UNIVERSITY OF LEEDS RESEARCH ETHICS COMMITTEE APPLICATION FORM [1]

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 (eg[8]) 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:	
Student number and/ or grant reference:	

PART A: Summary

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

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

A.2 Title of the research[3]

The 'Big Picture', India: Adapting visual methods to enhance local approaches to understanding youth substance abuse in India

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

A.4 Purpose of the research:[5] (Tick as appropriate)

- [x] Research
- [ ] Educational qualification: ***Please specify:*** _____
- [ ] Educational Research & Evaluation[6]
- [ ] Medical Audit or Health Service Evaluation[7]
- [ ] Other

A.5 Select from the list below to describe your research: (You may select more than one)

- [x] Research on or with human participants
- [ ] Research which has potential adverse environmental impact.[8] ***If yes, please give details:***

  _____
- [ ] Research working with data of human participants
  - [x] 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 (*Please inform the relevant Persons Designate if the research will involve human tissue)*[9]

A.6 Will the research involve NHS staff recruited as potential research participants (by virtue of their professional role) or NHS premises/ facilities?

- [ ] Yes
- [x] No

If yes, ethical approval must be sought from the University of Leeds. Note that approval from the NHS Health Research Authority may also be needed, please contact FMHUniEthics@leeds.ac.uk 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 research rather than service evaluation or audit and involves any of the following an application must be made to the NHS Health Research Authority via IRAS www.myresearchproject.org.uk as NHS ethics approval will be required. ***There is no need to complete any more of this form****. Further information is available at http://ris.leeds.ac.uk/NHSethicalreview and at http://ris.leeds.ac.uk/HRAapproval. You may also contact* ***governance-ethics@leeds.ac.uk*** *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]
- [ ] Use of human tissue (including non-NHS sources) where the collection is not covered by a Human Tissue Authority licence[9]

☐ Foetal material and IVF involving NHS patients

☐ 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 http://www.hra-decisiontools.org.uk/ethics. 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 participants be from any of the following groups? (Tick as appropriate)

✓ Children under 16[16] ***Specify age group:*** 15-18 years

☐ Adults with learning disabilities[12]

☐ Adults with other forms of mental incapacity or mental illness

☐ Adults in emergency situations

☐ Prisoners or young offenders[14]

☐ Those who could be considered to have a particularly dependent relationship with the investigator, eg members of staff, students[17]

☑ 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.

(1) Young people 15-18 years not currently, but at risk of, engaging in substance abuse: the research seeks to understand the experience of this demographic and, in particular, their resilience to engaging in risky behaviour (i.e. substance abuse).
(2) Young adults 19-24 years who are in successful recovery from substance abuse: the research seeks to understand the journey to recovery of this demographic.

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 http://www.homeoffice.gov.uk/agencies-public-bodies/dbs and http://store.leeds.ac.uk/browse/extra_info.asp?modid=1&prodid=2162&deptid=34&compid=1&prodvarid=0&catid=243.

A.9 Give a short summary of the research[18]

*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.*

This is a study to be conducted in Assam, India. The Research Fellow – Dr Raginie Duara - is former PhD student of Anna Madill and Siobhan Hugh-Jones, and they will supervise the RF. The project will be conducted in partnership with MIND India (http://www.mindindia.org/ President Dr Sangeeta Goswami) and NIRMAAN (http://nirmaanrehab.org Service provider Sri Ratul Dey). MIND India, Institute of Positive Mental Health & Research, is a registered society in Assam, India dedicated to ushering in the benefits of positive mental health & wellbeing to the general population. NIRMAAN is a rehabilitation centre that aims to treat individuals suffering from drug addiction and alcoholism. All appropriate contracts and agreements between these organisations and the University of Leeds are established as part of project management.

The aim of the research is to explore how to adapt visual methods to enhance local approaches to understanding youth substance abuse in India, and via these, to enhance our understanding of substance abuse risk and recovery.

This application seeks approval for two related strands of work.

Strand 1 Two demographic groups are of interest: **(a)** Young people 15-18 years not currently abusing substance but self-report as being at risk of doing so: the research seeks to understand the experience of this demographic and, in particular, their resilience to substance abuse; **(b)** Young adults 19-24 years who are in successful recovered from substance abuse, defined as having abstained from use for one year or more.

MIND India and NIRMAAN will provide access to relevant participants and help us recruit. We will also seek to recruit participants from other youth-focused organisations in Assam as appropriate as the project progresses and we may utilise snowballing. We aim to recruit around 15 participants from each group. Dr Duara, who currently lives in Assam, will communicate with potential participants (telephone, e-mail, face-to-face as appropriate), to explain the process of data collection which involves participants taking or collecting photographs and / or images which capture their experiences of resilience and/or recovery (this method Photovoice, is the visual method being adapted in this study). Participants can be given a disposable camera if they do not have a smartphone or other camera type. The RF will interview participants with a focus on the images they have brought. Interviews will be audio-recorded with consent. Audio-recordings will be analysed using qualitative methods. Dr Duara undertook this methodology in her PhD and is competent in this form of data collection.

Participants will be invited to contribute their fully anonymised interview data and images to the project website as an illustration of visual methods research. We will be developing an e-mental health **website** (projectresilience.co.uk) to facilitate our aim of raising awareness and understanding of the ways young people manage risks around substance abuse in order to stay well. It will also serve as a platform to provide culturally sensitive guidance on how to deliver, analyse and evaluate Photovoice mental health projects, through to flexible ways that outputs can inform service development.

Strand 2 will invite strand 1 participants to take part in a choice of two further activities:

i. **Poster production:** each participant will be invited to create a poster with the RF based on the images (anonymised) and spoken content (i.e., anonymised quotes) from the Photovoice interviews. We plan to produce about 20 posters to be exhibited to draw attention to the issues around substance abuse, promote further discussion, and celebrate the achievement and resilience of participants. Planned exhibition spaces include the project website, impact events and social media.

ii. **Film-making:** we will conduct a film-making activity whereby approximately 6 short films will be produced that will involve about 3 groups of 4 resilient-to-risk participants and 3 groups of 4 resilient-to-recovery participants. Participants will be fully supported and given authorship over the film-making process. Project CoI Professor Paul Cooke from the University of Leeds is highly experienced managing this activity with young people in developing countries and will train and supervise the RF and provide hands-on support during a planned visit to Assam. Participants can contribute to film-making without being in the film. The aim of this aspect is knowledge exchange and stigma reduction. Films will be displayed on the project website, at impact event and social media. If we do not recruit enough participants for film-making from Strand 1, we will recruit additional participants through our partner organisations, similarly supportive institutions and / or snowballing.

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.

We have aligned our application with the ethical guidelines of the Indian Council of Medical Research (2017) and the British Psychological Society. Following advice, we are first applying for ethical approval to the Institute Ethics Committee (IEC) of the Assam Regional Institute of Mental Health, and upon approval there, to the School of Psychology University of Leeds (Faculty of Medicine and Health) Research Ethics Committee.

Participant Consent and Safety: Participants are welcome to bring a chaperone to any project activity. Their travel expenses, and those of the chaperone, will be covered. Our study will adhere to standard ethical practices for interviewing (i.e., informed consent, right to not answer any particular question, right to withdraw, anonymity, safe and secure data storage). We will ensure study information is tailored to low levels of literacy.
We will ask participants to recite their understanding of the study, the way their data will be used and what would happen if they disclosed the following as occurring anytime from their consent into the study to the point when their participation in the study ends: being the victim or perpetrator of harm and / or serious criminal activity. This includes physical, sexual and or psychological harm, stealing/robbery, kidnapping, selling illicit drugs and homicide. These have been decided upon in consultation with our partner organisations and follow legal requirements in Assam. We have a detailed risk protocol (Appendix A) and general information on how to access psychological support at any point post-study will be provided to participants in the study information letter (Appendix B). At the end of the Photovoice interview, participants will be asked to confirm their ongoing consent for their data to be retained for this study (Appendix C, Part B). This will give them the chance to give true informed consent (i.e., based on knowing what they disclosed in the interview). Consents will be taken verbally and audio recorded for added anonymity. If they have concerns about sharing the data in the way intended, we will work with participants to ensure they are happy with intended data use (e.g. removing sections or images). Participants can take up to one week to make decisions about data use post-interview. We believe Photovoice and our various consenting options give participants high levels of control in this study. With permission, Dr Duara will maintain participant names and contact details for the duration of the project in order to contact them in relation to making their poster, film-making workshops, and relevant events. These details will be stored on a password protected computer separately from research data, in a way that makes it impossible to match participant details to their data. These will be deleted once the person's participation in the study ends.

We wish to request that the IEC of the Assam Regional Institute of Mental Health waive the need to gain consent from guardians or parent(s) for under 18s to take part in this study.
This is because **Strands 1 and 2** will be conducted with robust safety and security measures, and because young people may feel more able to take part if they could do so of their own volition, and without the need for parental consent. Experiences of risk and recovery around substance abuse in young people are likely to be very private and potentially stigmatised. Having to gain parental consent would risk marginalising some young people's voices from this study. We are confident that we have vigorous safety procedures in place to protect young people from harm, and to respond to risks that might be identified during the course of the study.

Anonymity: All participant data will be anonymised, including interview transcripts and posters. The use of images in this study will be ethical. Since the participants will be asked to collect images relevant to their experiences, they will be provided with guidance related to dos and don'ts associated with this activity. For example, participants will be asked to take verbal consent from people in the photos that they bring; they will be asked not to bring photos of under 19s since consent cannot be appropriately obtained (i.e., in Assam, 18 year olds and under are legally children); and they will be informed of the limits to confidentiality (e.g. if harm or risk is suggested in an image). Participants will be advised not to bring sensitive or incriminating images to the interview but instead to think of other non-sensitive images that could convey the important issues; examples will be given. This will all be conveyed in a guidance sheet provided to participants (Appendix D), and we will check their understanding of this. Photovoice has been described as therapeutic and empowering by some young people, and exhibitions/impact events and film-making can give participants a chance to use their experiences for positive action.

Photovoice interview and image data will be anonymised and stored safely, and separately from personal information (e.g. email addresses). Post-interview, and with consent to continue to use their data for the study (Appendix C, Part B) we will offer participants various ways to share their interview data, or be involved in, Strand 2 (Appendices G, K and L). They will be invited to give consent for:

- parts of their fully anonymised *interview data* to inform poster-making, film-making and / or project website case studies, with alteration of key details of their story (or extracts from it) to ensure no participant, other person and/or institution, for example, would be identifiable.
- each *image* to be used in **Strand 2.** On a case by case basis, we will discuss with participants the level of obscuring needed to ensure that they (or anyone who has given consent to be in the image), or an organisation / institution would not be identifiable. Pixilation and /or cropping will be used with discretion by the RF to conceal identifying features in images that are made public (with participant permission) in research outputs, project website, social media or impact events. Some images will simply be unsuitable for sharing in the public domain. Symbolic images are likely to be the safest to progress to the public domain.

Participants will be encouraged to take their time to think about consenting to the sharing of their data in the public domain, and they will be reminded of their right to withdraw their data from each strand separately. This is conveyed in our study information letter (Appendix B).

Confidentiality: participants' personal details (e.g. email, mobile number), where necessary to record, will be stored safely and separately from research data. These will be deleted once the person's participation in the study ends.

Physical Safety: Participants are welcome to bring a chaperone to any project activity. Their travel expenses, and those of the chaperone, will be covered. We have carefully considered the physical safety of both participants and researchers whilst undertaking all strands. This is detailed in the appended approved risk assessment (Appendix N).

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 Siobhan Hugh-Jones
Position	Associate Professor
Department/ School/ Institute	Psychology
Faculty	Medicine and Health
Work address *(including postcode)*	School of Psychology
Telephone number	X35744
Email address	S.Hugh-Jones@leeds.ac.uk

Name (Title, first name, surname)	Dr Raginie Duara
Position	Research Fellow
Department/ School/ Institute	School of Psychology
Faculty	Medicine and Health
Work address (including postcode)	Assam, India
Telephone number	/
Email address	r.duara@leeds.ac.uk
Name (Title, first name, surname)	Professor Paul Cooke
Position	Centenary Chair of World Cinemas, University of Leeds
Department/ School/ Institute	Centre for World Cinemas and Digital Cultures
Faculty	Faculty of Arts, Humanities and Cultures
Work address (including postcode)	University of Leeds, Leeds, LS2 9JT
Telephone number	0113-34-30210
Email address	P.Cooke@leeds.ac.uk
Name (Title, first name, surname)	Dr Rebecca Graber
Position	Senior Lecturer
Department/ School/ Institute	School of Applied Social Science
Faculty	University of Brighton

Work address (including postcode)	University of Brighton
Telephone number	/
Email address	R.Graber@brighton.ac.uk

Part C: The research

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

The aims of the study are

Strand 1: to understand:

(1) the experience of young Indian people 15-18 years showing resilience to the risk of substance abuse; and

(2) the journey to recovery of young Indian adults 19-24 years who are in successful recovery from substance abuse.

Strand 2: To promote young Assamese people's voice with respect to substance use in order to reduce stigma, raise public awareness and inform mental- and public-health policy and practice, by:

(1) collaborating with participants to design **posters** based on their images brought to the Photovoice interviews and exhibiting them (with anonymised interview quotes) in workshops, during impact events, on our project website, and via social media.

(2) creating short resilience-focused **films** in collaboration with participants and exhibiting them during impact events, on our project website, and via social media.

(3) developing a **website** providing guidance in Photovoice methods for research and intervention, to showcase visual methods projects (case studies) and to promote the impact of our research (projectresilence.co.uk).

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 an interview study with follow up participatory arts components.

Strand 1 About 15 relevant people in two groups, aged 15-18 years and aged 19-24 years will be recruited for a Photovoice interview.

Strands 2 Strand 1 participants will be invited to take part in poster-making and / or film-making. If we do not have sufficient numbers opting in to this, our Partner Organisation (and other similar organisations) will help us to recruit new participants to be involved in poster marking and / or film-making (separate recruitment materials appended- Appendix K and L). We may also use snowballing based on Strand 1 participants. In total, we hope to involve approximate 20 young people in poster making and 24 in film-making.

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

Strand 1 Having shown interest and having received information about the study, potential participants will be invited to discuss the study with the researcher by e-mail, over the phone, or face to face in a private room at the premises of MIND India (or other relevant organisation as appropriate). If the potential participant meets the study inclusion criteria and agrees to continue, he/she will be invited to collect photos on their own mobile phone (or disposable cameras provided) and /or other images as appropriate (e.g., existing photos, pictures from magazines or from the internet) relevant to the aims of the study to bring to interview approximately 10 days later. The interview will take place in a private room at the premises of MIND India, NIRMAAN or other participating organisations, be audio-recorded with consent, and will last for about 60-90 minutes. Participants will be asked to describe the images they have brought, with the researcher following up lines of enquiry to better understand the participant's experience.

Strands 2 Strand 1 participants will be invited to collaborate with the RF to develop a poster (Appendix G) and/or to work with the study team in film-making workshops (Appendix K and L). Both posters and the film-making will draw

upon images and narrative from the Photovoice interview. Participants recruited to film-making who did not take part in A Photovoice interview can still contribute via workshops.

For **poster-making**, participants can choose to: (i) work with the RF to create a poster (this could be managed through emails or in face-to-face meetings as described above); (ii) give consent for the RF to use their images (from the photo-led interviews) and some quotes to make a poster, but without wishing to be involved in making a poster themselves; or (iii) fully decline to make a poster (in which case their data will not be used for the posters).

Every Strand 1 participant will be invited to take part in **film-making**, generated through workshops held on the premises of MIND India, and led by the RF under the training and supervision of Professor Cooke. Participants will be given the option of being identifiable or non-identifiable in film-making, although we anticipate mostly the latter. g. Participants can contribute to film-making without being in the film. Once the films are completed, anyone who is in the film will be asked to sign a **release form** (Appendix M) to ensure they are happy for the film to proceed to public dissemination. If a participant objects, we will work with them to modify the film. However, we hope that by working closely with participants to generate these films, participants will have felt able to produce a film that they are happy to be made public.

Posters and films will be exhibited at impact events, the project website and on social media.

C.4 Does the research involve an international collaborator or research conducted overseas:[24]
(Tick as appropriate)

☑ Yes ☐ No

If yes, describe any ethical review procedures that you will need to comply with in that country:

Ethics application is to be written and submitted to the University of Leeds, Faculty of Medicine and Health (School of Psychology) Research Ethics Committee in UK and to the Regional Institute of Mental Health Ethics Committee in Assam, India.

Describe the measures you have taken to comply with these:

This ethics application has been written in collaboration with Dr Goswami, president of MIND India and in consultation with Ratul Dey of Nirmaan Rehabilitation Facility.

Study progression will be reliant on ethical approval from both of the above named institutions.

Include copies of any ethical approval letters/ certificates with your application.

C.5 Proposed study dates and duration

Research start date (DD/MM/YY): 01/10/18 Research end date (DD/MM/YY): approx 31/03/21

Fieldwork start date (DD/MM/YY): approx 01/01/19 Fieldwork end date (DD/MM/YY): approx 31/03/21

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

In Assam, India with interviews taking place in the premises of MIND India NIRMAAN, and other participating organisations. Poster making will likely be via email but if necessary, via face to face meetings as above. Film-making workshops will take place in the premises of MIND India.

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?

Strand 1 and 2 Participants will be identified as those meeting our inclusion criteria: (1) an Indian national; (2) aged 15-18 years old and, despite risk, managing to resist drugs and problematic use of alcohol OR aged 19-24 years old and in successful recovery from drug and/or alcohol abuse; (3) abstinent from drugs and/or alcohol use for one year or more; and (4) feel well enough to take part without any foreseeable risks to themselves and (4) able and willing to take part in the Photovoice task.

(ii) approached?

MIND India and Nirmaan Rehabilitation Facility will identify potential participants from their service user communities, by word of mouth and by distributing the information about the study (Appendix B) within their networks which includes other youth-focused organisations. We may also use snowballing from Strand 1 participants to recruit; in this case, Strand 1 participants will be invited to give a study information letter to people they believe might be interested in taking part.

(iii) recruited?[26]

Strand 1 Potential participants will be provided with an information letter (Appendix B) (likely in person or via email) which provides the University of Leeds e-mail of the RF and PI. They will be invited to discuss the study with the researcher over e-mail, by phone, or meeting in a private room at the premises of MIND India, Nirmaan or other relevant organisations. They will be recruited only once they have been able to correctly recite the aims of the study, the Photovoice task, and what will happen to their data, and have given consent (Appendix C, Part A).

Strand 2 Strand 1 participants will be invited to take part in Strand 2, with varying levels of participation available (Appendices G, K and L). If there are not enough participants from Strand 1 willing to be involved in Strand 2, our Partner Organisation and other similar organisations will help us recruit additional young people to be involved in posters and film-making.

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

Strand 1 and 2 To avoid involving very vulnerable individuals, for our **resilient-to-risk group**, we will only accept people into the study who self-define as not currently abusing substances, as not seeking or receiving support for a mental health issue and who self-report as feeling well enough to participate without any foreseeable risk to their well-being. Participants must also be Indian nationals. For the **resilient-to-recovery group**, we will only accept participants who have been abstinent from substance use for one year or more and feel well enough to participate without any foreseeable risk to themselves. Participants must also be Indian nationals.

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.

Strand 1 Approximately 15 relevant people aged 15-18 years and approximately 15 relevant people aged 19-24 years. This sample size is enough to obtain data for a qualitative research that will involve in-depth analysis of both visual and verbal materials.

Strand 2 We hope to involve ~20 young people in poster making and 24 in film-making (3 groups of 4 resilient-to-risk participants and 3 groups of 4 resilient-for-recovery participants to develop a total of around 6 short, resilience-focused films.

If you have a formal power calculation please replicate it here: n/a

C10 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 deception will be used.

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

☑ Yes ☐ No

If yes, give details 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.

Strands 1 and 2 Participants will be provided with a consent form (Appendix C) to keep which provides a written record of the conditions of their consent and contact details of the research team. To provide additional assurance of anonymity participants will NOT be asked to sign the consent form but their consent will, instead, be **audio-recorded** (and stored safely) before the interview itself commences. The audio recording of consent will be retained until the study ends. This procedure has been approved in the past by the University of Leeds, Faculty of Medicine and Health (School of Psychology) Research Ethics Committee and is an acceptable ethical procedure with populations who may have reasons to be unsure about signing formal documents. At interview end (Strand 1) we will invite participants to give on-going consent for the data to be used as intended (Appendix C, Part B). This will give them the chance to give true informed consent (i.e., based on knowing what they disclosed in the interview). This will be audio recorded. If they have concerns about sharing the data in the way intended, we will work with participants to ensure they are happy with intended data use (e.g. by removing sections of interview data or images). Participants can take up to one week to make decisions about data use post-interview.

With permission, Dr Duara will maintain participant names and contact details for the duration of the project in order to contact them in relation to making their poster, film-making workshops, and relevant events. These details will be stored on a password protected computer separately from research data, in a way that makes it impossible to match participant details to their data. These will be deleted once the person's participation in the study ends.

Strand 2 Informed consent will be obtained for **poster-making** (Appendix G) and audio-recorded at the end of the Photovoice interview. Informed consent for **film-making** will also be audio-recorded on an individual basis at the start of film-making workshops (Appendices K and M).

Once the films are completed, anyone who is in the film will be asked to sign a **release form** (Appendix M) to ensure they are happy for the film to proceed to public dissemination. If a participant objects, we will work with them to modify the film appropriately. However, we hope that by working closely with participants to generate these films, participants will have felt able to produce a film that they are happy to be made public.

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

A minimum age of 15 years is set for participation in the study. The research will be conducted in a child-friendly setting with psychological support available through services from MIND India (where we anticipate most of the interviews will be conducted). Our risk management and safety protocol has been devised in collaboration with MIND India and are appended (Appendix A).

Our resilient-to-risk participants will be required to self-define as not currently seeking or receiving support for a mental health issue and to report feeling well enough to participate without any foreseeable risk to their well-being.

Our resilient-for-recovery group will be required to self-define as feeling well enough to participate without any foreseeable risk to their well-being and who have successfully abstained from problematic use of alcohol and drugs for one year or more.

The contact details of MIND India will be provided on the information sheet should a participant wish to seek support.

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 not 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.

Strand 1 The study information letter (Appendix B) consent form (Appendix C; Part a) explains that participants can stop taking part in the interview at any point and, post-interview (Appendix C: Part b) can (a) immediately opt to retract the interview (or part therefore) and/ or images for use as intended by the study team or (b) completely withdraw their data from the study. They have one week in which to decide on either (a) or (b).

Strand 2 Participants can withdraw from poster-making and the film workshops at any point during the process and without giving a reason. Participants can withdraw their poster from the study up to **one week** after poster completion. Participants who appear in the final films will be invited, post-production, to sign a **release form (Appendix M)** to ensure they are happy for the film to proceed to public dissemination (with steps following refusal as outlined in C11).

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.*

This is only likely to be relevant to **Strand 1.** Since the participants will be from Assam, and Assamese is the vernacular language, most participants can speak and understand Assamese. Thus, the study material will be in English and Assamese (presented only in English for ethics applications) and the explanations will be delivered in the local vernacular language. However, study materials will be offered in both English and Assamese as will the interview given that the RF is fluent in both languages. The RF will read the study materials and consent items to support participants with low levels of literacy.

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 information sheet should explain under what circumstances action may be taken.*

☑ Yes ☐ No *If yes, give details of procedures in place to deal with these issues.*

The interviews are primarily participant-led because they involve images that have been brought by the participants themselves in preparation for discussion of their experiences. Although interview topics and questions have been prepared (Appendices E and F), interview questions will be directed to a large extent by what the participants bring and hence the conversation is driven by them. Due to the research being about substance abuse, some topics discussed in the interview may be upsetting or sensitive. However, it is clear in the information sheet (Appendix B), and will be reiterated verbally prior to the start of interview, that there is no obligation on the participant to engage with a particular line of interview questioning and that no reason need be given for wishing to skip any particular question. If a participant is upset or distressed, he/she will be reassured and invited to take a break, with the option to discontinue the interview as well as the option to speak to someone at MIND India counselling services or other suitable professional (for example, if they already have someone suitable supporting them). The details of this are included in the risk management protocol (Appendix A).

The participant will be informed that they can leave the interview, stop poster production, or leave film-making workshops at any time without having to give a reason. They will be informed, on the study information (Appendices K and L) and verbally, that if they disclose being the victim or perpetrator of harm and / or serious criminal activity anytime from their consent into the study to the point when their participation in the study ends, that the study team may need to take action. Actionable disclosures include physical, sexual and or psychological harm, stealing/robbery, kidnapping, selling illicit drugs and homicide. Our risk management protocol (Appendix A) and

general information explains what action would be taken as well as how to access psychological support during and / or after the study.

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.

Research participants will be reimbursed their travel expenses for attending any pre-interview meeting, the interview, film-making workshops, and a planned impact event in Guwahati. Refreshments (water, hot drink) will be provided at interview and refreshments and lunch will be provided at film-making workshops. If a chaperone is required, their travel expenses will also be reimbursed. As a small thank you, each participant who agrees to the making of a poster will be provided a copy of their poster printed on canvas posted to their chosen address supplied to the RF. This information is explained to participants on relevant documents. Small project-branded items will also be offered to all study participants, such as a pen, note-pad, and linen bag. All participants will also be offered a certificate for each project part they engaged with, acknowledging their contribution to research; some participants may decline this in cases where they do not wish for any documentation to reveal their participation.

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]

Strand 1 There should be no significant risks in taking part. Although the topic of research is about a potentially illegal activity – substance abuse – clear guidance is provided on selecting and generating images that avoid direct representation of an illegal activity (Appendix D). Given that the content of the interview will be largely participant-led, directed by the images that they bring to the interview, participants will have considerable control over the topics discussed in the interviews. However, through the process of the conversation in the interview, participants may talk about things that they did not anticipate, which may be upsetting or difficult. Participants will be informed and reminded during the course of the interview that questions do not have to be answered if preferred and they will know about the researcher's obligations around disclosure of harm or criminal activities. Furthermore, how to contact a free relevant source of support will be outlined to all participants on the information sheet.

This research has significant potential applicability and will be used to inform a large project funded by the UK ESRC/AHRC Global Challenges Research Fund (mental health theme) to support culturally-sensitive approaches to understanding substance abuse in developing countries. Although it is not the purpose of the interview, participants may benefit through being listened to carefully by an interested other. This was noted in the study of the quarter life crisis among young people conducted by the RF (Dr Duara) where participants reported the process of photo-led interviews to be 'therapeutic' given the opportunity to externalize their experiences in visual form and having someone listen to them.

Strand 2 Given our safeguarding processes, no risks are anticipated in the development and exhibition of posters and films. This activity will help draw attention to issues raised, promote further discussion and celebrate the achievement and resilience of the participants. It will serve as an inspiration for collaborative workshops with young people at risk of, or in recovery from substance abuse, and engage policy-makers in the development of mental health approaches and services in Assam and across India.

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

☐ Yes ☑ No

If yes, please describe: _____

Is a risk assessment necessary for this research?

☑ Yes ☐ No If yes, please include a copy of your risk assessment form with your application.

Our risk assessment (Appendix N) has been undertaken because the research is being conducted outside the UK. It has been approved by the School of Psychology, University of Leeds.

NB: If you are unsure whether a risk assessment is required visit http://ris.leeds.ac.uk/HealthAndSafetyAdvice 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 http://ris.leeds.ac.uk/ConfidentialityAnonymisation and http://ris.leeds.ac.uk/ResearchDataManagement for guidance.

Strand 1

Participant personal details: We will need to store participant contact details to manage their engagement with the project. These details will be stored separately to any participant data and will be destroyed once their involvement is the project is concluded.

Photovoice task: Participants will be asked to obtain verbal consent from people before they photograph them, and faces and identifying places will be pixilated prior to any public dissemination. Participants shall be informed not to bring photos that have clear images of children under the age of 19, because appropriate consent cannot be obtained from them (Appendix D).

Project data: Care will be taken in the way data is stored so that individuals are highly unlikely to be identifiable. Any computer on which data is stored will have been encrypted and locked with a username and password.

- The RF will transfer **audio-recordings** and images from the Photovoice interviews to a secure University of Leeds One Drive. This process already been fully tested from Assam and proven effective and secure.

- Photovoice **transcripts** will be fully anonymised with any identifying details removed. If a transcription company is used, we will only use one who comply with University of Leeds confidentiality regulations (transcriber confidentiality statement Appendix P)).This includes destroying their copies of interview recordings once transcription has been relayed to the research team. Transcripts will be anonymised at the time at which they are checked against audio-recordings for accuracy by the RF.

- Photovoice **images** that a participant has consented to permit into the public domain will be anonymised (via cropping and/or pixilation of faces and identifying places). Non-anonymised images may be stored safely purely for analysis but will not enter the public domain. This is standard in Photovoice projects and their associated publications. Consent will be sought from participants to use anonymised interview quotes and anonymised photos/images in reports of the research and in other project outputs (posters, films and website).

- The different data and materials collected from each participant will be linked only through the use of **a unique participant identifier**.

- Members of the **partner organisations** (MIND India and Nirmaan) may become aware of who is taking part in the research, but will keep this information confidential unless it is decided by the research team that a participant's disclosure warrants action (as detailed earlier).

Strand 2 Anonymisation will occur for use of participants' narrative and images on posters and the website.

There are **three options** that the participants can choose post-interview in Strand 1 for **poster making (Appendix G):**

(1) not willing to share data for posters (no further action)
(2) willing to share anonymised images along with linked short quotes for poster making, but not take part in the creation process itself (audio record consent)
(3) willing to share anonymised images along with linked short quotes for poster making and work with the researcher to make the poster (audio record consent).

There are **two options** that the participants can choose post-interview in Strand 1 for the **project website (Appendix H):**

(1) not willing to share data for website (no further action)
(2) willing to share aspects of the interview data and images (suitably anonymised) (sign release form).

There are **four options** that the participants can choose post-interview in Strand 1 for **film-making (Appendix K):**

(1) not willing to share their interview data or images for film-making (no further action)

(2) not willing to take part in film-making, but consent to share anonymised data to include in films (audio record consent and later a post-production release form).
(3) willing to take part in film-making but not be on screen (audio record consent and later a post-production release form).
(4) willing to take part in film-making and be on screen (audio record consent and later a post-production release form; Appendix M).
Participants can decide to be on screen as they see how the film making is progressing. Participants newly recruited into film-making (ie who did not do a Photovoice interview) will have options (3) and (4) (Appendix L).

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 guidance.

The data management plan, and our plans to share the data, is appended (Appendix O).

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: _____ (further guidance)

☑ Other electronic transfer of data E-MAIL INFORMATION ABOUT THE STUDY TO PARTICIPANTS; PARTICIPANTS E-MAIL PHOTOS/DIGITAL IMAGES TO RESEARCHER

☑ Use of personal addresses, postcodes, faxes, e-mails or telephone numbers TO COMMUNICATE WITH PARTICIPANTS WHEN PROVIDED BY THE PARTICIPANT OR WITH THEIR CONSENT

☑ Use of audio/ visual recording devices (NB this should usually be mentioned in the information for participants) AUDIO-RECORDING OF INTERVIEW IS MENTIONED IN THE INFORMATION SHEET

☐ FLASH memory or other portable storage devices

Storage of personal data on, or including, any of the following:

☑ University approved cloud computing services (Microsoft Office 365 for email (Exchange online) and Microsoft OneDrive for Business) RESEARCHER TRANSFERS AUDIO-RECORDING AND PHOTOS/DIGITAL IMAGES LINKED TO ANONYMOUS PARTICIPANT IDENTIFIERS TO UNIVERSITY OF LEEDS ONE DRIVE

☐ Other cloud computing services

☐ Manual files

☐ Private company computers

☑ Laptop computers FOR CREATING REPORTS OF THE RESEARCH AND COMMUNICATING ELECTONICALLY WITH PARTICIPANTS ABOUT THE STUDY

☐ 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.)

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 DATA IS, RATHER, GENERATED OUTSIDE THE EU

☐ Sharing data with other organisations

☑ Publication of direct quotations from respondents IN ANONYMISED FORM AND WITH PARTICIPANT CONSENT

☐ 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 THIS WILL INVOLVE ANONYMISED DATA ONLY AND WITH THE CONSENT OF PARTICIPANTS

☐ Informal peer-to-peer exchange

☐ Depositing in a specialist data centre or archive

☐ Other, please state: _____.

☐ No plans to report or disseminate the data

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

☑ Conference presentation

☑ Peer reviewed journals

☐ Publication as an eThesis in the Institutional repository

☑ Publication on website

☑ ☐ Other publication or report, please state: REPORT FOR FUNDER ESRC/AHRC, REPORT TO POLICY MAKERS IN ASSAM/INDIA MAY BE APPROPRIATE

☐ Submission to regulatory authorities

☑ Other, please state: ___see below_____.

☐ No plans to report or disseminate the results

We will:

- launch a **social media mental health photographic/image campaign** to raise awareness and understanding of how young Assamese people manage risks around substance use in order to stay well.
- strengthen research capacity through **training staff** in our Partner Organisations and, where appropriate other organisations, in the design, delivery and analysis of photo-led interviews and support them drive implementation where it will improve services.
- engage with **key decision-makers** pan-India who are able to facilitate wider service and/or policy level implications of outputs and contribute to the development of an Assam State mental health policy.

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 RCUK Common Principles on Data Policy 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.*

5 years after publication of the last report of the research because this is the standard timeframe required by publishers. However, materials disseminated via our project website, and social media (e.g. posters and films) 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** ☑ **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 http://ris.leeds.ac.uk/ConflictsOfInterest.*

☑ 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 has been organised between MIND India, Nirmaan, the University of Brighton (where one CoI is employed) and the University of Leeds.

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

✓ Yes No ***If yes, what is the source of this funding?***

Economic and Social Research Council/Arts and Humanities Research Council 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 http://ris.leeds.ac.uk/FWAcompliance and you may also contact your FRIO for advice.

PART D: Declarations

Declaration by Chief Investigators

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.
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 Ethics Committee 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: .. signed by Anna Madill..... (This needs to be an actual signature rather than just typed. Electronic signatures are acceptable)

Print name: .....Anna Madill..... Date: (dd/mm/yyyy): .....10.12.18.....