**ASCOT: Addressing the Social Determinants and Consequences of TB in Nepal**

**PARTICIPANT INFORMATION LEAFLET FOR FOCUS GROUP DISCUSSION AND WORKSHOP**

**Invitation:** You are being invited to take part in a research study piloting a social and economic (socioeconomic) support package for households affected by tuberculosis (TB). Please read the information sheet carefully, which our team will now also go through with you step by step. You will be given a copy of the information leaflet to keep. Please feel free to ask us if you would like more information or do not understand anything. Please also feel free to discuss this with friends, relatives, and healthcare professionals. You do not have to accept this invitation and should only agree to take part if you want to. Thank you for reading this leaflet.

**What is the purpose of this study?** TB is a disease which affects many people in Nepal. Our previous research shows that TB can have an impact on social life, quality of life, mental health, and household finances. Together with people with TB, from the National TB Centre, and others, we developed a socioeconomic support package for people with TB-affected households. We are now running a pilot trial of the package. This means that, at random, some people TB-affected households will receive the package and some will not. The aim of the pilot trial is to see how well we are able to deliver this package in practice in Nepal. To help with this assessment, we are also doing focus group discussions and workshop to collect feedback and perspectives on the successes and challenges of implementing the package identified during the pilot trial. If this research finds that we are able to deliver the package well, we aim to do a larger trial in the future. The larger trial would evaluate if the package improves TB and socioeconomic outcomes and could potentially be scaled-up to be included in routine TB care.

**Why have you been chosen to take part?** We are inviting key stakeholders in Nepal to participate in this research. A key stakeholder is someone with interest, concern, experience, and/or knowledge in a particular thing, in this case TB and/or social support, economic support, poverty reduction, community cooperation, and activism. You are being invited to participate in this research because you have been identified as a key stakeholder. We are inviting approximately 50 key stakeholders in Nepal to take part in this research.

**Do you have to take part?** It is important for you to understand that your participation in this study is completely voluntary. We would be really grateful if you took part in this study but do feel free to decline. We appreciate it may be important to discuss this with others including your family. We encourage this and would ask if you would be able to decide if you wish to participate within 72 hours. If you decline, there will be no consequences for you and, if you are someone who has TB, you will receive all the care you need at the TB treatment centre as usual.

**What will happen if you agree to take part?** You will be invited to participate in two activities:

* *Focus group discussion:* A focus group is a small group of people who are asked their opinions on an area of interest, in this case TB. Throughout Nepal, there will be approximately 6 focus groups (each consisting of 5 key stakeholders) but you will only be invited to participate in one of them. There will be up to four other stakeholders, who share your area of interest, concern, experience, and/or knowledge, in the focus group. The focus group will be run by the Research Coordinator and Birat Nepal Medical Trust field team whose role is to make sure that everyone is allowed to express an opinion when they want and to support group interaction. Focus groups will take place at hired venues in your district and we will cover the costs of any transport and accommodation required (see reimbursement below). The focus group will review the challenges of successful delivery of socioeconomic support for TB-affected households from different perspectives. When you attend, we will ask you to confirm your agreement to participate by re-reading and approving the consent form, and then providing a confirmatory signature of your consent. The focus group you attend will last approximately 2 hours, be audio-recorded and, in some cases, video-recorded or photographed. If you do not wish to be audio-recorded, video-recorded, or photographed then please let us know on the consent form and we will not audio-record, video-record, or photograph the particular focus group in which you take part.
* *Workshop:* We will also invite you to participate in a two-day workshop. The aim of the workshop is for stakeholders to review the findings of the ASCOT pilot trial and focus group discussions. The first day of the workshop will consist of interactive presentations and discussions exploring the challenges and successes of the ASCOT pilot trial and the findings from the focus group discussions. The afternoon section of the workshop will consist of working groups discussing refinements of the socioeconomic support package for future scale-up in a large trial in Nepal, and also the potential policy implications and funding issues related to the package. The workshop will last two approximately 8-hour days (including 1.5 hours of break each day with lunch and refreshments provided). It will be audio-recorded and, in some cases, video-recorded or photographed. If you do not wish to be audio-recorded, video-recorded, or photographed then please let us know on the consent form and we will not audio-record, video-record, or photograph the workshop.

**What are the costs to you and will you receive any reimbursement?** There are no costs to you of participating in this research. We will reimburse you and cover relevant travel costs as follows:

* *Focus group:*We will reimburse you for the time that you spend completing the brief pre-focus group survey (total reimbursement of 200 rupees) and for the time that you spend at the focus group (total reimbursement of 500 rupees) regardless of whether you later decide to withdraw from the study. We will also cover costs of transport, food, and accommodation required for participation in the focus group at an appropriate daily amount agreed with BNMT. During the focus group, we will provide refreshments and a hot meal.
* *Workshop:* We will reimburse you for the time that you spend at the workshop (total reimbursement of 2000 rupees). We will also provide and cover costs of transport, food, and accommodation required for participation in the workshop at an appropriate daily amount agreed with Birat Nepal Medical Trust. During the workshop, we will provide refreshments throughout the two days plus three hot meals.

**Are there any risks in taking part?** We cannot envisage any risks to you of taking part in the focus group or workshop but if you had any concerns, please contact us using the contact details below. We would like to emphasize that participants in the focus group and workshop are asked to respect the confidentiality of the other participants. While we cannot guarantee that all participants will maintain confidentiality, we respectfully ask that no details shared in the focus group and/or workshop are disclosed to any other third party not involved in the focus group and/or workshop either during or at any time following the focus group and/or workshop. A section of the consent form can be used to indicate if you are happy for your name to be used in any forms, reports, or publications from this research. Thank you for respecting confidentiality.

**What are the benefits of participating in this research?** There are no direct benefits to participating in this research. This research will help us to understand if a support package for TB-affected households is achievable and suitable in Nepal and strengthen the case to do a larger trial and scale-up the package. Improving support could mean that more people with TB can become cured, the risk of TB in the community lowered, and people with TB do not become poorer because of the disease or incur catastrophic costs.

**What to do if you need more information, have queries,** **are unhappy, or have complaints about this research:** we can give you further, more detailed information about the research and answer any of your questions. If you want to have further information at any stage of the research or want to express any concerns then you can speak to us now and/or contact the Chief Investigator, Dr Tom Wingfield, and Research Coordinator, Mr Bhola Rai: Birat Nepal Medical Trust, Lazimpat, Kathmandu, Ward No. 2, Tel: +977 1-4436434, 4428240 Email: tom.wingfield@lstmed.ac.uk and bhola@bnmt.org.np

**Safeguarding:** the study team and data collectors are expected to behave ethically and responsibly at all times and follow the LSTM and BNMT code of conduct. This means that they must not ask you for any financial, physical or sexual favours in return for taking part in this research. If you experience any abuse, harassment or neglect by a study team member you can contact the study Safeguarding Lead – Mr Rajesh Parajuli, Birat Nepal Medical Trust, Lazimpat, Kathmandu, Ward No. 2, Tel: +977 1-4436434, 4428240, [rajesh.parajuli@bnmt.org.np](mailto:rajesh.parajuli@bnmt.org.np). You may call this number at any time. You may also raise a safeguarding concern directly with LSTM Designated Safeguarding Officer Philippa Tubb on +44 (0)151 705 3744/safeguarding@lstmed.ac.uk. LSTM’s safeguarding commitment is described on LSTM Safeguarding webpage (<https://www.lstmed.ac.uk/safeguarding>).

**What will happen to the information you give us and will your participation be kept confidential?** The information that you choose to share will be used for research purposes. This information will be stored on a computer and will only be shared with other researchers in our group who are affiliated with BNMT. Within the months following the completion of both the focus groups and workshop, we will analyse all the answers at BNMT and Liverpool School of Tropical Medicine (LSTM) and report the findings of the study when completed but all your personal information will first be deleted to ensure full confidentiality.

**What will happen to the results of this study?** We aim to present our findings to the Nepal National TB Program and at international conferences. We also plan to publish our findings in scientific journals and press releases. All the publications will be made “open access” which means that they are available to anyone to download from the internet and print. If you would like us to tell you more about obtaining a copy of any reports, publications, or articles resulting from this study or receiving an email or phone call to summarise the study findings please indicate this by ticking the relevant box on the consent form. This is your choice and entirely optional. As stated above, we will try to ensure as far as possible that you and the information you give us will not be identifiable in any outputs from this study.

**What if you choose to withdraw from the study?** If you choose to take part in this study, you may still withdraw from the study at any time up to 31st July 2022 without giving any explanation for your withdrawal. From the time you decide to withdraw, all study activities in which you were involved will cease including reimbursement, social support, economic support, and socioeconomic support. By the 31st July 2022, the information that you and the other people taking part in the focus group and workshop gave us will be put together and analysed with the aim of being published in a medical journal. All answers that you give us will be kept confidential and your name will not appear on any of the forms, reports, or publications resulting from this research unless you have indicated otherwise on the consent form. Please be aware that the consent form will allow you to decide whether you want to take part in only some parts of the study. For example, you could decline to participate in a focus group and agree to participate in the workshop or vice versa.

**Who is conducting this research?** The Liverpool School of Tropical Medicine (LSTM), UK; the University of Liverpool (UoL), UK; the University of York (UoY); UK Karolinska Institutet (KI), Sweden; and Birat Nepal Medical Trust (BNMT), Nepal. The researchers include: Chief Investigator, Dr Tom Wingfield (LSTM/KI); Research Coordinator, Mr Bhola Rai (BNMT); Co-investigators, Dr Poonam Rishal (BNMT), Mr Gokul Mishra (BNMT/NTCC), Ms Kritika Dixit (BNMT/KI); Mr Suman Chandra Gurung (BNMT); Mr Raghu Dhital (BNMT); Dr Noemia Siqueira (UoY); Dr Maxine Caws (LSTM); Professor Knut Lonnroth (KI); Professor Bertie Squire (LSTM); and Dr Laura Bonnett (UoL).

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