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

**PARTICIPANT INFORMATION LEAFLET FOR SURVEY**

**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 – we are grateful for your time.

**What is the purpose of this study?** TB is a disease which affects many people in Nepal. Our previous work 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 Control Centre, and others, we developed a support package for people with TB and their 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 can deliver this package in practice in Nepal. To help with this assessment, we are also doing detailed surveys of people with TB and their households to ask about the costs faced when seeking and accessing TB care. We are also asking questions about: TB-related knowledge; the stigma that people with TB face; community security; mental health; wealth or poverty; and quality of life. Finally, we are asking people from TB-affected households who received a support package, what their experience was like and for their feedback on what we could do to improve the package. We hope that the information that we gather will help us to better support people affected by TB in Nepal so that they do not unnecessarily suffer socially, financially, or physically because of the disease.

**Why have you been chosen to take part?** You have been chosen to take part in this research because you are someone who has recently been diagnosed with TB in a clinic in Pyuthan, Chitwan, Mahotari, or Morang districts of Nepal. We will be inviting you and approximately 100 other people with TB in these districts to take part.

**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 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, you will receive all the care you need at the TB clinic as usual. In addition, regardless of your decision, we will provide you with an information leaflet on TB and can revisit your household or meet somewhere else at a convenient time to talk further, if you felt this would be beneficial to you.

**What will happen if you agree to take part?** First, you will be randomly assigned to one of four study arms. Participants in all study arms will receive three visits to their household to do the survey described above. The first household visit will take place at 2-3 weeks, the second at 10-12 weeks, and the third at 20-24 weeks after starting TB treatment. These visits will be scheduled in advance where possible and will be conducted regardless of whether you are still taking TB treatment at that time. At the first visit, participants in all study arms will receive education about TB and a one-off nutritional food basket (contents may vary but the basket’s monetary value will be about 2500 Nepalese rupees). In addition, participants randomised to the following study packages will receive:

1. **Social Support:** counselling to reduce stigma at first and second household visit and an invitation to a community cooperative meeting of TB-affected people in your district
2. **Economic Support:** cash, bank, or phone transfers during TB treatment
3. **Socioeconomic Support:** a combination of social and economic support

Randomisation means that the BNMT team will open an envelope in front of you, inside of which there will be a piece of paper with the study package you will go into written on it. There is an equal 1 in 4 chance of being allocated to each study package and 3 in 4 chance of being allocated to a study package where you will receive some form of support (e.g. social, economic, or socioeconomic). The study package is decided by chance before the study begins by computer and neither the BNMT team or TB clinic staff know what package you will be in nor can they influence or change that package. People selected by chance to receive the social, economic, or socioeconomic support packages will be shown a video and given an information leaflet, which explains in more detail the activities of that study package. We understand some people may not be comfortable to receive the packages, for example, because it feels like charity or they are concerned it will cause problems in their households. If you feel like this or for any other reason, you do not have to accept the package.

For participants receiving economic or socioeconomic support, the economic component will be provided for at least two months and a maximum of 6 months (the usual length of TB treatment) and be equivalent to a maximum of approximately 16,000 Nepalese Rupees in total. For participants receiving economic or socioeconomic support, this will continue regardless of whether you have continued your TB treatment but will stop if you choose to withdraw from the study. The frequency, timing, location, and method of social, economic, and socioeconomic support provision may change during the study including location of stigma reduction activities or providing a cash equivalent such as food support. This is to help us to understand what works best in practice in Nepal and make the support better in the future. The amount of cash provided will not change.

In addition, some participants will be invited to participate in a future focus group and workshop. Finally, with your permission, we will access your TB care records to clarify your treatment outcome.

**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 for the time that you spend completing the three surveys (500 Rupees each time, total of 1500 rupees) even if you are not selected to receive social, economic, or socioeconomic support. If you decide to withdraw, you will receive reimbursement and/or support up to that time but not thereafter. If you are receiving TB treatment, you will have to pay the normal costs of medical care but TB treatment is provided free by the National TB Program. If you decide to participate, we would like to stress that you will not receive any reimbursements for expenses that you report in this interview (for example, the costs of your travel to the clinic or medical costs such as consultations or medicines). However, if you are selected by chance to receive the economic support or socioeconomic support packages then you are free to use the economic support provided in any way you and/or your household see fit.

**Are there any risks in taking part?** You may find some of the survey questions about your household finances, your mental and physical health, and stigma to be sensitive. Our team has previously used these surveys in hundreds of people with TB in Nepal and will aim to help you to feel comfortable but you do not have to answer any questions that you do not wish to. If the survey identifies you as someone who may require additional psychological or mental health support, we will initially ask a member of our project team who was trained in psychological first aid in Nepal following the 2015 earthquake, to look at your survey responses and contact you for further review. If necessary, that team member may then suggest that you receive further psychological consultation. We will support transport and costs of the initial psychological consultation if this is advised. Please note, all of your responses during the survey and throughout the study will remain confidential (see below). There is a small risk that, if you are randomly selected to receive the social support, economic support, or socioeconomic support packages, other people with TB, whether in this study or not, or other people you know who don’t receive such a package may feel bad that they are not receiving this support. However, we have conducted similar studies in other settings and have rarely found this to be the case and it is entirely your decision as to whether you share details with others about your involvement in the study. Although we cannot envisage any significant risks to you of taking part in the survey or pilot trial, if you had any concerns, please contact us using the contact details below.

**What are the benefits of participating in this research?** This research will help us to understand if a support package for TB-affected households is feasible and acceptable in Nepal and strengthen the case to do a larger trial and scale-up the package. Improving support could mean more people with TB can become cured, the TB risk in the community lowered, and people with TB do not become poorer because of TB or TB-related costs. In addition, there will be monetary benefits (cash transfers) if you are randomised to receive the economic or socioeconomic package.

**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. 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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