UNIVERSITY OF LEEDS RESEARCH ETHICS COMMITTEE APPLICATION FORM¹

UNIVERSITY OF LEEDS

Please read each question carefully, taking note of instructions and completing all parts. If a question is not applicable please indicate so. The superscripted numbers (eg⁸) refer to sections of the guidance notes, available at http://ris.leeds.ac.uk/uolethicsapplication. Where a question asks for information which you have previously provided in answer to another question, please just refer to your earlier answer rather than repeating information. Research ethics training courses: http://www.sddu.leeds.ac.uk/research-innovation/research-ethics-training-and-guidance

To help us process your application enter the following reference numbers, if known and if applicable:

Ethics reference number:	PSYC-26 21.04.20
Student number and/ or grant reference:	EP/TO23813/1

PART A: Summary

A.1 Which Faculty Research Ethics Committee would you like to consider this application?²

- Arts, Humanities and Cultures (PVAR)
- O Biological Sciences (BIOSCI)
- C ESSL/ Environment/ LUBS (AREA)
- MaPS and Engineering (MEEC)
- O Medicine and Health (Please specify a subcommittee):
 - C School of Dentistry (DREC)
 - School of Healthcare (SHREC)
 - School of Medicine (SoMREC)
 - School of Psychology (SoPREC)

A.2 Title of the research³

Mainstreaming Global Mental Health: A Praxis Nexus Approach

A.3 Principal investigator's contact details ⁴	
Name (Title, first name, surname)	Professor Anna Madill
Position	Professor
Department/ School/ Institute	School of Psychology
Faculty	Medicine & Health
Work address (including postcode)	School of Psychology, 4 Lifton PI, Leeds LS2 9JZ
Telephone number	X35750
University of Leeds email address	a.l.madill@leeds.ac.uk

A.4 Purpose of the research: ⁵			
Research			
Educational qualification: <i>Please specify:</i>			
Educational Research & Evaluation ⁶			
Medical Audit or Health Service Evaluation ⁷			
Other			
A.5 Select from the list below to describe your research:			
Research on or with human participants			
Research which has potential adverse <u>environmental impact</u> . ⁸ If yes, please give details:			
Research working with data of human participants			
New data collected by qualitative methods			
New data collected by quantitative methods			
New data collected from observing individuals or populations			
Routinely collected data or secondary data			
Research working with aggregated or population data			
Research using already published data or data in the public domain			
Research working with human tissue samples			
A.6 Will the research involve NHS staff recruited as potential research participants (by virtue of their professional role) or NHS premises/ facilities?			
If yes, ethical approval must be sought from the University of Leeds. Note that <u>approval</u> from the NHS Health Research Authority may also be needed, please contact <u>FMHUniEthics@leeds.ac.uk</u> for advice.			
A.7 Will the research involve any of the following: ¹⁰ (You may select more than one) If your project is classified as <u>research</u> rather than service evaluation or audit and involves any of the following an application must be made to the <u>NHS Health Research Authority</u> via IRAS <u>www.myresearchproject.org.uk</u> as NHS ethics approval will be required. There is no need to complete any more of this form . Further information is available at <u>http://ris.leeds.ac.uk/NHSethicalreview</u> and at <u>http://ris.leeds.ac.uk/HRAapproval</u> . You may also contact <u>governance-ethics@leeds.ac.uk</u> for advice.			
Patients and users of the NHS (including NHS patients treated in the private sector) ¹¹			
Individuals identified as potential participants because of their status as relatives or carers of patients and users of the NHS			
Research involving adults in Scotland, Wales or England who lack the capacity to consent for themselves ¹²			
A prison or a young offender institution in England and Wales (and is health related) ¹⁴			
Clinical trial of a medicinal product or medical device ¹⁵			
Access to data, organs or other bodily material of past and present NHS patients ⁹			

L	Use of human tissue (including non-NHS sources) where the collection is not covered by a Human
	Tissue Authority licence ⁹



The recently deceased under NHS care

None of the above

You must inform the Research Ethics Administrator of your NHS REC reference and approval date once approval has been obtained.

The HRA decision tool to help determine the type of approval required is available at <u>http://www.hra-</u> <u>decisiontools.org.uk/ethics</u>. If the University of Leeds is not the Lead Institution, or approval has been granted elsewhere (e.g. NHS) then you should contact the local Research Ethics Committee for guidance. The UoL Ethics Committee needs to be assured that any relevant local ethical issues have been addressed.

A.8 Will the p	articipants be f	from any of the	following groups?
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- Children under 16¹⁶ Specify age group: ____
- Adults with learning disabilities¹²

Adults with other forms of mental incapacity or mental illness

- Adults in emergency situations
- Prisoners or young offenders¹⁴
- Those who could be considered to have a particularly dependent relationship with the investigator, eg members of staff, students¹⁷
- Other vulnerable groups

~

No participants from any of the above groups

Please justify the inclusion of the above groups, explaining why the research cannot be conducted on non-vulnerable groups N/a

It is the researcher's responsibility to check whether a DBS check (or equivalent) is required and to obtain one if it is needed. See also <u>http://www.homeoffice.gov.uk/agencies-public-bodies/dbs</u> and <u>http://store.leeds.ac.uk/browse/extra_info.asp?modid=1&prodid=2162&deptid=34&compid=1&prodvarid=0&catid=2</u> 43.

A.9 Give a short summary of the research¹⁸

This section must be completed in **language comprehensible to the lay person**. Do not simply reproduce or refer to the protocol, although the protocol can also be submitted to provide any technical information that you think the ethics committee may require. This section should cover the main parts of the proposal.

Our ambition is to trigger a step-change in how the research community thinks about where, how and by whom mental health in Low and Middle Income Countries (LMIC) can be impacted to benefit people experiencing poor mental health. Specifically, we believe there is untapped potential for global researchers to impact mental health whilst delivering their core (non-mental health) project aims, and that this can be done without significant resource implications. Therefore, to accelerate global action on mental health our long-term aim is to produce a Global Mental Health Impact Framework with potential for use in all research in developing countries. Our first stage project will establish a foundation and pathway towards this long-term aim by creating a beta version of the Impact Framework, based on arts and humanities methodologies first, ready for future testing and development across a broad range of GCRF projects in a second stage application. At this second stage, we will also develop an implementation plan to support funders, researchers and LMIC partners to understand and use the Framework.

Measurable, realistic, achievable objectives for the first-stage 12-month project are to:-

1. Complete a scoping review of (i) material practices and (ii) implicit and explicit mental health activities in non-mental health focused GCRF projects funded to date;

2. Complete a report outlining the basis for a Global Mental Health Impact Framework around collaborative material practices;

3. Develop and strengthen equitable international academic, policy and practitioner partnerships and build capacity in LMIC and the UK; and,

4. Use this work to assist in developing the agenda and programmes of research to be undertaken in the second stage application.

A.10 What are the main ethical issues with the research and how will these be addressed?¹⁹

Indicate any issues on which you would welcome advice from the ethics committee.

Our ethical practice is informed by RCUK and DFID guidelines. The PI has responsibility for ethical conduct and will report to the Steering Group. The University of Leeds has a policy on good conduct in research, in line with the requirements of the Research Councils (http://ris.leeds.ac.uk/info/71/good_research_practice). The Framework will explain ways that diverse projects in developing countries could achieve mental health impact as part of their routine activities without overstretching project expertise or resources. Hence, Framework development will involve full consideration of the ethical issues involved. This includes: researcher and participant safety, guidance on developing a protocol, including lines of responsibility and processes to monitor and respond to participant risk, negotiating boundaries, and involving local mental health professionals. The PI will therefore consult also with the Safeguarding Developer at contributing AHRC-GCRF Network Plus 'Changing the Story'.

PART B: About the research team

B.1 To be completed by students only	/20
Qualification working towards (eg Masters, PhD)	n/a

B.2 Other members of the research team (eg co-investigators, co-supervisors) ²¹	
Name (Title, first name, surname)	Dr Tolib Mirzoev
Position	Associate Professor
Department/ School/ Institute	Faculty of Medicine and Health, University of Leeds

Name (Title, first name, surname)	Professor Jane Plastow
Position	Professor
Department/ School/ Institute	School of English, University of Leeds

Name (Title, first name, surname)	Professor Paul Cooke
Position	Professor
Department/ School/ Institute	Sch of Languages, Cultures, and Societies, University of Leeds

Name (Title, first name, surname)	Dr Siobhan Hugh- Jones
Position	Associate Professor
Department/ School/ Institute	School of Psychology, University of Leeds

Name (Title, first name, surname)

Dr Erminia Colucci

Position	Senior Lecturer
Department/ School/ Institute	Faculty of Science & Technology, Middlesex University
Name (Title, first name, surname)	Dr Rebecca Graber
Position	Lecturer
Department/ School/ Institute	Sch of Applied Social Sciences, University of Brighton
Name (Title, first name, surname)	Professor Stuart Taberner
Position	Professor
Department/ School/ Institute	Sch of Languages, Cultures and Societies, UoL
Name (Title, first name, surname)	Dr Karina Croucher
Position	Lecturer
Department/ School/ Institute	Faculty of Life Sciences, University of Bradford
Name (Title, first name, surname)	Professor Owen Greene
Position	Professor
Department/ School/ Institute	Faculty of Social Sciences, University of Bradford
Name (Title, first name, surname)	Dr Adrian Evans
Position	Lecturer
Department/ School/ Institute	Faculty of Life Sciences, University of Bradford
Name (Title, first name, surname)	Professor Andrew Wilson
Position	Professor
Department/ School/ Institute	Faculty of Life Sciences, University of Bradford
Name (Title, first name, surname)	Professor Raghu Raghavan
Position	Professor
Department/ School/ Institute	School of Nursing and Midwifery, De Montfort University
Name (Title, first name, surname)	Professor Brian Brown
Position	Professor

School of Applied Social Sciences, De Montfort University

Part C: The research

Department/ School/ Institute

C.1 What are the aims of the study?²² (Must be in language comprehensible to a lay person.)

Our long-term strategic aim is to accelerate global action on mental health by producing a Global Mental Health Impact. Framework with potential for use in all research in developing countries. Our first stage project will establish a foundation and pathway towards this long-term goal by creating a beta version of the Impact Framework, based on arts and humanities methodologies first, ready for future testing and development across a broad range of GCRF projects in a second stage application. Measurable, realistic, achievable objectives for the first-stage 12month project are to:-

1. Complete a scoping review of (i) material practices and (ii) implicit and explicit mental health activities in non-mental health focused GCRF projects funded to date;

2. Complete a report outlining the basis for a Global Mental Health Impact Framework around collaborative material practices which:

-consolidates learning across the Cluster, associated partners, collaborators, and networks;

-identifies ways in which collaborative material practices can be used in LMIC to generate micro/meso interventions and macro impacts;

-identifies missed opportunities to promote, document, and provide a lasting legacy;

-identifies gaps in knowledge, and challenges in application and up-scaling, which are barriers to achieving impact;

-posits new insights, questions, and ways of working to accelerate and amplify impact.

3. Develop and strengthen equitable international academic, policy and practitioner partnerships and build capacity in LMIC and the UK;

4. Use this work to assist in developing the agenda and programmes of research to be undertaken in the second stage application.

C.2 Describe the design of the research. Qualitative methods as well as quantitative methods should be included. (Must be in language comprehensible to a lay person.)

It is important that the study can provide information about the aims that it intends to address. If a study cannot answer the questions/ add to the knowledge base that it intends to, due to the way that it is designed, then wasting participants' time could be an ethical issue.

This is a qualitative methods study with some limited collection and analysis of quantitative demographic and workshop feedback/evaluation data.

<u>Scoping review</u>: A scoping review of (i) material practices and (ii) implicit and explicit mental health activities in nonmental health focused GCRF projects funded to date. Relevant information is publically available online and will be contented analysed.

Interviews: Transcribed, audio-recorded, and e-mail consultation interviews conducted by the PI with a wide range of international development stakeholders including existing or previous LMIC Cluster project partners and other relevant key informants and stakeholders. Our target is at least one from each GCRF in the Challenge Cluster (~n=20). Interviews allow us to raise awareness in new portfolios of the project ambition for mental health impact, help us learn where past non-mental health projects 'brushed up' against mental health, and to consult closely with LMIC partners about the developing Framework and second stage application. Interviews will be conducted remotely: online (e.g., Skype/e-mail) and/or by telephone. Transcripts will be analysed using Thematic Analysis.

Workshop data:

Audio-recordings, in situ field notes, materials created within the workshops, and participant feedback/evaluations of workshop/knowledge exchange events (~n=8). Qualitative data will be content analysed. Quantitative data will be analysed used descriptive statistics. Workshops will be adapted for online delivery as required.

(a) 3 x UK 2-day Challenge Cluster Workshops for collaborators, PO representatives and other relevant invitees;

(b) Global Mental Health strand meetings at 4 x 3-day Praxis Nexus Events which reach out to GCRF projects that engage arts and humanities researchers, themes or approaches. Praxis: Arts and Humanities for Global Development is an AHRC-led GCRF Hub at the University of Leeds which is one of the GCRF-funded projects contributing to this research. The current research will piggy-back on workshops organised by Praxis and lead the mental health strand of Praxis meetings; and

(c) 1 UK 1-day Praxis Learning Event for UK researchers. Praxis has a budget to fund specialist workshops and has committed to fund one mental health learning event to be organised and run by the team undertaking the current project.

C.3 What will participants be asked to do in the study?²³ (e.g. number of visits, time, travel required, interviews)

All participants will be asked to complete a short demographic questionnaire. This should not take longer than 15 minutes to be completed. The answers will provide basic demographic information enabling the most efficient use of participant's time if they decide to participate and to use in anonymised form in reports of the research.

<u>Interviews</u>: Potential participants, who will be purposefully sampled, having shown interest and having received information about the study, will be invited to discuss the study with the PI by e-mail, phone, or online (e.g., Skype). Participants who have consented to participate in the study will be given the choice between a phone or online interview (e.g., Skype/e-mail). One interview will be required from each participant, which will last for approximately one hour and will be conducted by the PI.

<u>Workshops</u>: (a) Cols, partner organisation representatives and further purposefully-sampled stakeholders, and other relevant attendees as accepted will take part in a variety of theme-relevant workshop events as described above. About 15-25 attendees are expected. (b) Approximately 70-80 attendees will attend Praxis-organised workshops in which the team for the current project will lead the mental health strand. (c) Approximately 20 UK researchers will take part in a Praxis Learning Event organised by the team for the present project.

Workshop participants will take part in discussions, activities and knowledge exchange associated with global challenges as part of normal workshop activities. Intelligence from these workshops will be gathered unobtrusively by the PI and project administrator, with permission: e.g., audio-recordings, field notes, and activity-created products (such as bullet point presentations) collected. Workshop participants will be asked to complete feedback evaluation. Praxis will have overview and design of this feedback when the workshops are run by them.

C.4 Does the research involve an international collaborator or research conducted overseas:

Yes No

If yes, describe any ethical review procedures that you will need to comply with in that country: University of Leeds ethical approval is sufficient for this seed-funding stage project as interviews will be conducted from the UK and workshops organised under the auspices of the University of Leeds. Participants from overseas will be from multiple countries so there is no other relevant, overview ethics committee to which to submit. This arrangement has been accepted by UKRI who are funding the study.

Describe the measures you have taken to comply with these: n/a

C.5 Proposed study dates and duration

Research start date (DD/MM/YY): 01/06/20 Research end date (DD/MM/YY): 30/05/21

Fieldwork start date (DD/MM/YY): approx. 01/06/20 Fieldwork end date (DD/MM/YY): 30/05/21

C.6. Where will the research be undertaken? (i.e. in the street, on UoL premises, in schools)²⁵

<u>Scoping review</u>: will take place on University of Leeds premises, in the School of Psychology, and can be undertaken remotely, from home while CD-19 lockdown is in force.

<u>Interviews</u>: will be conducted online (e.g., Skype/e-mail) or by phone by the PI. The PI will be in a private room to conduct the interviews and will request that participants similarly make arrangements to undertake the interview in a private room to ensure confidentiality is maintained.

<u>Workshops</u>: will take place in a variety of locations and in line with any CD-19 requirements, e.g., online/remotely while lock down is in force. Workshops organised specifically for CoIs and collaborators, when face-2-face is possible, will take place at the University of Leeds. Those organised by Praxis, on which the currently study is piggy-backing, will be held in a variety of UK and overseas locations. This project will provide expertise and lead by

invitation the mental health strand of Praxis events but the events will be organised by and come under the auspices of Praxis. All events will follow CV-19 guidelines and adapt as necessary.

RECRUITMENT & CONSENT PROCESSES

How participants are recruited is important to ensure that they are not induced or coerced into participation. The way participants are identified may have a bearing on whether the results can be generalised. Explain each point and give details for subgroups separately if appropriate.

C.7 How will potential participants in the study be: (i) identified?

<u>Interviews</u>: Potential participants for interviews will be identified as being key international development stakeholders (including mental health practitioners, advocates, policy-makers and researchers) in the UK and in LMIC. Networks of members of the research team (such as former GCRF partners) and Partner Organisations will be used to identify suitable individuals. The scoping review component of this research may also help to identify suitable persons. A snowballing strategy will be used to identify further potential participants.

<u>Workshops</u>: (a) Cols, partner organisation representatives (from India and Indonesia), and further purposefullysampled stakeholders, and other relevant attendees as recommended by team members will be invited to take part in study-organised workshops. (b) Praxis will organise the advertising and invitations to the workshops on global challenges that they run and on which the current study is piggy-backing. (c) The current study has budget to mentor a small number of early career scholars. They will be supported to organise a Praxis Learning Event for the study and to advertise and select appropriate attendees.

(ii) approached?

<u>Interviews</u>: Potential interviewees will be approached through Col and partner organisation networks, by e-mail by the PI when identified through the scoping review, via word of mouth, and by distributing the information about the study through available networks. When appropriate, the initial contact will be made by the partners on behalf of the research team, with follow up contact by the PI.

<u>Workshops</u>: (a) Workshops run under the auspices of the present study will issue invitations and information to Cols, partner representatives, and other recommended attendees as a normal part of running the project. (b) Praxis will organise the advertising and invitations to the workshops on global challenges that they run and on which the present study piggy-backs. (c) The study Praxis Learning Event will be advertised through our networks and on the Praxis website.

A paragraph for inclusion in workshop information and invitations which outlines the data recording aspects of the events for the present study is included in the appendices.

(iii) recruited?²⁶

<u>Interviews</u>: An initial email, and a single reminder will be sent to potential participants. They will be invited to discuss the study with the PI over e-mail, by phone or online (e.g., Skype). They will be recruited only once they have given informed consent.

<u>Workshops</u>: (a) Workshops run under the auspices of the present study will issue invitations to Cols and partner representatives, and other recommended attendees as a normal part of running the project. (b) Praxis will organise the advertising and invitations to the workshops on global challenges that they run and on which the present study piggy-backs. (c) Potential attendees for the study-organised Praxis Learning Event will be asked to provide a short statement as to why they would like to attend the event. If there are more requests to attend than places, this will be used to prioritize the allocation of places.

C.8 Will you be excluding any groups of people, and if so what is the rationale for that?²⁷ Excluding certain groups of people, intentionally or unintentionally may be unethical in some circumstances. It may be wholly appropriate to exclude groups of people in other cases.

No groups of people will be systematically excluded. However interview participants will be purposively sampled to ensure that data collected will be appropriate to the research aims. Moreover, (a) study-organised workshops are intended for the Cols, partner organisation representatives, and a small number of additional recommended

contributors; (b) Praxis workshops will have limited places and may organise a system to priorities attendance; and (c) our Praxis Learning Event will have limited places and may also have to prioritise places on a fair and transparent basis as described above.

C.9 How many participants will be recruited and how was the number decided upon?²⁸

It is important to ensure that enough participants are recruited to be able to answer the aims of the research. Remember to include all advertising material (posters, emails etc) as part of your application.

<u>Interviews</u>: Approximately 20 participants will be recruited for the one-to-one interviews. This sample size is enough to obtain data for a qualitative research that will involve in-depth analysis and to fulfil the aims of this part of the study.

<u>Workshops</u>: (a) Project workshops are mainly for Cols and partner organisation representatives so attendance number of about 15-25 is suggested accordingly. (b) Praxis is very experienced in workshop organisation and they expect from past workshops that between 70 people with attend. (c) The Praxis Learning Event is expected to run with about 20-25 attendees. This is determined by the ability to have meaningful large and small group interactions while maintaining a personal atmosphere.

C.10 Will the research involve any element of deception?²⁹

If yes, please describe why this is necessary and whether participants will be informed at the end of the study.

No element of deception will be used in this research.

C.11 Will informed consent be obtained from the research participants?³⁰

Yes No

If yes, <u>give details</u> of how it will be done. Give details of any particular steps to provide information (in addition to a written information sheet) e.g. videos, interactive material. If you are not going to be obtaining informed consent you will need to justify this.

If participants are to be recruited from any of potentially vulnerable groups, <u>give details of extra steps</u> taken to assure their protection. Describe any arrangements to be made for obtaining consent from a legal representative.

Informed consent will be obtained from all participants for the interviews and data collection aspects of the workshops. This will include consent for audio-recording. All participants will be provided with the opportunity to discuss or ask questions about the consent form before giving their consent. All participants are working at a professional level and will be fluent in written and spoken English and so we will not translate information.

<u>Interviews</u>: Written information on the consent procedures will be provided in the information sheet. Audio-recorded consent or written consent via e-mail will be obtained before commencing the interview. For audio-recorded consent, the consent form will be emailed to the participant, at least one week, in advance of the interview. Item-by-item audio-recorded consent will be taken for all items on the consent form.

<u>Workshops</u>: Written information on the consent procedures will be provided in workshop information and invitations at least one week in advance of attendance. Due to the numbers involved in the workshops, and the lack of sensitivity of the workshop foci (i.e., professional and academic knowledge), consent will be on the basis of personal responsibility to avoid offering information during the workshops that one does not wish to be included as anonymous research data and alerting the PI within one week of the workshop if specific information provided is not to be included in the research.

Copies of any written consent form, written information and all other explanatory material should accompany this application. The information sheet should make explicit that participants can withdraw from the research at any time, if the research design permits. Remember to use meaningful file names and version control to make it easier to keep track of your documents.

Sample information sheets and consent forms are available from the University ethical review webpage at http://ris.leeds.ac.uk/InvolvingResearchParticipants

C.12	Describe whether participants will be able to withdraw from the study, and up to what point (eg	if data
is to	be anonymised). If withdrawal is <u>not</u> possible, explain why not.	

Any limits to withdrawal, eg once the results have been written up or published, should be made clear to participants in advance, preferably by specifying a date after which withdrawal would not be possible. Make sure that the information provided to participants (eg information sheets, consent forms) is consistent with the answer to C12.

The study information sheets and consent form explains that for the interviews and workshops, participants can pause or stop taking part in the interview/workshop at any point without having to give a reason and, post-interview/workshop can retract their data (or part therefore) from the study. If retracting data, they are requested to do so within one week of data collection.

C.13 How long will the participant have to decide whether to take part in the research?³¹ It may be appropriate to recruit participants on the spot for low risk research; however consideration is usually necessary for riskier projects.

At least 24 hours.

C.14 What arrangements have been made for participants who might have difficulties understanding verbal explanations or written information, or who have particular communication needs that should be taken into account to facilitate their involvement in the research?³²

Different populations will have different information needs, different communication abilities and different levels of understanding of the research topic. Reasonable efforts should be made to include potential participants who could otherwise be prevented from participating due to disabilities or language barriers.

All participants are working at a professional level and will be fluent in written and spoken English.

C.15 Will individual or group interviews/ questionnaires discuss any topics or issues that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could take place during the study (e.g. during interviews or group discussions)?³³ The <u>information sheet</u> should explain under what circumstances action may be taken.

Yes

No

If yes, give details of procedures in place to deal with these issues.

Mental health may be a sensitive topic due to social stigma. However, the interview questions will be focused at policy-level, practitioner, and research level and are therefore unlikely to be sensitive, embarrassing, or upsetting to the professionals being interviewed or who are taking part in workshops. Nevertheless the participant will be informed that they can leave or stop the interview or leave workshops at any time without having to give a reason.

There is a small possibility that a disclosure of professional misconduct could be made during an interview or within a workshop. If there are any serious disclosures, the PI will discuss with appropriate team members and the Chair of the school of Psychology Ethics Committee to determine what, if any, action needs to be taken.

C.16 Will individual research participants receive any payments, fees, reimbursement of expenses or any other incentives or benefits for taking part in this research?³⁴

Yes No

If Yes, please describe the amount, number and size of incentives and on what basis this was decided.

Cols receive a small % of salary as part of the grant and a budget is provided for their travel to workshops. A budget is also provided for a representative from each partner organisation to travel to the UK to co-lead one workshop. Refreshments have been budgeted and will be provided for face-to-face workshops where these are possible.

We will offer, and advertise widely, 3 mentoring opportunities for UK ECR to develop their competencies to engage in Global Mental Health research and to establish connections with LMIC networks and partners. Mentored ECRs will: 'meet' the POs; join the UoL Global Mental Health Network; attend Praxis Nexus Events; be invited to all Cluster events; co-organise and host the Cluster Praxis Learning Event; and be asked to blog about their skill and

knowledge development as ECRs in Global Mental Health. The 3 mentees will be provided a maximum of £1500 each for travel, accommodation, and subsistence.

An additional 6 UK ECR will be subsidised to attend the Praxis Learning Event (Leeds: March 2021). This opportunity will be advertised widely, with ECR selected on potential and passion to engage in Global Mental Health research. They will be offered development opportunities at the Learning Event, including securing their own mentor. The 6 winners will be provided a maximum of £200 each for travel, accommodation, and subsistence. A refreshment budget for the Praxis Learning Event for these Cluster-sponsored attendees has also been costed.

RISKS OF THE STUDY

C.17 What are the potential benefits and/ or risks for research participants in both the short and medium-term?³⁵

This research should not put participants at any significant risk in either the short or medium term. Participants are professionals in the area of global mental health who are being consulted in light of their expertise and academics wishing to learn about and contribute to initiatives in global mental health as part of their continuing professional development. Where partner organisation representatives travel to the UK to co-lead workshops, the necessary risk assessments and insurance requirements will be undertaken and the PI will be the main contact for overseas visitors while they are in the UK. The usual risk assessment and safety procedures will be put in place for all face-to-face workshops.

<u>Interviews</u>: Data collection and will potentially provide some indirect benefits for participants. These include the opportunity during interviews and workshops to reflect on professional knowledge, skills and practice, which could contribute to professional development.

<u>Workshops</u>: The workshops will pool expertise and contribute to developing the research, and will potentially provide some direct benefits to participants. The workshops present an opportunity to learn about research findings that may be directly useful to participants' own work, as well as that of their organisations. The workshops will also allow networking, and to learn from, and interact with other global mental health stakeholders.

In the medium-term, by participating in this research, participants will contribute to our understanding of how to support global mental health.

C.18 Does the research involve any risks to the researchers themselves, or people not directly involved in the research? ³⁶ *Eg lone working*³⁶

Yes 🔽 No

If yes, please describe: One-to-one interviews with mental health stakeholders in Assam, India.

Is a risk assessment necessary for this research?

~ Yes No

When events take place on campus under the direct auspices of this project, the usual event risk assessment forms will be completed at that time. If a University of Leeds risk assessment is required for overseas visitors attending project workshops these will be completed at that time. The PI will also check with visitors what assessments they require for their own organisation and request a copy for our records.

NB: If you are unsure whether a risk assessment is required visit <u>http://ris.leeds.ac.uk/HealthAndSafetyAdvice</u> or contact your Faculty Health and Safety Manager for advice.

RESEARCH DATA

C.19 Explain what measures will be put in place to protect personal data. E.g. anonymisation procedures, secure storage and coding of data. Any potential for re-identification should be made clear to participants

in advance.³⁷ Refer to <u>http://ris.leeds.ac.uk/ConfidentialityAnonymisation</u> and <u>http://ris.leeds.ac.uk/ResearchDataManagement</u> for guidance.

Demographic information will be held separately to anonymised study data and linked via unique identifiers stored in such a way that only members of the research team will be able to decode, if necessary, for audit and checking purposes. Research data will be anonymised by the PI and project administrator. That is, transcripts, field notes and other data will have direct and indirect identifiers (age, community, family, etc.) and any other sensitive material removed prior to storage. The only exception to this is in relation to the scoping review as this information (i.e., roles, institutions and work contact details of author/research teams) is in the public domain.

Description of project data

Data will be collected from interviews and knowledge exchange events (i.e., workshops). Data types include (i) interview data; (ii) field notes and audio recordings of knowledge exchange events; and (iii) evaluation / feedback data. We will use file format suitable for sharing and long-term validity. Audio recordings of interviews (~n=20) and knowledge exchange events (~n=8) will be stored as Waveform Audio Format files or Free LossLess Audio Codec. Transcription will be in MS Word files. Field notes and evaluation / feedback data will be in MS Word and Excel files. We adhere to UK Data Service ESRC guidance on file formats.

Quality Assurance

The project administrator will: check the accuracy of transcription against audio; ensure anonymization and obscuring, cross-checked by the PI.

C.20 How will you make your research data available to others in line with: the University's, funding bodies' and publishers' policies on making the results of publically funded research publically available. Explain the extent to which anonymity will be maintained. (max 200 words) Refer to http://ris.leeds.ac.uk/ConfidentialityAnonymisation and http://ris.leeds.ac.uk/ResearchDataManagement for

http://ris.leeds.ac.uk/ConfidentialityAnonymisation and http://ris.leeds.ac.uk/ResearchDataManagement for guidance.

Most of the data will be suitable for sharing given our consent procedures and data anonymization procedures. Our planned consenting procedure will explain to participants that they will have the option to exclude their anonymised data entering the public domain, i.e. in published reports, or on ReShare. ReShare is the UK Data Service's online data repository, where researchers can archive, publish and share research data, as open or safeguarded data. ReShare is where ESRC grant holders (this research has received funding from UKRI as part of the Global Challenges Research Fund) submit the data from their research grants. We will not share the interview data without participant consent and / or where we believe anonymisation does not fully protect the individual or poses a risk to others.

Non-sensitive information such as the field notes and scoping review will be open-data. The PI will publish our data sharing policy on our project website, along with the location of the data in ReShare at project end. This location will also be reported in publications arising from the project. The PI will ensure accurate project reporting on RCUK Gateway to Research.

C.21 Will the research involve any of the following activities at any stage (including identification of potential research participants)? (Tick as appropriate)

Examination of personal records by those who would not normally have access

Access to research data on individuals by people from outside the research team

- Electronic surveys, please specify survey tool: ______
- Other electronic transfer of data

Use of personal addresses, postcodes, faxes, e-mails or telephone numbers USE OF EMAIL TO CONTACT POTENTIAL PARTICIPANTS AND THEIR PHONE NUMBER WITH THEIR CONSENT TO CONDUCT INTERVIEW IF THIS IS THEIR CHOICE

Use of audio/ visual recording devices (NB this should usually be mentioned in the information for participants)	
FLASH memory or other portable storage devices	
Storage of personal data on, or including, any of the following:	
University approved cloud computing services (<u>Microsoft Office 365 for email</u> (Exchange online) and <u>Microsoft OneDrive for Business</u>) ONEDRIVE TO STORE PROJECT INFORMATION	
Other cloud computing services	
Manual files	
Private company computers	
Laptop computers ENCRYPTED BY UoL	
Home or other personal computers (not recommended; data should be stored on a University of Leeds server such as your M: or N: drive where it is secure and backed up regularly: http://ris.leeds.ac.uk/ResearchDataManagement .)	
Unclassified and Confidential University data must be kept on the University servers or in approved cloud services such as Office 365 (SharePoint or OneDrive). The N: Drive or Office 365 should be used for the storage of data that needs to be shared. If Highly Confidential information is kept in these shared storage areas it must be encrypted. Highly Confidential data that is not to be shared should be kept on the M: Drive. The use of non-University approved cloud services for the storage of any University data, including that which is unclassified, is forbidden without formal approval from IT. Further guidance is available via http://ris.leeds.ac.uk/ResearchDataManagement .	
C.22 How do you intend to share the research data? (Indicate with an 'X) Refer to	
http://library.leeds.ac.uk/research-data-deposit for guidance.	
Exporting data outside the European Union	
Sharing data with other organisations THOSE OF Cols – ALL UK	
Publication of direct quotations from respondents ANONYMISED	
Publication of data that might allow identification of individuals to be identified	
Submitting to a journal to support a publication	
Depositing in a self-archiving system or an institutional repository	
Dissemination via a project or institutional website	
Informal poor to poor evolution	
Informal peer-to-peer exchange	
 Informal peer-to-peer exchange Depositing in a specialist data centre or archive 	
 Depositing in a specialist data centre or archive 	
 Depositing in a specialist data centre or archive Other, please state: No plans to report or disseminate the data The full data management plan for this project, and our plans to share the data, is given in the 	
 Depositing in a specialist data centre or archive Other, please state: No plans to report or disseminate the data 	

Data archiving and sharing

We will store project data on UoL OneDrive and UoL servers for 10 yrs or up to 5 years post final publication, whichever is longer. We have planned data sharing from outset of project planning.

Permission for sharing

Most of the data will be suitable for sharing given our consent procedures, our data anonymization procedures and the detail of our contextual and metadata. Ethical approval will involve rigorous review of our data collection, handling, informed consent, and sharing protocols. Our planned consenting procedure will explain to participants that they will have the **option to exclude** their anonymised data (transcripts) entering the public domain, i.e. on our website, on ReShare or in published reports. They will be able to opt in or out of each of these distinct options. Participants will be asked to make a final decision on data sharing at interview end (considering their disclosures). We will record written consent for this, or audio consent where written consent is feared or impossible. We will not share the interview data without participant consent and / or where we believe anonymisation does not fully protect the individual or poses a risk to others.

Timelines and accessibility

We will deposit the data for archiving and re-use with UK Data Service ReShare and within three months of the end of the award, with a 12 month embargo for public access to permit the research team to publish. Prior to archiving, the data files will be converted to suitable open formats for long term preservation as described above. Non-sensitive information such as the field notes and policy mapping database will be **open-data**. It is likely that the interview transcripts will also be open-data but we will review with our Steering Group and the UK Data Service whether a **safeguarded** position is more suitable once the full extent of the data is known, and its accordance with the ICO's Code of Practice on Anonymisation. If a safeguarded option to adopted, we will establish a data sharing agreement for sensitive elements of the data (aligned with our approved ethics protocol and participant consent). We will publish our data sharing policy on our project website, along with the location of the data in ReShare at project end. This location will also be reported in publications arising from the project. We will ensure accurate project reporting on RCUK Gateway to Research. We will test the discoverability of the data to ensure effective metadata.

C.23 How do you intend to report and disseminate the results of the study? (Indicate with an 'X) Refer to <u>http://ris.leeds.ac.uk/ResearchDissemination</u> and <u>http://ris.leeds.ac.uk/Publication</u> for guidance.

- Conference presentation
- Peer reviewed journals
- Publication as an eThesis in the Institutional repository
- Publication on website
- Other publication or report, please state:
- Submission to regulatory authorities
- Other, please state:

 \Box

No plans to report or disseminate the results

C.24 For how long will data from the study be stored? Please explain why this length of time has been chosen.³⁸ Refer to the <u>RCUK Common Principles on Data Policy</u> and http://ris.leeds.ac.uk/info/71/good research practice/106/research data guidance/5.
 Students: It would be reasonable to retain data for at least 2 years after publication or three years after the end of data collection, whichever is longer.

Anonymised data will be stored by the University of Leeds for up to 5 years after the last publication from the study and will be used for this study only. This is the standard timeframe required by publishers. However, materials disseminated via our project website, and social media may be there for an infinite period of time.

CONFLICTS OF INTEREST

C.25 Will any of the researchers or their institutions receive any other benefits or incentives for taking part in this research over and above normal salary or the costs of undertaking the research?³⁹

□ Yes ^{II} No

If yes, indicate how much and on what basis this has been decided

C.26 Is there scope for any other conflict of interest?⁴⁰ For example, could the research findings affect the any ongoing relationship between any of the individuals or organisations involved and the researcher(s)? Will the research funder have control of publication of research findings? Refer to <u>http://ris.leeds.ac.uk/ConflictsOfInterest</u>.

Yes No

If so, please describe this potential conflict of interest, and outline what measures will be taken to address any ethical issues that might arise from the research.

Any partnership between organisations has the potential for conflict of interests. Hence, a Collaboration Agreement is being organised between the UoL Col HEIs and our partner organisations.

C.27 Does the research involve external funding? (Tick as appropriate)

🗹 Yes 🗖

If yes, what is the source of this funding? UKRI Global Challenges Research Fund.

NB: If this research will be financially supported by the US Department of Health and Human Services or any of its divisions, agencies or programmes please ensure the additional funder requirements are complied with. Further guidance is available at <u>http://ris.leeds.ac.uk/FWAcompliance</u> and you may also contact your <u>FRIO</u> for advice.

PART D: Declarations

Declaration by Principal Investigators

No

- 1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.
- 2. I undertake to abide by the University's ethical and health & safety guidelines, and the ethical principles underlying good practice guidelines appropriate to my discipline.
- 3. If the research is approved I undertake to adhere to the study protocol, the terms of this application and any conditions set out by the Research Ethics Committee (REC).
- 4. I undertake to seek an ethical opinion from the REC before implementing substantial amendments to the protocol.
- 5. I undertake to submit progress reports if required.
- 6. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the University's Data Protection Controller (further information available via http://ris.leeds.ac.uk/ResearchDataManagement).
- 7. I understand that research records/ data may be subject to inspection for audit purposes if required in future.
- 8. I understand that personal data about me as a researcher in this application will be held by the relevant RECs and that this will be managed according to the principles established in the Data Protection Act.
- 9. I understand that the REC may choose to audit this project at any point after approval.

Sharing information for training purposes: Optional – please tick as appropriate:

- I would be content for members of other Research Ethics Committees to have access to the information in the application in confidence for training purposes. All personal identifiers and references to
 - researchers, funders and research units would be removed.

Principal Investigator:

Signature of Principal Investigator:

(This needs to be an actual signature rather		
Print name:Anna Madill	Date:	(dd/mm/yyyy):210520

APPENDIX: INTERVIEW PARTICIPANT INFORMATION SHEET

Participant Information Sheet (Version 1) Mainstreaming Global Mental Health: A Praxis Nexus Approach

Principal Investigator: Professor Anna Madill, University of Leeds UK (a.l.madill@leeds.ac.uk)

Partner Organisations: MIND India (http://www.mindindia.org/), National Institute of Mental Health & Neurosciences, India (http://nimhans.ac.in/), and Center for Public Mental Health, University of Gadjah Mada, Indonesia (https://iup.psikologi.ugm.ac.id/center-for-puclic-mental-health/).

The study is funded by **UKRI GCRF** (EP/TO23813/1) and is led by the University of Leeds with the University of Bradford, De Montfort University and Middlesex University UK.

Ethical approval: Ethics Committee of the School of Psychology, University of Leeds, PSYC-26 21.04.20.

We are inviting a wide range of international development stakeholders to take part in a research study. To allow you to decide if you might like to participate, this information sheet explains why the research is being done and what it involves.

What is the aim of the study? Our long-term strategic aim is to accelerate global action on mental health by producing a Global Mental Health Impact Framework with potential for use in all research in developing countries. This first stage project will establish a foundation and pathway towards this aim by creating a beta version of the Impact Framework, based on arts and humanities methodologies first, ready for future testing and development across a broad range of UK Research & Innovation Global Challenges Research Fund projects.

What does the study involve?

This study has three parts. This sheet provides information about participating in part two, i.e., an interview: (1) a scoping review of material practices and mental health activities in non-mental health focused GCRF projects funded to date; (2) one-to-one interviews of approximately one hour with about 20 international development stakeholders; and, (3) a variety of consultation and knowledge exchange workshops.

Do I have to take part?

Taking part is entirely voluntary. If you decide to take part, you will be asked to confirm verbally at the beginning of the audio-recording conditions of consent that will be provided to you beforehand to make sure that you are happy to take part and understand the implications. Even if you agree to participate, you can change your mind at any time and without having to give a reason. You can also remove your data – which will be anonymised - from the study by e-mailing the PI (a.l.madill@leeds.ac.uk). However, we ask that, if you wish to do this, you do so within one week of participation. Please be aware that it may be impossible to withdraw your contribution once reports are accepted for publication or are in the public domain.

Where will the research take place?

One-to-one interviews will take place over the telephone or online (e.g., Skype/e-mail) at a time convenient to you. Interviews will be conducted by the PI from a quiet and private room. Similarly, we recommend that you find a quiet and private room in which to undertake the interview in order to ensure confidentiality.

What will I be asked to do?

You will be asked to complete a short demographics questionnaire a few days before the interview. The questionnaire should not take longer than about 5 minutes to complete. Your demographical information will allow the interviewer to make the most effective use of your time by steering her questions towards your experience and the contexts in which you work. Demographic information will be held separately to anonymised study data and linked via unique identifiers stored in such a way that only members of the research team will be able to decode, if necessary, for audit and checking purposes. If you choose to take part in an real-time interview, it will last approximately one hour. You will be able to reply to questions via e-mail interview

questions at your convenience. You will be asked questions that will inform the development of a Global Mental Health Impact Framework with potential for use in all research in developing countries. The interview will be audio-recorded with your consent. You are not obliged to answer any question, or line of questioning, and can stop the interview at any time without having to give a reason.

Are there any benefits to taking part?

Although we cannot promise any direct benefits to you, taking part in the interview may provide an opportunity to reflect further on your knowledge, skills and practice, and might be considered a contribution to continuing professional development.

Are there any risks to taking part?

This study poses little or no risk. To protect your identity, audio-recordings will be stored on a password protected University of Leeds secure drive and separately from your personal information, such as your name and e-mail address, in such a way that they cannot be matched-up by anyone outside the research team. Reports of the research will need to offer some information about participants, but individuals should not be recognisable. A professional company, who will adhere to a confidentiality agreement, will type-up the audio-recordings into transcripts. These transcripts, field notes and other data will be stored on a secure drive only in anonymised form. Anonymised data will be stored by the University of Leeds for up to 5 years after the last publication from the study and will be used for this study only. Our funder requires that we lodge our anonymised data in an open access repository to allow other researchers to benefit.

If I am interested in taking part in this study, what are the next steps?

Please e-mail the PI Anna Madill who will be happy to answer questions and, if you would you like to continue, organise the next step. If you have any complaints about being contacted or about what happens during the study, please e-mail the Chair of the University of Leeds, School of Psychology Ethics Committee Professor Graham Finlayson (g.s.finlayson@leeds.ac.uk) who will be happy to discuss what action to take.

Thank you for taking the time to read this information sheet



APPENDIX: INFORMATION ABOUT THE RESEARCH FOR WORKSHOPS

Following is a paragraph for inclusion in workshop information and invitations at least one week in advance of attendance which outlines the data recording aspects of the events for the present study:-

*Elements of/*This workshop is funded by the UK Research & Innovation Global Challenges Research Fund project **Mainstreaming Global Mental Health** (EP/TO23813/1). You will be invited to take part in discussions, activities and knowledge exchange associated with producing a Global Mental Health Impact Framework with potential for use in all research in developing countries. Intelligence from the workshop will be gathered unobtrusively by the PI and project administrator, with permission: e.g., audio-recordings, field notes, and activity-created products collected (such as bullet point presentations). You will be invited to complete a short demographics questionnaire and to sign a consent form, both of which will be provided at least 24 hours in advance. The consent form outlines that you can retract your data (or part therefore) from the study up to one week after the workshop. Ethical approval for the study has been obtained from the Ethics Committee of the School of Psychology, University of Leeds **PSYC-26 21.04.20**.

APPENDIX: CONSENT FORM – INTERVIEW

Consent Form: Interview (Version 1) Mainstreaming Global Mental Health: A Praxis Nexus Approach

Principal Investigator: Professor Anna Madill, University of Leeds UK (a.l.madill@leeds.ac.uk)

Partner Organisations: MIND India (http://www.mindindia.org/), National Institute of Mental Health & Neurosciences, India (http://nimhans.ac.in/), and Center for Public Mental Health, University of Gadjah Mada, Indonesia (https://iup.psikologi.ugm.ac.id/center-for-puclic-mental-health/).

The study is funded by **UKRI GCRF** (EP/TO23813/1) and is led by the University of Leeds with the University of Bradford, De Montfort University and Middlesex University UK.

Ethical approval: Ethics Committee of the School of Psychology, University of Leeds PSYC-26 21.04.20.

Audio consent will be taken before a real-time interview commences or in writing by e-mail. You will be asked if you agree to each of the following statements. Verbal answers will be audio-recorded. You will have received a copy of this consent form at least 24 hours before your interview.

- 1) I have read and understood the study information sheet (version 1).
- 2) I have had the opportunity to ask questions and have received satisfactory answers. I have received enough information to take an informed decision about taking part.
- 3) I understand that I can pause or stop the interview at any time, do not need to answer any particular question or line of questioning, and do not have to give a reason.
- 4) I give consent for a real-time interview to be audio-recorded.
- 5) I agree that the study team can store my demographic and contact details for use in this study only. I understand that my details will be kept confidential, stored safely and separately from my data, and will be used in reports of the research to contextualise findings only in anonymised form.
- 6) I know that I can retract my data (or part therefore) from the study and have up to one week after the interview to inform the PI. (Please contact Anna Madill at a.l.madill@leeds.ac.uk).
- 7) I agree that my data can be used in reports of the research on the understanding that my anonymity will be maintained.
- 8) I agree that my anonymised data can be stored by the University of Leeds for up to 5 years after the last publication from the study and will be used for this study only.
- 9) I agree that my anonymised data can be shared with other researchers via an official archive designed for this purpose, such as 'ReShare' (the UK Data Service's online data repository).
- 10) I agree to take part in the study.

Please keep a copy of this form for your own records.



APPENDIX: CONSENT FORM - WORKSHOP

Consent Form: Workshops (Version 1) Mainstreaming Global Mental Health: A Praxis Nexus Approach

Principal Investigator: Professor Anna Madill, University of Leeds UK (a.l.madill@leeds.ac.uk)

Partner Organisations: MIND India (http://www.mindindia.org/), National Institute of Mental Health & Neurosciences, India (http://nimhans.ac.in/), and Center for Public Mental Health, University of Gadjah Mada, Indonesia (https://iup.psikologi.ugm.ac.id/center-for-puclic-mental-health/).

The study is funded by UKRI GCRF (EP/TO23813/1) and is led by the University of Leeds with the University of Bradford, De Montfort University and Middlesex University UK.

Ethical approval: Ethics Committee of the School of Psychology, University of Leeds PSYC-26 21.04.20.

Written consent will be taken before the workshop commences. You will have received a copy of this consent form at least 24 hours before the workshop is scheduled.

Statement			Initial
1. I have read the study information	tion sheet (version	on 1).	
2. I have had the opportunity to	ask questions an	d have received satisfactory answers.	
I have received enough inform	nation to take an	informed decision about taking part.	
3. I understand that I can leave t	he workshop at a	any time, and I do not need to take	
part in any particular line of d	iscussion, and d	o not have to give a reason.	
4. I give consent for the worksho	op to be audio-re	ecorded and for the research team to	
take, and collect written notes	created during	the workshop, as appropriate.	
5. I agree that the study team can	n store my demo	graphic and contact details for use in	
this study only. I understand t	hat my details w	ill be kept confidential, stored safely	
and separately from my data,	and will be used	in reports of the research to	
contextualise findings only in	anonymised for	m.	
6. I understand that I know that	I can retract my	data (or part therefore) from the study	
and have up to one week after	the workshop to	o inform the PI. (Please contact Anna	
Madill at a.l.madill@leeds.ac	.uk).		
7. I agree that my data can be us	ed in reports of	the research on the understanding that	
my anonymity will be mainta	ined.		
8. I agree that my anonymised d	ata can be stored	l by the University of Leeds for up to	
5 years after the last publication	on from the stud	y and will be used for this study only.	
9. I agree that my anonymised d	ata can be share	d with other researchers via an	
official archive designed for t	his purpose, suc	h as 'ReShare' (the UK Data	
Service's online data repositor	ry).		
10. I agree to take part in this stud	ły.		
		use rules that state, "When a meeting,	
		ouse Rule, participants are free to use	
the information received, but			
		nay be revealed." All participants	
will be asked to follow this ru	le.		
Name of Participant	Date	Signature	

Please keep a copy of this form for your own records





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APPENDIX: DEMOGRAPHIC QUESTIONNAIRE

Demographic Questionnaire

Mainstreaming Global Mental Health: A Praxis Nexus Approach

Principal Investigator: Professor Anna Madill, University of Leeds UK (a.l.madill@leeds.ac.uk)

Partner Organisations: MIND India (http://www.mindindia.org/), National Institute of Mental Health & Neurosciences, India (http://nimhans.ac.in/), and Center for Public Mental Health, University of Gadjah Mada, Indonesia (https://iup.psikologi.ugm.ac.id/center-for-puclic-mental-health/).

The study is funded by **UKRI GCRF** (EP/TO23813/1) and is led by the University of Leeds with the University of Bradford, De Montfort University and Middlesex University UK.

Ethical approval: Ethics Committee of the School of Psychology, University of Leeds PSYC-26 21.04.20.

Thank you for taking an interest in participating in this study. I would be grateful if you would complete this short demographic questionnaire. Your answers will be stored safely and separately from your data, and will be used in reports of the research to contextualise findings only in anonymised form. This information will be stored until 5 years after the last publication from the study and will be used for this study only.

For which organisation do you currently work?
For how long have you worked for this organisation?
What is your current role within this organisation?
For how long have you been in your current role?
What previous roles have you had in this organisation?
How many years have you worked in a field relevant to international development/mental health?
Please describe your highest level of academic and/or professional qualification. (Please also state if you are currently working towards a qualification).
What is your gender?FemaleMaleOther
What is your age? 18-29yrs 30-39yrs 40-49yrs 50-59yrs 60-69yrs 70+yrs
Please describe your ethnicity.
Is there any other information you would like to tell us about you for the purposes of this study?
Are there any documents that you recommend as being relevant for this study and/or can you suggest anyone I should speak to?
www.projectres @UKProResilience @UKProjectResilience @ukprojectresilience

THE BIG PICTURE \mathbf{O}

APPENDIX: EMAILS TO POTENTIAL INTERVIEW PARTICIPANTS

<u>Initial Email</u>

Dear XXX,

I hope you are well. I am the Principle Investigator of a study funded by the UK Research & Innovation Global Challenges Research Fund titled **Mainstreaming Global Mental Health**.

I am e-mailing to invite you to participate in a research interview in relation to accelerating action on mental health by producing a Global Mental Health Impact Framework with potential for use in all research in developing countries. I anticipate that the interview will take place online (e.g., Skype/e-mail) and will take about one hour, although I can be flexible with timing in order to fit your busy schedule. Please see the attached information sheet for further details.

From your role as [for each participant insert a clause about how their experience would make their potential contribution to the study valuable], I understand that you are a key stakeholder. I am therefore keen to hear your views.

If you would be willing to participate, or have any questions before you make a decision, please let me know.

Thank you for considering my request.

Kind regards, Anna Madill

Reminder Email

Dear XXX,

I hope you are well. I am the Principle Investigator of a study funded by the UK Research & Innovation Global Challenges Research Fund titled **Mainstreaming Global Mental Health**.

I am just following-up my earlier invitation to participate in a research interview in relation to accelerating action on mental health by producing a Global Mental Health Impact Framework with potential for use in all research in developing countries. Please see the attached information sheet for further details.

From your role as [for each participant insert a clause about how their experience would make their potential contribution to the study valuable]. If you are interested in participating, the invitation is still open. If you would be willing to participate, or have any questions before you make a decision, please let me know. If I do not hear from you in response to this e-mail, I will understand that you do not wish to take part and will not contact you again.

Thank you again for considering my request.

Kind regards, Anna Madill

APPENDIX: DRAFT INTERVIEW SCHEDULE

Draft Interview Schedule Mainstreaming Global Mental Health: A Praxis Nexus Approach

Audio consent will be taken before the interview commences

Thank you for taking part in this interview. Do you have any questions about the study before we start?

Before we start the interview, I would like to audio-record your consent. I will read out the conditions of consent and ask you to confirm each. You have a copy of these to keep. I want to remind you, though, that you don't have to answer any of my questions and can leave at any point.

I am starting to audio-record now. TAKE CONSENT. Thank you. We will start the interview now.

	Ouestions
(~60 minutes)	1 Can you tall man hit shout your involvement in CODE
Background	1. Can you tell me a bit about your involvement in GCRF research/international development/development work?
Learn where past non- mental health projects	2. Did any of this work engage deliberately with issues related to mental health?
'brushed up' against mental	3. If so, can you tell me about this?
health	4. If not, thinking about this now, what opportunities might there have been to engage with issues related to mental health in this work?
Awareness of mental health policy and initiatives	5. What mental health related policies or initiatives are you aware of in your country?
	6. What mental health related policies or initiatives are you aware of globally?
	7. If aware, do you see an opportunity to engage with any of these mental health policies or initiatives in the work you do?
Explore acceptability of incorporating mental health impact into ODA-oriented work	 8. What do you see as the main challenges of incorporating mental health impact into the kind of work you do? 9. How might these challenges be overcome? 10. To what extent do you think there is an appetite to incorporate mental health impact into the kind of work you do?
Consult on the developing Framework	 11. The current research is interested in 'material practices' which we define as 'people working together with concrete things.' Does this concept resonate with you as an aspect of you work? 12. What is your immediate reaction to the idea that this aspect of your work could be developed to extend the mental health impact of what you do? 13. What support might you need to do this?
Concluding questions	14. Is there anything else on incorporating mental health impact into the kind of work you do that we have not yet covered?15. I would like to stay in touch with you about this work. Are
	you happy for me to send you updates by e-mail and to re- contact you in relation to developing this work?

APPENDIX: DRAFT WORKSHOP FEEDBACK SHEET

Draft Workshop Feedback Mainstreaming Global Mental Health: A Praxis Nexus Approach

What is your overall opinion of the workshop (elements relating to Mainstreaming Mental Health)?

1	2	3	4	5
poor	moderate	satisfactory	good	excellent

What did you like about the workshop (elements relating to Mainstreaming Mental Health)?

How might the workshop (elements relating to Mainstreaming Mental Health) be improved?

Can you suggest any person or organisation who might be interested in being contacted about Mainstreaming Mental Health (e.g., for a research interview, to explore capacity development, to join our network and ongoing research).

What is your gender?	Female	Mal	le	Other		
What is your age?	18-29yrs	30-39yrs	40-49yrs	50-59yrs	60-69yrs	70+yrs
Please describe your	ethnicity.					

Please crease and tear to keep study details below

Principal Investigator: Professor Anna Madill, University of Leeds UK (a.l.madill@leeds.ac.uk)

Partner Organisations: MIND India (http://www.mindindia.org/), National Institute of Mental Health & Neurosciences, India (http://nimhans.ac.in/), and Center for Public Mental Health, University of Gadjah Mada, Indonesia (https://iup.psikologi.ugm.ac.id/center-for-puclic-mental-health/).

The study is funded by **UKRI GCRF** (EP/TO23813/1) and is led by the University of Leeds with the University of Bradford, De Montfort University and Middlesex University UK.

Ethical approval: Ethics Committee of the School of Psychology, University of Leeds PSYC-26 21.04.20.









APPENDIX: TRANSCRIBER CONFIDENTIALITY AGREEMENT

Transcriber Confidentiality Agreement

Project title	Mainstreaming Global Mental Health
Funded by	UKRI Global Challenges Research Fund
Principal Investigator	Professor Anna Madill School of Psychology, University of Leeds, LS2 9JT <u>a.l.madill@leeds.ac.uk</u>

Transcriber statement

I understand that I will be hearing recordings of confidential interviews. The information on these recordings has been revealed by interviewees who agreed to participate in this research on the condition that their interviews would remain strictly confidential. I understand that I have a responsibility to honour this confidentially agreement.

I agree not to share any information on these recordings, about any party, with anyone except the PI of this project. Any violation of this and the terms detailed below would constitute a serious breach of ethical standards and I confirm that I will adhere to the agreement in full.

I, _____ (print name), agree to:

- transcribe the audio-recordings in an agreed format and to an agreed schedule;
- not to pass on, divulge or discuss the contents of the material provided to me for transcription to any third parties;
- ensure that material provided for transcription, and the transcripts are stored securely on password protected devices;
- return transcribed material to the research team in an agreed secure format;
- destroy any research materials regarding this project at the earliest time possible after transcripts have been transferred to the research team.

Transcriber

Signature:

Date:_____

APPENDIX: DATA MANAGEMENT PLAN

0. Proposal name

Mainstreaming Global Mental Health: A Praxis Nexus Approach

1. Description of the data

Type of study, Type of Data, Format and Scale of the Data.

Data will be collected from interviews and knowledge exchange events. Data types include (i) interview data; (ii) field notes and audio recordings of knowledge exchange events; and (iii) evaluation / feedback data. We will use file format suitable for sharing and long-term validity. Audio recordings of interviews (~n=20) and knowledge exchange events (~n=8) will be stored as Waveform Audio Format files or Free LossLess Audio Codec. Transcription will be in MS Word files. Field notes and evaluation / feedback data will be in MS Word files.

2. Data collection / generation

2.1 Methodologies for data collection / generation Data will be generated via interviews using social science community standards, and via knowledge exchange events using normative academic participatory activities.

2.2 Data quality and standards Interviews will be designed by PI Madill in consultation with the Research Team. Madill will also conduct the interviews. Interviews will be audio recorded with permission and transcribed using standard 'playscript' conventions. The PI will have ultimate responsibility for ensuring the quality of data collected from the knowledge exchange events. A combination of audio recordings and field notes by multiple attendees / team members will be used to ensure comprehensive data collection. These will be synthesised by the Project Administrator, with detailed reviews for completeness and accuracy by the PI and Research Team. Evaluation / feedback data will be carefully planned by the Research Team and will be collected at each key event.

3. Data management, documentation and curation

3.1 Managing, storing and curating data. We anticipate all data being low sensitivity and therefore plan to store data on the approved University of Leeds (UoL) OneDrive. Should the need arise, sensitive data can be shared through OneDrive using encryption. Only the UoL Investigators will have authorised access, with access granted on a file-by-file basis to external Cols and partners as needed. Interview data will be deleted from recording device once uploaded to OneDrive. We anticipate the interview data being linked and identifiable since we will need to link data to specific, named GCRF projects with named Pls. For all data storage, we will use a consistent system of file naming and an organised folder structure. The Research Team will establish a protocol for version control and edit histories, and the PI will have responsibility for master file protection and master file destruction at the designated time. The PI will allocate edit or read-only permissions. We will not store data overseas and data will not be sent overseas via email.

3.2 Metadata standards and data documentation. Interview data, knowledge exchange data and evaluation data will be accompanied by contextual descriptions and metadata, meeting UK Data Service standards and FAIR principles, operationalised in a protocol established by Col Hugh-Jones early in the project. PI Madill will have full oversight. For qualitative data, we will follow standardised protocols and report relevant context to support appropriate interpretation and re-use of data. Contextual descriptions and metadata will include: project aims, objectives, investigators and funders; work strands; structure of data files; descriptions of data provenance; methods used for data generation (including recruitment processes, ethical safeguards, interview schedules, workshop structures, KE events etc.); and data preparation procedures (including transcription, checking, anonymising, obscuring and/or cleaning). PI Madill will document publications, presentations and other research outputs that explain or draw on the data.

3.3 Data preservation strategy and standards The PI will store project evaluation data for 3 years and the remainder of data on UoL OneDrive for 10 years.

4. Data security and confidentiality of potentially disclosive information

4.1 Formal information/data security standards Although we do not anticipate any sensitive data arising (as defined by the Data Protection Act), data will be protected by encryption software to FIPS 140-2 standard and stored in the University of Leeds Storage Area Network, accessed by authorised members of the project with the appropriate encryption software installed on their desktop PCs. Highly sensitive data is not available from off-campus.

4.2 Main risks to data security There are no risks relating to the confidentiality of the majority of project data since it will originate from public events. UoL OneDrive provides a secure system for data access and storage controllable on a case-by-case basis. There is a very low risk that an authorised person could access the interview data via erroneous sharing. To safeguard this, file access is controlled solely by the PI.

5. Data sharing and access

5.1 Suitability for sharing. Most of the data will be suitable for sharing given its public origin (via workshops) and for interview data, because of our consent and anonymization procedures and our contextual and metadata. Ethical approval will involve review of our data collection, handling, informed consent, and sharing protocols. Our consenting procedure will explain to interview participants our intention to share the data in an appropriate format.

5.2 Discovery by potential users of the research/innovation data Our data sharing policy will be published on our Cluster-associated websites, alongside Project updates. We will make the data available via ReShare, and its location there will be reported in publications arising from the project. The PI will ensure accurate project reporting on RCUK Gateway to Research. The Research Team will test the discoverability of the data to ensure effective metadata. Data from the project will also be offered to the University of Leeds Research Data Repository (Research Data Leeds). Research Data Leeds holds deposited data for a minimum of 10 years and datasets are associated with digital object identifiers.

5.3 Governance of access PI Madill will have responsibility for ensuring the data is correctly deposited on ReShare.

5.4 The study team's exclusive use of the data PI Madill will deposit the data for archiving and re-use with ReShare and within 3 months of project end, with a 12 month embargo for public access to permit the Research Team to publish and to plan their second stage application.

5.5 Restrictions or delays to sharing, with planned actions to limit such restrictions

As above, there are no anticipated restrictions beyond a 12 month embargo.

5.6 Regulation of responsibilities of users We will require any parties external to the University of Leeds to complete a data sharing agreement, based on the standard University template. PI Madill will ensure this has been signed before access to data is granted.

6. Responsibilities

Study-wide data management will be the responsibility of the Research Team, supported by UoL Research Data Leeds Service. Metadata will be created PI Madill and Col Hugh-Jones. Data quality assurance will be managed by PI Madill and the Project Administrator, with ultimate responsibility held by the PI. The Project Administrator will review the DMP once during the life of the project.

7. Relevant institutional, departmental or study policies on data sharing and data security

Policy	URL or Reference
Data Management Policy & Procedures	https://library.leeds.ac.uk/info/14062/research_data_management/6 8/research_data_management_policy

Data Security Policy	https://leeds.service- now.com/it?id=kb_article&sys_id=6038bfbc0fae728089d7f55be105 0e9d		
Data Sharing Policy	https://library.leeds.ac.uk/info/14062/research_data_management/6 8/research_data_management_policy		
Institutional Information As above			
8. Author of this Data Management Plan (Name) and, if different to that of the Principal Investigator, their telephone & email contact details			
Dr Siobhan Hugh-Jones; <u>s.hugh-jones@leeds.ac.uk;</u> 0113 343 5744			

UREC Ethics form version 37 (updated 13/03/19)