. conducting visits at night)
  - o **Providing training and support to PWLE to mitigate the risk of harms associated with participation** (e.g. the distress that might be occur when sharing their lived experience)
  - o **Training research staff** in the principles of active listening and basic emotional support skills

- o **Adopting enhanced care protocols** for if a participant shows signs of distress (e.g. providing information about local health facilities, helplines etc.)
  - o **Adopting protocols that empower PWLE to make independent decisions** (e.g. providing information in an appropriate format and level of detail, inviting them to identify the caregiver to support their involvement, use of capacity assessments and advance directives).

- **There's a crucial role for research funders in directing resources and agenda setting by requiring co-creation and engagement with PWLE in research.** Research Ethics Committees (RECs) should also ask researchers to describe their inclusion/engagement plans. **Long term funding is required for projects that evaluate the ethical challenges and propose solutions for the inclusion of PWLE, and to build and maintain researchers' expertise for meaningful involvement of PWLE in research.** Examples of best practice are needed to support feasible, inclusive, and non-tokenistic involvement of PWLE in research in ways that don't exacerbate stigma and harm.

Governance of research involving people with mental health conditions

- **In many jurisdictions, the governance of research involving people with MHCs is approached from a safeguarding and protectionist stance towards research participants, often leading to their exclusion**. This approach is starting to change: The United Nations' Convention on the Rights of Persons with Disabilities (CRPD) guarantees the right to universal legal capacity for all individuals living with disabilities, including those with 'long-term mental impairments', and requires states to develop measures to support and promote their autonomy.

- This represents a shift from the notion of harms of being included in research, to the harms from being excluded. It emphasises that **incapacity in and of itself is not a sufficient reason *a priori* for excluding people from research**. This approach recognises that **protection due to 'vulnerability' excludes people with MHC, making them *more* vulnerable through a lack of access to evidence-based care**. The default presumption should be that the individual has capacity with support to promote their decision-making autonomy ('empowerment'), instead of presuming incapacity and a need to protect people from research ('safeguarding').

- **Contextually rich models of empowerment are not well accommodated within existing regulation and governance documents**. When designing governance or regulation documents for an empowerment approach **communities must be engaged to identify where the disempowerment arises, and/or where vulnerabilities genuinely lie,** in order to address or remove these to facilitate empowerment.

- The Council for International Organizations of Medical Sciences (CIOMS) states that "some psychiatric conditions" can cause incapacity, in which case surrogate decision-making is permitted. In contrast, CRPD guarantees the right to universal legal capacity, meaning surrogate decision-making arguably contravenes the CRPD. However, **not all surrogate decision-making frameworks are necessarily disempowering and can be compatible with an empowerment approach when it is the only means of ethical inclusion of persons with psychiatric conditions in research**.

- **The language of *supportive* decision-making should be promoted instead of *surrogate* decision-making**. The purpose of decision-making assessments is not to deny legal capacity, but to strengthen its exercise by helping the caregiver, research teams and RECs understand *what* and *the extent* to which a person with MHC understands in order to provide them with appropriate support in accordance with their own characteristics and preferences.

- **Supportive decision-making should be underpinned by mechanisms and guidance to ensure the decision to participate in research is based on the participant's will and values and that there are no conflicts of interests, with oversight by the REC**. Guidance should clarify:
  - **who can act as a supporter, and the hierarchy** of proxy decision-making
  - **whether participant dissent (verbally or behaviourally) would be respected over supporter consent**
  - **the use and nature of advanced directives** to allow people with MHC and experiencing cognitive decline to state whether or not they want to continue participating in research as their condition advances.

Consent, decisional capacity and guardianship

- **Decisional capacity should be assessed, arguably not only for people with MHCs but everyone involved in research**. The approach to assessments should be contextualised and evidence-based, understanding that decisional capacity is heterogeneous across populations and changes (within the individual) over time. It is important to view consent as a process, and for researchers to use every opportunity to maximise the choices of the person themselves. As such, **capacity assessment should be performed when the person has the best capacity, and be reassessed at multiple points, allowing meaningful opportunities to reconfirm or withdraw consent.** This is especially true for longitudinal research.

- **Who performs the capacity assessment will depend on the context**. Assessment by a treating physician may provide a comprehensive clinical and decisional capacity evaluation. However, concern about the risk of coercion or a conflict of interest may result in choosing a non-treating physician. In LMIC settings where there are a limited number of specialist clinicians, task-sharing in research could be required. **Trained research assistants and psychiatric nurses could assess capacity, bringing more complex cases to senior clinicians.**

- **Understandings and recognition of decisional capacity vary globally**. The concept is unfamiliar to some mental health practitioners in LMICs, and this may limit the quality of capacity assessment. **Capacity is not a universal phenomenon: someone can be incapable of making certain decisions but capable of making others. This means rule-based approaches may not be sufficient**.

- Tools for assessing decisional capacity (e.g. MacCAT-T) may act as useful aids, and more research is needed to develop these. All tools should be applied in conjunction with wider personalised assessments of the participants emotions, values, and authenticity of their choices.

- **There are a number of important ethical concerns when thinking about consent, decisional capacity and guardianship: navigating the tension between empowerment and protection of the participant, looking after the participant's interests, making sure the researchers are acting appropriately, conducting research that is socially valuable, and meaningful for the groups enrolled in the research**. There is no formula to resolve the tensions; instead **the research process requires 'sensitive moral agents' throughout the research ecology – researchers, REC members etc. – to negotiate the tensions to determine the best approach in individual, situated circumstances**.

Introduction

The Global Forum on Bioethics in Research (GFBR) convened online in December 2021, to explore the topic '**Ethical issues arising in research with people with mental health conditions**'. Meaningful research is required to advance the health of people with MHC, but this has been stymied by a lack of mental health resources in LMICs, and the complex ethical and legal landscape faced by researchers globally. The meeting focused on how mental health is understood and experienced in diverse contexts, decisional capacity and how to assess it, how stigma and discrimination can be mitigated, and how to address the complex vulnerabilities that people living with MHCs may experience. These issues apply not only to mental health research, but to research more broadly where exclusionary criteria may prevent the participation of people with MHCs, resulting in an evidence base for their care that is poorer than for other populations. This is a significant issue given the comorbidity between MHCs and physical illness. By exploring these ethical and legal challenges, GFBR aims to advance the health of people with MHCs by promoting their appropriate and ethical inclusion in research.

Case studies and governance papers were invited through an open application process. An international, expert Planning Committee[2] selected the speakers and structured the meeting around the following themes:
- **Theme 1 Conceptualisation of mental health conditions**
- **Theme 2 Maximising impactful, locally-relevant research**
- **Theme 3 Engagement and co-creation**
- **Theme 4 Governance of research involving people with mental health conditions**
- **Theme 5 Consent, decisional capacity and guardianship**

With experts in bioethics, research ethics, psychiatry, psychology, policy, regulation, journalists and researchers from 39 countries (see map of GFBR participants' countries), the meeting delved into the key ethics and governance issues facing mental health research and the ethics of involving people with mental health problems in research.

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[2] Ross Upshur, Canada; Caesar Atuire, Ghana; Anna Chiumento, UK; Charlotte Hanlon, London and Ethiopia; Sharon Kaur, Malaysia; David Wendler, USA; Eleni Misganaw, Ethiopia; Kaustubh Joag, India; Ana Palmero, Argentina; Rosemary Musesengwa, UK; Karen Athie, Brazil; Dan Stein, South Africa; Dixon Chibanda, Zimbabwe; Katherine Littler, Switzerland

Figure 1 GFBR participants: The 126 participants from 39 countries brought a wide range of expertise to this important topic: bioethicists, clinicians, **psychiatrists**, **psychologists**, community practitioners, policymakers, social scientists, journalists, regulators, and funders, at all career stages. 94 participants were from LMICs.

1. Conceptualisation of mental health conditions

Conceptions of mental health, mental health disorder, and mental healthcare are often influenced by contextual and culturally grounded cosmovisions. This generates a need for cultural translation when researchers grounded in academic psychology and psychiatry engage with persons living in/from different cultures[3]. This first Forum session focused on the importance of understanding how people in different parts of the world think about and perceive mental health: what are their conceptualisations? The discussion was informed by two case studies (from India and South Africa) of how researchers navigate epistemic and linguistic challenges to attain mutual understanding, meaningful engagement, and effective collaboration.

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[3] In this report "culture" is being used as shorthand for considerations such as geography, living conditions, education exposure / level, language, social norms, religion / traditional beliefs.

Understanding the local context and conceptions of mental ill health

[Olivia Matshabane's](#)[4] case explored the impact of a genetic explanation for schizophrenia on internalised stigma experiences of South African Xhosa people with this condition. In many traditional cultures in sub-Saharan Africa mental illness may be attributed to the influence of ancestors or bewitchment factors. In their research, **supernatural and cultural explanations were commonly cited as important for understanding the cause of MHCs such as schizophrenia, in addition to other psychological, social and environmental factors**. This conceptualisation of mental illness differs from the biopsychosocial framework often applied in other contexts, which emphasises genetics, biological, psychological, environmental, and social factors, with limited consideration of cultural and/or spiritual domains. It is possible therefore that **using a biopsychosocial framework in the African and perhaps other LMIC contexts may not resonate with local conceptualisations of mental illness**.

Researchers need to understand local cultural and spiritual context, and the way that communities conceive of mental health and mental health disorders so they can:

- **Understand the right kind of research question to ask**. Going into the community and learning about the local context and cultural belief system should be a *precondition* to understanding what research question is most relevant to the community. This might necessitate flipping research funding models on its head or requiring that researchers learn from communities *before* applying for research funding.
- **Communicate effectively** in language that is sensitive to – and understandable in – the local context
- **Devise appropriate engagement strategies**
- **Avoid imposing or prioritising their own biomedical views or value systems** on communities who may hold different beliefs about the causes and appropriate responses to mental ill health
- **Design research that does not create or compound stigma**, but aims to mitigate and challenge such views.

The relationship between biological and cultural definitions of mental illness *necessitate* understanding the local context. **Researchers should engage with communities about their conceptualisations as they design, plan and conduct research**. The process should be dynamic, recognising that most researchers are trained according to a certain biomedical framework and the communities they work with do not necessarily share the same conceptualisations of mental health. **Learning should be bi-directional: researchers should learn from the communities, and the communities should learn from researchers**. This is especially important when community views about mental ill-health result in negative attitudes towards people with MHCs. Engagement should be long term to build (trusting) social bonds and relationships with communities, and will require dedicated funding. In reality, securing funding for such long-term engagement can be challenging.

It is crucial for researchers to engage with all community stakeholders, not just those immediately involved in the study – and to take extra steps to reach marginalised community members and groups. **Engagement could involve PWLE, their families and their communities. Community Advisory Boards can provide valuable perspectives to inform research design, implementation, and meaningful impact**. Communication and learning should be genuine and multi-directional, and include the potential to lead to changes to the research design or conduct. However, **listening to community stakeholders does not necessarily mean embracing all their values. Dialogue and values exchange** is essential to informing a synthesis that enriches the views and experience of both the community and researchers.

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[4] See: https://www.gfbr.global/wp-content/uploads/2021/12/Olivia-Matshabane_GFBR-2021_Theme-1.pdf

This perspective proposes that mental health research extends beyond facts and biological universals (the classical view of mental health) to include societal and cultural values which are also influenced by power and politics. As such, mental health research as a social activity can be considered both value ladened and theory bound. Researchers need theoretical frameworks that allow engagement with, and weighing of, different values, with the objective of promoting the well-being of participants. The challenge is how best to balance the two perspectives to create inclusive theoretical frameworks that resonate with the diverse views and perspectives of both mental health researchers and people with MHC in a range of global settings?

Language and linguistics

Conceptualisations naturally reflect themselves in the language people use to communicate about mental health. **If researchers are not using language that is understood in the local context, they are unlikely to get meaningful answers**. It is also unlikely that community members would partake in research that doesn't mean anything to them. Using language that is not meaningful is disrespectful, will not engender trust, and it may be harmful to future research. In order to avoid 'outside-in' parachute research, it's important to use language that local people use themselves.

Priscilla Giri[5], described a research program that evaluated teacher-delivered transdiagnostic mental healthcare for school-aged children in rural India where access to mental health services is severely limited. The research team approached child mental health from a diagnostic framework whereby the challenges faced by children were expressed through labels of disorder derived from the DSM IV, for example "conduct disorder" and "attention deficit hyperactivity disorder". Parents reacted strongly to this language and it became apparent that the use of diagnostic labels was pathologising and stigmatising already vulnerable children, and stood in direct contrast to community understandings of the children's behaviour. Through engagement with teachers, parents and community the study team learnt the community language and ways to describe mental (ill)health. The project changed its approach and adopted these community-led descriptions of the children's observable behaviours. This new focus allowed the research team to consider the importance of context around the behaviours, pursuing a richer, ecological understanding of children's mental health struggles and creating an intervention with many more tools to target their struggles.

There are also challenges with language and terminology, particularly the use of scientific and diagnostic terms in mental health research. Olivia explained there is no word for Schizophrenia in the Xhosa language, with the community instead referring to the symptoms of Schizophrenia. In order to bridge the language gap, researchers adopted the participants' own language and descriptions. Translation of a stigma scale was performed in collaboration with individuals from the cultural group of interest, and who had biomedical training. Once translated, the stigma measures were tested community members who fed-back about the terms they found most useful or confusing, and who provided suggestions for how the items could be re-phrased to be better understood.

GFBR participants agreed on the need for open, bidirectional discussions with potential participants, giving them a greater say and an opportunity to inform the researchers' work, as well as a way of making the research more relevant and understandable to the community.

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[5] See: https://www.gfbr.global/wp-content/uploads/2021/12/Priscilla-Giri_GFBR-2021_Theme-1.pdf

Stigma

Sensitising communities: Priscilla's project was initially couched in terms of 'behavioural health' rather than 'mental health' in order to avoid stigmatisation. However, in time the researchers felt the need to be more direct and talk about mental health in order to challenge the stigma that was present in the community. **Sometimes, researchers' need to walk a fine line between avoiding language that might consolidate stigmatisation, and purposefully choosing language that challenges stigmatising views in the community**.

In situations where participants and communities hold conceptions that promote stigma, researchers should make efforts to de-stigmatise MHCs by sensitising the community on these conditions, as was done during the early stages of HIV/AIDS. Sensitisation may extend to other stakeholders, such as religious leaders, who have a strong impact on participants' knowledge and perceptions of themselves. Fostering collaborations will have a long-term effect on the understanding and acceptance of mental health and is the best way to challenge stigma. An example was given from Ghana where there is strong advocacy for collaboration between faith-based stakeholders and biomedical practitioners which has had a positive impact on researchers in the mental health space.

Empowering individuals: Olivia's study sought to assess the internalised and associative stigma experienced by Xhosa people with schizophrenia, prior to exploring how that stigma may be impacted by genomics research. Bi-directional strategies of community engagement were used to engage with Xhosa people and share accurate mental health information. This approach empowered individuals to be able to articulate their beliefs and experiences in ways that were meaningful for themselves and for others around them, thus addressing some of their own internalised stigma and stigma they may face in their family and/or communities.

2. Maximising impactful, locally-relevant research

This session explored three research projects that demonstrate important considerations in how mental health research can remain both impactful and locally relevant. The presenters shared their experiences of seeking to integrate mental health and psychosocial interventions, services, and outcome measurements into research, highlighting connections to wider social determinants of mental health. They touched on methodological issues of research design and measurement, how to respectfully engage with local communities, and the importance of effective partnerships with local government and non-governmental organisations. These raise considerations of community expectations of research(ers), with implications for ancillary care, and for supporting local researchers engaging with the complexities of research participants' lives.

Defining and articulating the 'impact' of research

Mental health research capacity and infrastructure in many LMICs are limited, with a scarcity of trained mental health research personnel. **These limitations call for contextualised and culturally grounded research methodologies to maximise scare resources to produce meaningful and impactful outcomes** (i.e. preventions or treatments that can feasibly be implemented in a given context).

'Impact' likely means different things to different stakeholders in the research process. Aspects of impact identified during the discussion include:
- **Academic outputs** (e.g. publications, impact factors)
- **Academic collaboration** (e.g. strengthening local research capacity)

- **The social value of the research for the participants**, or the community in which research is conducted
- **Ancillary care** provided to participants or communities during (and beyond) the conduct of research
- **The social value of the scientific or mental healthcare outputs for wider communities**.

Researchers should articulate what 'impact' looks like for their research and how impact will be achieved and monitored during the research process. In doing this, researchers will need to:
- **Understand community needs and perspectives,** accounting for these in research design and conduct
- **Be alert to how diverse communities are** – recognising, for example, the differences between the experiences and needs of rural and urban communities within the same geographical area
- **Involve both formal authorities who can drive change at a broader level (politicians, advocates, etc.) and less formal 'influencers'** who will reach out to more marginalised parts of communities.

GFBR participants identified tensions that may arise in the processes of maximising impact:
- **Social impact vs scientific rigour**: maximising social impact could undermine scientific rigour, while some research designs may reduce the social potential of research in favour of academic rigour.
- **Community priorities vs researcher priorities**: the research may not be a priority for the community, who may value physical health over mental health.
- **Obligations for ancillary care**: in the context of scare physical and mental health care in many LMIC, where does a researcher's moral obligation end during mental health research and what level of ancillary care, if any, is necessary, appropriate, and feasible?

During the discussion, GFBR participants identified the need for researchers to:
- **Be trained in how to develop research with social value** and local impact, including manage the tensions that can arise
- **Be aware of local power dynamics** when engaging the local community in defining what impact means to them, and what impact is important to them
- **Understand that local communities may experience different impacts to the ones experienced by the research team**. To understand impact there should be a balance between hearing the communities' stories (qualitative research), and quantitative approaches.
- **Re-evaluate impact** during the research process, and where required, making modifications to impact goals or pathways.

Partnerships and collaboration

As demonstrated in the first session, a range of partnerships and collaborations (with community-based organisations, NGOs and PWLE) are required to provide a contextual understanding of MH, and to identify community priorities for mental health care and research in the context of other competing priorities (e.g. physical health, employment, education, etc). GFBR participants highlighted the importance of engaging and empowering the next generation of mental health researcher with information, training, and mentorship. **Collaboration helps foster trust and can sustain interest in mental health research**.

Impact isn't just about the research that is conducted, but also what happens *after* the research concludes. In this respect, **impactful research should be sustainable and scalable, making collaboration with local government and policy makers important** to ensure compliance with local regulations and laws, as well as promoting uptake of research findings or outputs.

GFBR participants discussed how to achieve effective partnerships, and what formal mechanism should be in place to ensure it. The term 'partnerships' – like the term 'impact' – is often used but needs to be unpacked. What does 'partnerships' mean, who might it involve, and how meaningful is the partnership relationship (i.e. are partnerships equitable or tokenistic)? This is particularly important in the context of the meaningfulness of collaboration between HIC and LMIC both at the project level, and also in terms of responsibilities and each partners' engagement and contribution to the overall collaboration.

Partnerships between HIC and local LMIC-based researchers should be underpinned by policies that promote equity (e.g. publication policies) and strike a balance between the objectives and needs of the different partners. Many GFBR participants reported that their countries do not have formal mechanisms or agreements to ensure equal research partnerships.

The case studies in this session demonstrated that **partnerships and bi-directional conversations with local researchers are a foundation for impactful, ethical research**. [Clara Calia](https://...)[6] described the 'From the Field' project which placed Syrian and host community researchers at the centre of the design and implementation of the study. The project collected data using standardised measures on the mental health of respondents who were facing significant pressures and diminishing supports in their day-to-day lives, exploring the linkages between their psychological wellbeing and food security. Local research collaborators helped ensure that the project's measures were fit-for-purpose in the sociocultural context in which they were used. They helped the research team avoid adopting the mental health constructs that are not cross-culturally valid where a focus on illness and disorder may exacerbate cultures of stigma, misinterpret local idioms of distress, and potentially lead to an overemphasis on the role conflict-trauma at the expense of social determinants of mental health. The local researchers' involvement was fundamental to the project's use of appropriate and locally understood language, and the selection of appropriate research methods. Only the local researchers could tell the international research team about the current situation in their humanitarian context.

'From the Field' also invested in the capacity of their local mental health research partners, and supported the development of ethical systems of research care so they could safely undertake research with those experiencing mental health distress. This recognised that the sociocultural background which made the local researchers more knowledgeable of the particular expressions of mental distress, also exposed them to stress when conducting research in humanitarian contexts. **Mental health researchers require access to suitable training, clear referral pathways to respond to participants' needs, protocols for situations of harm or risk, and clinical supervision**.

Research design

[Emmanuel Sarabwe](https://...)[7] demonstrated the difficulties that can arise due to highly structured research designs, drawing on his experience with the COSTAR project. In normal practice, sociotherapy participants are invited by sociotherapists who know their community well and are able to identify who is likely to benefit from the sociotherapy program. For COSTAR, community based sociotherapy was adapted to a predesigned trial protocol, involving random recruitment of participants by research assistants who were external to the community. After determining whom to assign to the sociotherapy arm and whom to the control arm, a different research assistant linked the selected participants to sociotherapists. Emmanuel argued the trial did not evaluated sociotherapy as usually practiced and instead evaluated the adapted approach which did not

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[6] See: https://www.gfbr.global/wp-content/uploads/2021/12/Clara-Calia_GFBR-2021_Theme-2.pdf
[7] See: https://www.gfbr.global/wp-content/uploads/2021/12/Emmanuel-Sarabwe_GFBR-2021_Theme-2.pdf

benefit from the early involvement of local sociotherapists and the foundation of trust that they usually provide. The length of the process prior to the engagement of sociotherapists might have reduced the motivation of people selected to participate, potentially impacting negatively on their attendance, evaluation results and the impact of the project. In addition, using research assistants who didn't know the local culture and did not know the vernacular language well could also have reduced the potential impact of the research.

Exclusion criteria

Emmanuel's case highlighted how a research project's **exclusion criteria (scientific rigor) can result in reduced impact for people who might otherwise benefit from being involved (social impact)**. During COSTAR's screening process, people experiencing severe symptoms of mental health distress, such as suicidal ideation, were excluded from further involvement in the project and referred for more specialist care. However, some participants who didn't report suicidal ideation at the screening process, later indicated that they had planned to commit suicide but that sociotherapy led them to abandon the idea. The COSTAR screening process may have excluded people who may otherwise have been included in the usual practice of sociotherapy and benefit from it.

Procedural ethics requirements

Emmanuel's case also demonstrated the **challenges of meeting the procedural ethics requirements whilst remaining responsive to changing research contexts**. Adaptations to the research protocol during the COSTAR research process had to be approved by the sponsor, and the ethics committees in the UK, Uganda and Rwanda. These approvals delayed and disrupted the intervention for participants, which sometimes gave rise to frustrations amongst the participants and sociotherapy group facilitators. Emmanuel recommended that only the local ethics committee based where the research is being conducted should give approval to the necessary adaptations, thereby minimising disruptions to the intervention.

Ancillary care

In low-resource settings, communities have physical health as well as mental health care needs. **Guiding the community to different care options, or including the provision of health care in research designs, are important factors or mitigation strategies for better research uptake and acceptance**.

[Amit Chakrabarti](8) drew on his experience of developing a cohort of participants among children of coal mine workers belonging to low socio-economic groups from rural and semi-urban areas of India (Box). The low levels of awareness about the existence of mental illness in the population posed an ethical challenge in research implementation. Understanding the struggles this population faced in accessing adequate physical and mental health services, and mindful that benefits of research and advancement of knowledge are intangible to the population, the research team facilitated a range of necessary services to all in the local community to address their physical and mental health needs, ensuring direct benefits.

Amit argued that in a country like India, the availability of (mental) health services at the primary or secondary care level is a necessary pre-requisite for ethical community based mental health research. Not only in terms of the social value and impact for research participants by creating an evidence base for locally relevant and

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[8] See: https://www.gfbr.global/wp-content/uploads/2021/12/Amit-Chakrabarti_GFBR-2021_Theme-2.pdf

effective treatments for underprivileged populations, but for the local community more broadly. **Amit**'s experience suggests that when participants are offered more information, awareness, and necessary services, it creates a bond of trust between the researchers and the population. **When trust is fostered there is greater community advocacy about the study resulting in more spontaneous participation; which ultimately improves the quality of the study, as a whole**.

3. Engagement and co-creation

This session looked at ethical challenges related to the involvement of people with lived experience (PWLE) of MHCs in the co-creation or delivery of interventions in India and Nepal, as well as involvement in community-based research in Ethiopia. It examined how co-creation and community engagement may exclude or expose specific vulnerabilities faced by some in a society and even cause harm, while intersecting disadvantages can undermine co-creation and engagement efforts. The potential to exacerbate stigma and exclusion was a cross-cutting concern in the case studies, and presenters shared their experiences of finding ways to balance these concerns while upholding the imperative to achieve inclusion.

Co-creation with communities

[Nikhil Jain](#)[9] discussed the Suicide Prevention and Implementation Research Initiative (SPIRIT) which co-developed communication strategies to encourage farming households to store their pesticides at a community storage facility in the village to limit access to the means of suicide. Managers of the facility and the community members were asked their opinion about the project's proposed awareness raising activities including: posters, door-to-door visits, a booklet and pamphlets, and a theatre campaign. The participants recommended using fear and graphic images showing the consequences of suicide by pesticide use, reflecting a tradition of explicit visual health messaging in areas such as smoking and cancer. But in the context of suicide prevention such images can be triggering and risky, and could culminate in unintended repercussions including increased likelihood of suicide particularly in individuals with known depressive or suicidal symptoms. In addition, such messaging can lead to normalizing or sensationalizing suicide among exposed non-target groups.

Balancing co-creation of contextually acceptable mental health education messages with global evidence of potential harm is very complex. **Nikhil** recommended that in co-creation activities, the concern for ethical language should extend to visuals. Given that the facilitator and the participants may not have a common background, effectively debating the latent meanings of a picture may require its own set of tools and skills. Deliberative discussions and innovative ways of presenting multiple perspectives were recommended, highlighting that such processes should nurture community awareness and empower them to grasp the sensitivity of the subject matter. This could help the community understand the advantages and disadvantages of different approaches, and provide an opportunity for researchers to understand the reasons behind the communities' choices. Such discussions are crucial for multi-causal issues like suicide where stereotypical thinking and myths are common. **Educating members of the community about MHCs can help address stigma and marginalisation of PWLE**.

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[9] https://www.gfbr.global/wp-content/uploads/2021/12/Nikhil-Jain_GFBR-2021_Theme-3.pdf

Challenges and opportunities for the ethical inclusion people with lived experience in research

GFBR participants agreed on the ethical importance of including PWLE in research, however a number of challenges were identified:

- **Inclusivity and equitable participation** (e.g. of people of lower functioning or single women whose mobility may be restricted in some contexts)
- **Maintaining privacy and anonymity**
- **Unintended harms** that may arise while participating in research or anti-stigma programs
- **Autonomy of PWLE in close-knit communities,** and with respect to their family and/or caregivers.

It is important to apply critical frameworks such as intersectionality at every stage of the research design and process and to distinguish between inequalities and forms of harm that participants face prior to research involvement, and those that arise once they start participating in research. Researchers need to be careful about the stigma and discrimination that comes with the label 'vulnerable', for example, due to its potential to stereotype participants and to promote paternalistic behaviours in researchers. Involving PWLE in research design can bring a unique and important perspective to the issue of defining people as vulnerable and how to manage the challenges of inclusion.

Inclusivity and equitable participation

Researchers may need to adopt additional strategies or methods to ensure inclusion, taking account of the specific context. For example, adopting protocols that empower PWLE to make independent decisions about their participation by providing information in an appropriate format and level of detail, inviting them to identify a caregiver to support their involvement and using tools like capacity assessments and advance directives (see Themes 4 & 5).

Nikhil explained that SPIRIT recognised that conducting communication activities in the centre of a village and relying on mainstream gatekeepers for contextualization of the intervention implementation inadvertently excluded marginalised groups who often inhabit the outskirts of the village. In order to include marginalised people's voices in the intervention development process, SPIRIT developed a subset of objectives that focused on marginalised community members with the larger goal of influencing attitudes and behaviour at a community level. Strategies included covering meeting places in the locality of the marginalised groups (i.e. outskirts of villages) to encourage their participation. Although even then, the targeted approach can be challenged by a preference to maintain a low social profile due to fear of stigma. GFBR participants noted that research on suicide is particularly problematic and stigmatising in some LMICs where suicide is considered a crime.

Dristy Gurung[10] presented the RESHAPE project which involved PWLE in a contact-based stigma reduction program in Nepal aimed at healthcare providers. The project recruited people who were seeking mental health services from primary care facilities in rural communities. Collaboration with local health workers and psychosocial counsellors working with patients was key to inclusivity. Based on the recommendations of the psychosocial counsellors, a diversity of PWLE were recruited, in terms of MHCs (depression, alcohol use disorders, psychosis and epilepsy) and age group, caste and ethnicity.

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[10] See: https://www.gfbr.global/wp-content/uploads/2021/12/Dristy-Gurung_GFBR-2021_Theme-3.pdf

Maintaining privacy and anonymity

Discrimination and stigma are key challenges faced by people with MHCs who are involved in research. **Wubalem Fekadu**[11] presented a case study on the ethical implications of using family key-informants to understand the transgenerational impact of severe mental illnesses (SMI) in rural Ethiopia (Box). He explained that involving people with SMI and their families or caregivers could give important and valuable insights to research, but in the context of close-knit communities, it can potentially exacerbate stigma and marginalisation. **Taking steps to protect anonymity and confidentiality is fundamental to preventing discrimination**, such as exclusion from support systems or loss of jobs if others were to find out about their mental health problems. The project sought to maintain anonymity by conducting interviews with people with SMI and their family members one week before interviewing the community, and by not notifying community members about their interview with people with SMI and their family members.

Unintended harms that may be caused while participating in research or anti-stigma programs

The RESHAPE project **trained PWLE to communicate their experiences of stigma and recovery using a participatory research approach** called Photovoice which uses photography as an advocacy and empowerment tool that is literacy friendly. The PWLE attended training sessions that included practical training on use of digital camera, and also how to manage distress, answer difficult questions and disclose information to other people safely. The training aimed to mitigate the risk of harms associated with participation, namely, any distress that PWLE might experience due to reliving and sharing their recovery journey and exposing themselves and their story to potentially negative, stigmatising attitudes. The training prepared them - and helped them - to present their recovery narratives with more confidence, and in a safe space.

Training research staff and including enhanced care protocols are critical to supporting the involvement of PWLE in research and anti-stigma programs, as an important component of mitigating unintended harms. SPIRIT research staff were trained in the basic principles of active listening and providing emotional support. An enhanced usual care protocol was also in place for community members who indicated potentially being emotionally challenged or experiencing distress (e.g. providing information about available public health facilities, helplines etc.).

Autonomy of PWLE in close-knit communities and the role of family and care-givers

Autonomy can be compromised by capacity, for example, when patients with psychosis are symptomatic. In low resource settings where there is very little social welfare state, caregivers can be essential for PWLE to access healthcare and services, and they are often the only care people have. Given the carer's critical role, issues or tensions can arise both if they are excluded, or included, in research. **Wubalem's** case demonstrated this from the perspective of the person with SMI who expressed disappointment when they were left out of conversations that the research team had with families 'about them'. **Allowing people with SMI to speak for themselves not only affirms their agency but potentially avoids discord between the caregiver and person with SMI.**

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[11] See: https://www.gfbr.global/wp-content/uploads/2021/12/Wubalem-Fekadu_GFBR-2021_Theme-3.pdf

GFBR participants agreed that ethical frameworks tend to be 'passed down' or inherited from the Global North. However, concepts like 'autonomy' may not be fit for purpose in other cultural contexts where the family and shared decision-making is more highly valued. **While shared autonomy and combined decision-making are common in mental health research, especially in close-knit communities, it is important to retain respectful autonomy of PWLE,** empowering them to make independent decisions about their research participation. This can be achieved for example by first meeting with the PWLE to build trust, and later extending this engagement to persons identified by the PWLE as their preferred representative[12].

The RESHAPE project demonstrated the potential for caregivers to facilitate inclusion. The first batch of training with PWLE, which did not involve caregivers, resulted in significant dropout due to many issues that prevented effective participation, including the family being suspicious. In the second batch of training, PWLE were asked to bring at least one caregiver that they trusted (family or friend). There was no drop-out and the new approach had a positive impact on inclusivity of wider functioning levels because PWLE with lower functioning could be supported by their caregiver, and on greater inclusivity of female PWLE who in the cultural context face restrictions on travelling alone. **Giving PWLE control over who they identify as the right caregiver to be involved is an important expression of respecting the autonomy of that person**.

Role of counsellors or mental health professionals

GFBR participants agreed that it would be ethically advantageous to have a trained counsellor or mental health care professional present as part of any mental health research and associated co-creation and engagement activities to help with sensitisation, counselling of participants and caregivers to manage any distress. However, in low-resource settings where there are insufficient health professionals even in the clinical environment this would be very hard to achieve. **The nature of the research or intervention will determine whether or not there is an ethical imperative to include access to a mental health professional**.

During RESHAPE, PWLE were asked to narrate their recovery stories and during the preparation phase some showed distress when talking about their experiences of stigma. If the person delivering the training is not equipped to deal with this distress, participating in the activity could cause further harm to the PWLE. Given the nature of the RESHAPE intervention, there was an ethical imperative to have a mental health professional or counsellor in each participant training session to check in on the PWLE's emotional state, for distress management and to talk with them about whether or not they want to continue in the programme. Research assistants were also trained in basic emotional support.

Need for best practice and training

Engagement and co-creation in mental health research should be driven by the conviction that PWLE and the community bring unique perspectives to the research. GFBR participants discussed the **need for generalisable and accessible researcher training and best practice to support inclusion of PWLE in research**. The best practice needs to be feasible, avoiding tokenistic involvement and instead support a process of empowerment that allows meaningful community engagement, and meaningful involvement of PWLE. Achieving this may

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[12] The language of 'representative' seeks to reinforce the empowerment perspective which sees the decision-making choices of the PWLE as paramount. As such 'representative' may or may not encompass a recognised caregiver, depending on the view of the PWLE.

require additional resources to inform and educate PWLE and the community so they understand research processes and meaningful participation in co-creation.

Best practice can derive from speaking about the ethical issues that arise when engaging persons with MHCs, and the community, in research. Lessons learnt from GFBR and other such initiatives should be published to promote best practice.

Role of funders

More research is needed to create evidence that engaging PWLE at all stages in research brings in a unique perspective. GFBR participants agreed **there is a role for funders to set the agenda by directing resources into these activities, and requiring researchers to demonstrate how they intend to ensure engagement and co-creation in their work**. Long term funding support is required for projects that evaluate the ethical challenges and propose solutions for the inclusion of PWLE, to build and maintain the expertise for engaging and involving PWLE in research.

Role of Research Ethics Committees

RECs should also play a role by asking researchers to demonstrate how they are including PWLE in a way that doesn't exacerbate stigma and harm, but facilitates inclusion and allows people's voices to be heard. **RECs should consider the potential benefits and harms of proposals to co-create and involve PWLE in research**, ensuring a mental health professional is available (if the nature of the research requires it), and encouraging appropriate training of the research team. The research team should keep the REC updated as the research progresses, so that if issues arise, the committee would be in a position to provide guidance. Some GFBR participants suggested the REC's role should extend beyond review for approval, extending to spot checks during the research process to monitor compliance and ensure that PWLE are being ethically involved.

GFBR participants agreed that **it would be valuable to include people who have MHC on RECs** as a way to try to find the best approaches to addressing the challenges and tensions in recruiting people who lack capacity. The involvement of PWLE on RECs could be especially important in settings where mental health legislation is absent or not adequately enforced.

4. Governance of research involving people with mental health conditions

In many jurisdictions, the governance approach to research involving people with MHCs is traditionally and typically based on safeguarding and protecting research participants. Historical classifications of individuals with MHCs as 'vulnerable' can lead researchers (and RECs) to categorically exclude them from participation. This session explored and challenged this protectionist approach and considered the value of adopting an empowerment approach. The presenters discussed what an empowerment approach might look like, offering perspectives from Europe, Africa, Asia and Latin America.

Protection vs empowerment: CIOMS and CRPD

[Marisha Wickremsinhe](#)[13] provided an analysis of the divergence between international ethical guidelines developed by the Council for International Organizations of Medical Sciences (CIOMS) and the United Nations' Convention on the Rights of Persons with Disabilities (CRPD) with regard to the inclusion of individuals living with psychosocial disabilities (as a subset of people with MHCs) in research (Box).

While CIOMS takes a *safeguarding* and arguably protectionist approach, CRPD aims to empower individuals living with psychosocial disabilities. CRPD says that states should develop measures to support persons with disabilities in order to promote their autonomy. For research, this represents a shift in focus from the notion of harms of being included in research, to the harms from being *excluded*, and that **incapacity in and of itself is not a sufficient reason *a priori* for excluding people from research**. This approach recognises that **protection due to 'vulnerability' excludes people with MHCs, making them *more* vulnerable** through lack of access to evidence-based care. The default presumption should be that the individual has capacity and is supported as necessary to promote their autonomy to make a decision themselves, instead of a presumption of incapacity and exclusion from research. Researchers should protect research participants *through* research, rather than protecting participants *from* researchers.

This shift from protection by exclusion to inclusion and special scrutiny when needed raises difficult questions:
- How can researchers take into account principles of equity and justice, and balance these with safeguarding, especially when a persons' autonomy might be diminished or their capacity fluctuating?
- What do meaningful capacity assessments look like?
- Which instruments and tools are needed to help researchers understand what to do if someone lacks capacity?
- What changes are needed to regulatory and governance documents to support inclusion?

GFBR participants agreed that there is a need to support the autonomy of people with MHCs to make decisions about research involvement. However, **empowerment and protectionist approaches do not always need to be in tension**. The key is to find ways to protect people with MHCs, *and* to be inclusive at the same time. How this is best achieved will be decided on case-by-case basis considering the status of the individual participant and governance context.

Researchers need to think about what sort of information, tools or resources will be needed to convey information to people with MHCs and their representatives/caregivers in a meaningful way, and what spaces/environments would need to be created to support autonomous decision making. The approach would need to recognise that people with MHCs are on a spectrum, so a range of different methods of seeking consent may be required e.g. less cognitive and more relational methods may be called for. **Developing this empowering model requires special training for researchers in order to avoid paternalistic attitudes and stereotypes. Team work is also required** – e.g. involving the psychiatrist, the psychologist, the social worker, etc. to help empower not only the research participant but also their chosen representatives, carers, and family. During research design it is important to engage with communities, patient organisations, or PWLE or closer family members and friends to facilitate and encourage appropriate processes to support autonomous decision-making.

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[13] See: https://www.gfbr.global/wp-content/uploads/2021/12/Marisha-Wickremsinhe_GFBR-2021_Theme-4.pdf

Advance directives

The use of advanced directives for research could be one way of empowering people with irreversible cognitive decline, by allowing them to specify who should provide surrogate consent in the event they lose capacity. Consent can be obtained prior to cognitive decline, allowing individuals to continue participating in the study even when their condition advances. This can be done in combination with other oversight mechanisms like REC involvement. Researchers could actively provide information and promote awareness of advance directives in people living with mental illness and their surrogates.

However, **many GFBR participants noted that their countries have no provisions for advanced directives relating to research participation**. Aminu Yakubu[14] presented a scoping review of ethics regulation for research with cognitively impaired adults in Sub-Saharan Africa (Box). The majority of documents were categorised as 'controlling instruments' that stipulate what should be fulfilled before including persons with cognitive impairment in studies (i.e. actions from someone other than the participant). While the minority were 'empowering instruments' that recognise and seek to uphold the rights of the research participant to self-determination to the extent possible (e.g. requiring researchers to pay attention to consent or assent by the research participant where possible, recognition of advance directives, surrogate consent, and respecting refusal by research participants). Only a few countries were found to have provisions for advance directives. Aminu concluded there is a need to enhance legal provisions for advance directives in African countries as a way of empowering people with cognitive impairments.

Surrogate decision-making

Marisha explained that CIOMS recognises that a diagnosis of 'mental and behavioural disorders' does not necessarily imply incapacity to consent. However, Guideline 16 suggests that 'some psychiatric conditions' can cause incapacity, in which case surrogate decision-making is permitted. In contrast, CRPD guarantees the right to universal legal capacity for all individuals living with disabilities, including individuals with 'long-term mental impairments'. In this context **substituted decision-making of any kind contravenes the CRPD**.

To uphold the principles of the CRPD, specifically universal legal capacity, Marisha explained that the research enterprise should not accept surrogate decision-making. However, research with individuals who are unable to consent to participation may yield valuable scientific knowledge, or individual benefit to them. This raises the question of **when, if at all, surrogate decision-making should be permitted, even though it violates the CRPD** (e.g. if the prospect of individual or community benefit outweighs potential risks).

The CIOMS guidelines articulate a number of provisions for surrogate consent for situations where an individual is not capable of consenting for themselves. How these guidelines translate into practice, and the models adopted by different countries, are likely to vary. Aminu's scoping review demonstrated this variation in terms of who can act as a surrogate decision-maker and the extent to which, if at all, the provisions recognise and uphold the participant's refusal to participate as being superior to any surrogate consent. Aminu called for more work on the practical applications of the legally authorized representative provisions, as well as the issue of respect for participant dissent, either verbally or behaviourally.

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[14] See: https://www.gfbr.global/wp-content/uploads/2021/12/Aminu-Yakubu_GFBR-2021_Theme-4.pdf

In a review of the Malaysian Mental Health Act (Malaysian MHA) 2001, [Aimi Nadia Mohd Yusof](#)[15] noted that the Malaysian MHA empowers the patients' relatives to provide consent on behalf of the person who lacks capacity to consent (Box). However, there is no guidance on the hierarchy of the proxy decision maker and who should be contacted to provide consent for research participation if the individual is incapable of giving their own consent. This could ignite worry whether the relative understands the participant's wishes that would have been decided when they had the capacity to give consent. On the other hand, not having a strict hierarchy allows doctors flexibility when obtaining consent, taking into account the context and societal norms.

GFBR participants agreed that surrogate decision-making can be compatible with an empowerment approach as it may be the only means of ethical inclusion of persons with cognitive impairment in research, especially for people with advanced impairment. In such cases, mechanisms should be in place to ensure processes are conducted ethically and the decision is made based on the participant's will and values, and that there are no conflicts of interests. Other issues were discussed, such as whether surrogate decision-makers should also be assessed on their capacity to understand the scope and methods of the research and whether the surrogate should be someone close to the research participant (e.g., family members) or a neutral third party.

Supported decision-making

[Sarah Carracedo](#)[16], provided a review of Peru's Clinical Trial Regulation in light of the CRPD and the CIOMS guidelines. She argued for a shift from 'surrogate' decision-making to 'supported' decision-making where the supporters help people with cognitive disabilities decide whether to participate in research. In this context, **assessment of decision-making skills should not be considered discriminatory but compatible with the CRPD goals as it aims to inform and tailor the measures of support given to people with disabilities**. Sarah argued that an assessment of decision-making skills is not grounded in a person's disability, and its purpose is not to deny legal capacity to people with mental impairments. Instead, it aims to strengthen the exercise of legal capacity by helping the supporters, research teams and RECs understand *what* and *the extent* to which a person with disability understands, in order to give them the best support in accordance with their own characteristics and preferences.

In cases where a supporter has tried everything in their power but the person with mental disabilities is unable to understand the research, the supporter could decide on participation based on the best interpretation of their will and preferences. Where their preferences are not known, the decision could be made exceptionally, in their best interests, when the research intervention is the best available medical option. Sarah argued that best interest decisions should not always be considered as a violation of the CRPD because they do not always constitute a discriminatory denial of legal capacity. In this scenario, **these decisions carefully balance the potential individual benefits and risks of research, and other competing considerations – including relating to the legal capacity of people with disabilities – that ultimately protect their right to health and research participation**.

GFBR participants agreed **it would be problematic to remove surrogate decision makers altogether**. There will be cases where surrogate decision-making, among other mechanisms, may be the only means of ethically including persons with cognitive impairment in research studies, especially for people with advanced cognitive

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[15] See: https://www.gfbr.global/wp-content/uploads/2021/12/Aimi-Nadia-Mohd-Yusof_GFBR-2021_Theme-4.pdf
[16] See: https://www.gfbr.global/wp-content/uploads/2021/12/Sarah-Carracedo_GFBR-2021_Theme-4.pdf

impairment. Nonetheless, **it is important to promote the language of supportive decision-making** as compared to surrogate decision-making as a way to foreground an empowerment model.

In conclusion, GFBR participants agreed that **not all surrogate decision-making frameworks are disempowering**. It very much depends on how the frameworks and capacity assessments are framed and applied in specific situations. In order to assess this, we need to understand what we mean by 'empowerment' and what end we want to achieve. And then, what instruments, tools, and mechanisms are required to achieve it? This is likely to be very contextual and **researchers will need to engage with the communities to understand where disempowerment is arising and where vulnerabilities lie,** and how we can remove them to allow for a greater sense of empowerment.

Challenges in the governance and regulatory landscape

As discussed, approaches to the regulation and governance of research involving people with cognitive impairment has always been very protectionist. The law takes easily to this approach and the associated safeguards, which often result in exclusion. **The limitations of governance documents and regulatory frameworks come to the fore when the approach is changed to one that is more nuanced** as it is very difficult for law and governance documents to be so contextually rich. For example, when empowerment for research participation is put within a mental health legislation framework this may not fit well and may not be effective. Furthermore, it can be difficult and time consuming to amend legal instruments when they are found to be inadequate or unhelpful.

Aimi illustrated this point in the context of the Malaysian MHA 2001 which is restrictive in scope and only governs the consent process for participation in clinical trials, electroconvulsive therapy, and surgery which constitute medical treatments. Aimi argued that using the same standards of consent process for research and treatment may lead to the unnecessary exclusion of potential participants with MHCs from research due to the fear of ethical and legal consequences which are higher for treating doctors than researchers (e.g. being struck off). Furthermore, the Malaysian MHA does not define what constitutes a 'clinical trial' resulting in ambiguity, and it categorically excludes other types of research from its scope of governance. The Malaysian MHA stipulates that a psychiatrist should undertake the initial assessment of the individual's capacity. This may be relevant in the context of medical treatment, but may not be the necessary for research where capacity could be assessed by other relevant health professionals. Aimi argued that a separate guideline is required to govern the research process and to address the limitations of the Malaysian MHA.

In most contexts, **researchers often struggle to find practical guidance on what is required when conducting research with people with MHCs, and governance documents can be ambiguous or contradictory**. For example, Peru's Civil Code has been updated in accordance with the CRPD and recognises the legal capacity of people with disabilities, while Peru's Clinical Trial Regulation mandates consent from a legal representative for participants who lack capacity, conflicting with the CRPD and Peru's constitutional order. This demonstrates the challenges of guidance and of implementing the CRPD, which may require modifications to other laws and regulations. **It is critical for guidelines to be revised to provide clarity, not least with regards to what is required and who should provide surrogate consent** for persons who lack capacity.

Returning to the notion of empowerment, governance documents should make a clear statement that upholds the rights of research participants to an independent and autonomous determination of their participation. Stating the commitment and expectation of inclusion should prompt researchers to thoroughly examine and

justify their approach to demonstrate how inclusion and empowerment are supported in their protocol. In turn, **RECs should be trained on the importance of inclusion and empowerment** and play a critical role by:

- **providing the necessary (supportive) scrutiny** of the empowerment approach
- **challenging any proposed exclusion** and requiring a justification where exclusion is proposed
- **having members with lived-experience, knowledge and expertise on mental health research or disability rights** to represent the views and protect the interests of persons with MHCs
- **checking how a researcher will assess decisional capacity and provisions for surrogate or supported decision-making**.

GFBR participants agreed that it is important to think about governance as an empowering, rather than prohibitive, mechanism. However, governance is not enough to move towards an empowerment model. It is a starting point and guide but the change of paradigm requires team work – researchers, clinicians, psychologists, social workers, policy makers, RECs, families, communities – along with education and training.

5. Consent, decisional capacity and guardianship

The standard approach to consent maintains that individuals must have decisional capacity in order to provide their own consent to enroll and participate in research. This session evaluated this approach through two cases studies that considered what is required to have decisional capacity and how clinicians can assess whether individuals possess these things. The session also explored the conditions under which it is appropriate to enroll individuals who do not have decisional capacity in research; and when it is appropriate to exclude them. Building on the governance session, which discussed empowerment, inclusion, capacity assessments and surrogate consent, this session provided a practical look at how these issues were handled in the context of two research studies.

Decisional capacity assessments

Decisional capacity should be assessed and taken seriously as important to the ethical conduct of research. It is ethically important to ask: what can be done to optimise decisional capacity so individuals can make decisions themselves? This needs to be **informed by an evidence-based approach, understanding that decisional capacity is heterogeneous across populations and changes (within the individual) over time**. There can be no uniform way of dealing with decisional capacity - it must be resolved on case-by-case basis. Arguably, **researchers should do capacity assessments for everyone being recruited into research, and not only those perceived to lack decisional capacity.**

Research inclusion requires researchers to find the balance between protection and non-discrimination, and this can only be managed through the skills and moral agency of the researcher. It is the **responsibility of researchers and RECs to make sure the research is valuable and risks and benefits well balanced before seeking consent,** in order not to put excess moral weight on consent. It is also **important to think about whether the researcher is capacitated to do the assessment: what tools are they using and whether they are the right tools**. Researchers working in this field should have in-depth training to support them in negotiating these tensions.

Timing of decisional capacity assessments

[Juan Undurraga](#)[17] presented a case on the research ethics challenges in a cohort of first episode psychosis (FEP) patients from a psychiatric hospital in Santiago, Chile (Box). To date, 132 FEP patients have been recruited, and the cohort has supported a range of clinical studies. Because decisional capacity may vary for an individual over time, and because it should be assessed relative to a specific decision at a particular time and context, the study team decided to ask patients for consent to participate in the cohort when their decisional capacity was at its highest in the days before discharge from hospital.

The second case, presented by [Hanna Negussie](#)[18], focused on the TaSCS trial that aimed to assesses the effectiveness and safety of task-sharing mental health care through integration into primary health care in Ethiopia for people with severe mental health conditions. When a person was unable to consent because of lack of capacity, and as long as they were not communicating unwillingness to participate, caregiver permission was sought. The research team planned to formally reassess capacity whenever there was an indication that the person might have regained capacity (identified by the family or through contacts with health care professionals), and at each trial time-point. This approach to reassessment aimed to maximise the possibility for the person with a MHC to consent to involvement themselves. However, in practice re-assessment only took place at the trial time-points because of a lack of communication of changes in mental health status to trial staff from family members or health workers, demonstrating the practical challenges of the intended approach.

GFBR participants agreed on the importance of:
- **viewing consent as a *process*** and using every opportunity to maximise the autonomous choices of people with MHCs
- **conducting capacity assessments when the person has the best capacity**
- **assessing capacity at multiple points**, to reassess participants decision and consent for the study, especially for longitudinal research.

Who and how should decisional capacity be assessed?

Juan explained that in the context of the FES research, the treating physician decides when the patient has appropriate decisional capacity and then explains the study to the patient and caregivers and asks for informed consent. This approach permits a more comprehensive clinical and decisional capacity evaluation from the research team's perspective. In addition, the therapeutic relationship with the treating physician allows the patient and caregivers to ask questions openly in a protected and trustful environment. On the other hand, it has some risks, such as a less systematic evaluation than using standardized instruments and risks of coercion (see below).

GFBR participants had varying views on who should perform the capacity assessment. Some considered that **a clinician would be the best person to assess capacity but they should not be the treating physician in order avoid a conflict of interest**. **Others suggested that task-sharing in research is required, especially in low resource setting where there are limited numbers of specialist clinicians**. Trained research assistants and psychiatric nurses should be allowed to assess decisional capacity and bring more complex cases to senior research team members or clinicians. This was the case in the TaSCS trial, where psychiatric nurses were trained by psychiatrists to assess decisional capacity using a semi-structured form. Hanna reflected, however,

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[17] See: https://www.gfbr.global/wp-content/uploads/2021/12/Juan-Undurraga_GFBR-2021_Theme-5.pdf
[18] See: https://www.gfbr.global/wp-content/uploads/2021/12/Hanna-Negussie_GFBR-2021_Theme-5.pdf

that the concept of decisional capacity is unfamiliar to most mental health practitioners in Ethiopia, which may have limited the quality of assessment.

Juan proposed that the best person to do the capacity assessment is the person who knows the patient well. In the context of their study, the psychiatrist was the best person as they had daily interviews with the patient for many weeks. He recognised however that for other studies the best person could be the psychologist or the occupational therapist. Regardless, Juan stressed the importance of having the final decision made by just one person in order to avoid protracted discussion.

Juan explained that four psychiatrists work in the FES in-patient unit and each decides on the decisional capacity of their own patients and decided when to ask if they want to be involved in research. Having multiple assessors raises the question of how these assessments should be co-ordinated and standardised to promote consistency of approach. Juan's team approach this by meeting weekly to talk about all patients and undertaking group work as a way of standardising the psychiatrists' individual assessments. Standardised criteria have also been developed by doing clinical group evaluations involving interviews with patients. This team approach and regular communication with the local REC, has resulted in the development of standardised criteria so the psychiatrists generally agree in their determinations.

When should individuals who lack decisional capacity be included in research, and what safeguards should be in place

Hanna's case study outlined the TaSCS trial's justifications and safeguards for including people who lacked capacity, including:

- **Individual and group benefit**: The TaSCS trial was testing a task-shared intervention to be scaled up and inevitably delivered to people who lacked capacity in real world settings. Therefore, the evidence from the trial needed to be applicable to the target group for this intervention, particularly in relation to safety concerns.
- **Caregivers as surrogate decision makers** The legal concept of 'guardian' is not widely used in Ethiopia, and so the TaSCS trial decided on the practical option of involving caregivers. As long as the individual was not communicating an unwillingness to participate, permission was sought from one of three caregivers documented during a home visit by project outreach workers when they went to invite participants for screening. Information about the trial was explained to both the potential participant and the caregiver during the consent process.
- **Advanced directive**: For people who had capacity at baseline, the TaSCS trial asked for an advance directive from the person to guide what should happen if they subsequently lost capacity. With the permission of the participant, the contact details of the caregiver were recorded at baseline so that they could be contacted to provide permission for continued research participation if the person lost capacity during the course of the study.
- **Monitoring risk of inferior care**: The potential for inferior care due to the task-sharing nature of the intervention was disclosed in the information sheet and discussed during the consent process, alongside outlining the measures to minimise inferior care. These measures included a Data Safety and Monitoring Board that regularly reviewed proxy outcomes for potential inferiority of care and reviewed an interim analysis at 12 months. In addition, project psychiatric nurses conducted weekly supervision of the primary care workers delivering task-shared care for the first 3 months in the intervention arm and reviewed their follow up clinical sheets.

Risks of coercion

In many low-income country settings, caregivers play a critical role in facilitating access to care for people with MHCs. However, Hanna explained that studies from Ethiopia have indicated that the treatment priorities of people with MHC and caregivers sometime diverge. The relationship between a person with a MHC and caregiver may be complicated by the caregiver's complicity in coercive practices, including restraint or covert administration of medication.

Juan explained that the integration of research into clinical care settings may give rise to worries about coercion to participate in the research or to therapeutic misconception. In the context of the FEP research, risk is minimised by:
- **every patient having the same access to care** during in-patient stays, and outpatient clinics
- **there being no financial incentives** for clinicians or researchers
- **patients and family members being involved** and learning about the program
- **weekly meetings of the psychiatrists, nurses, psychologists and all people involved in care**, to address as a group the patient/participant's ability to consent.

However, there is still a potential risk of coercion due to a therapeutic misconception as the participants have access to additional measures that wouldn't otherwise be available to them e.g. MRI and more profound cognitive evaluations. So while the risk of coercion can be reduced, there will always be some tension. In this context, the research team discusses ethical issues and work closely with the local REC.

Tools to assess capacity

One of the most widely used instruments to help clinicians assess decisional capacity is the MacCAT-T, which is based on four abilities:
1. Understanding or comprehending the meaning of relevant information, including benefits and risks
2. Appreciating how the information applies and is relevant to one's own condition and situation
3. Reasoning with the information provided or comparing options based on the person's values and beliefs. In other words, the ability to weigh risks, benefits, and consequences of the decision
4. Evidencing or expressing clearly a choice.

Critics of this instrument agree that this model evaluates abilities necessary for capacity, but question if this is always sufficient. Other important capacities might be the person's emotions, values, and the authenticity of a person's choice. Juan explained that emotions are an essential issue to consider in the FES patients, as there is evidence that depressed patients weigh risks and benefits differently, and they may score well on the MacCAT-T. There are various validated tools, for assessing capacity which provide quality assurance and address some of the challenges regarding whether or not treating clinicians should conduct the assessment or a more neutral third party. However, none of the tools are universally accepted or used. GFBR participants agreed that **universally accepted and standardised capacity assessment procedures need to be developed**.

Annex 1: Background information on GFBR and meeting content

The Global Forum on Bioethics in Research (GFBR) is the principal global platform for debate on ethical issues pertaining to international health research. Its core aims are to give voice to low- and middle- income country (LMIC) perspectives in debates about global health research ethics and to promote collaboration.

The Forum meets annually to address a specific topic in research ethics and is generally case study based. This approach enables participants to understand the practical issues 'on the ground' in addition to broader ethical and governance questions. The current meeting was due to be held in person in Canada in 2020, hosted by the University of Toronto. Due to COVID-19 the meeting was postponed and ultimately took place online in 2021.

43 case studies and 19 governance papers were submitted for this meeting. 10 cases studies and 4 governance papers were selected for oral presentation at the meeting (see insets throughout the report). Three other case studies and guidance papers were available as on demand videos during the meeting, presented in the form of short Pecha Kucha presentations. In addition, a further 6 case studies and 3 governance papers were selected for presentation during an online seminar series (see Annex 2).

Pecha Kuchas

1	**Comparative effectiveness trial for agitation management in psychiatric emergency settings** Starlin Vijay Mythri, Makunda Christian Leprosy and General Hospital, India
2	**Ethics of screening for depression in antenatal clinics in Malawi** Genesis Chorwe-Sungani, University of Malawi, Malawi
3	**Regulation and ethical guidance for research in the mentally sick in Africa** Claude Kirimuhuzya, Kabale University, Uganda

Normally, up to 100 participants are selected for each meeting through a competitive process. This year, attendance was extended given the online nature of the meeting. Participants come from a diverse range of disciplines, countries and career stages and awards are available to LMIC colleagues to cover travel and accommodation.

All participants were encouraged to report the meeting recommendations in their home countries and to continue the discussion in their local context. Fellowships were available for LMIC participants to explore issues that arose during the GFBR meeting in greater detail, establish new collaborations, and develop new ideas for resolving issues that could not be resolved at the meeting itself. Past GFBR participants have given presentations on the meeting theme to their local RECs and at other conferences and published papers. It is anticipated that participants from this GFBR meeting will likewise take the discussion home and foster debate in their local context.

Annex 2: Seminar series

In the lead up to this meeting, GFBR hosted an open seminar series to provide an opportunity to discuss some of the key ethics and governance issues regarding mental health research. A summary of the series and abstracts are below, for further details and recordings please visit the [seminar webpage](#).

Seminar	Title	Recordings
1	The impact of COVID-19 on mental health research practice: ethical issues	[Watch now](#)
2	Equipping researchers to ethically involve people with mental health conditions in research	[Watch now](#)
3	Governance of research involving people with mental health conditions	[Watch now](#)
4	The ethics of neurodevelopmental disorders research	[Watch now](#)
5	Mental health research involving adolescents – ethical issues	[Watch now](#)

Seminar 1: The impact of COVID-19 on mental health research practice: ethical issues
This seminar explored the ethics of how mental health research practice has changed due to the COVID-19 pandemic. Discussion included the ethical implications of transferring face-to-face research online and what safeguards are needed to protect the wellbeing of participants at a time when support from the research team or external services may be reduced due to social distancing and other restrictions. How do we ensure ethically robust mental health research in the time of COVID-19 and how best can researchers involve people with lived experience in the design of research as it transitions to the digital world?

Seminar 2: Equipping researchers to ethically involve people with mental health conditions in research
This seminar drew on researchers' personal and shared experiences to discuss the ethical challenges of involving people with mental health conditions in empirical research. What creative approaches have researchers used to ethically involve people who face multiple vulnerabilities and how do these vulnerabilities impact on the practicalities of the research process (e.g. consent and community engagement)?

Seminar 3: Governance of research involving people with mental health conditions
International guidelines provide principles and values to guide research with people who have mental health problems. However, obstacles remain for implementation at a national level and achieving an ideal governance framework. What are the challenges to ensuring people with mental health conditions have equitable access and opportunities to participate in research, and balancing protections to safeguard their rights and welfare? This seminar explored three LMIC case studies and highlighted the need for culturally sensitive mental health law and guidance and training for researchers and research ethics committees.

Seminar 4: The ethics of neurodevelopmental disorders research
The three presentations in this seminar explored ethical issues in the study design and engagement of participants with neurodevelopmental disorders and their families in research to inform service development and delivery in low- and middle-income public health and community settings.

Seminar 5: Mental health research involving adolescents – ethical issues
An effective response to the high levels of mental ill-health among adolescents in many LMICs is made harder by community stigma, low levels of service provision, and lack of research into culturally-appropriate interventions. Challenging ethical questions arise with respect to the role of adolescents themselves, both in influencing the research agenda to be responsive to their needs, and in their own choices about research participation. These issues need to be navigated in ways that are sensitive to cultural context, recognising both adolescents' developing

capacity to make their own decisions, and cultural approaches to decision-making within families and communities that may favour the collective over the individual. Further important ethical questions arise in the context of the relevance of the research to local needs, and the likelihood of research findings feeding into service improvements.

Annex 3: List of abbreviations

GFBR: Global Forum on Bioethics in Research

LMIC: Low- and middle-income country

HIC: High income country

REC: Research ethics committee

WHO: World Health Organization

H3Africa: Human Heredity and Health in Africa

Case study and governance paper write-ups and presentations from this meeting are available on the GFBR website.