

**Research Protocol: Antibiotics and Activity Spaces:  
An Exploratory Study of Behaviour, Marginalisation, and Knowledge Diffusion**

**APPENDIX 1: JUSTIFICATION FOR VERBAL CONSENT**

We received a waiver for written consent requirements in order to not unfairly exclude illiterate population sub-groups in our field sites [1], and to ensure trust between the researcher and the rural respondents [2]. Instead of participant-dated signature, we follow a verbal consent process: (1) we seek permission from village leaders to carry out our survey in their villages, (2) the survey fieldworker reads out (and records on audio tape) an oral consent script to selected survey respondents and also provides them with a printed copy of the Participant Information Sheet, (3) the survey fieldworker asks the respondent to state her or his consent, name, and date on audio record, and (4) the survey fieldworker personally signs and dates a written record of oral consent. This proposed process:

- (a) responds to the nature of this study, which takes place in varied populations where 13% of adults in rural Northern Thailand and 27% in rural Salavan do not have any formal education and can be assumed to be illiterate [3 4].
- (b) appreciates that signatures and thumb prints in our rural field sites can over-formalise the relationship between the researcher and the respondents, which can make respondents uncomfortable and discourage participation in the research.
- (c) complies with International Ethical Guidelines for Biomedical Research Involving Human Subjects for minimal risk research among partly illiterate populations in non-Western research contexts [5].
- (d) ensures that respondents still have the opportunity to give informed consent freely, while enabling the transparent monitoring of the consent process through audio records and signed records of oral consent.

25 Our approach is not unique; it is based on existing guidelines and practice in biomedical and social  
26 research in low- and middle-income countries. For example, in a survey of 203 researchers from 90  
27 countries across low- and middle-income Asia, Africa, and South America, Hyder and Wali [6]  
28 report that one-third of the researchers use verbal consent processes. According to their analysis,  
29 verbal consent was more often employed in research with low-literacy populations, by non-physician  
30 researchers, and in lower-risk behavioural and cultural research. A survey among 387 US researchers  
31 working in low- and middle-income countries yielded a comparable fraction of 41% who obtain  
32 verbal consent in their studies [1]. Examples from empirical bioethics research demonstrate that  
33 verbal consent can be a viable alternative to written consent in low-risk health-related research with  
34 ethnically and culturally diverse groups:

- 35 • Killawi, et al. [7] carried out a qualitative research study in Qatar on health services quality  
36 among the general population. The authors obtained audio-recorded verbal consent (together  
37 with providing a written participant information sheet) for cultural reasons: “Signatures are  
38 usually reserved for formal transactions associated with major life events” [7].
- 39 • Lloyd, et al. [8] obtained verbal consent for a qualitative study among ethnic minority  
40 diabetes patients in the UK. Respondents were given an information sheet together with  
41 audio-recorded information about the research. They were then asked if they had any  
42 questions, the consent-taking process was explained, the respondents were asked to repeat the  
43 consent form items as read out by the researcher, and the respondents would then state their  
44 name, time, and date to give their consent. The process was documented via audio recording  
45 and participants would retain a copy of the audio record. Based on interviews with the  
46 participants, the authors concluded that, “this method of obtaining consent was found to be  
47 acceptable to all those [respondents] taking part” [8].
- 48 • Tindana, et al. [9] carried out qualitative research in Ghana about informed consent  
49 processes, indicating how illiterate respondents preferred verbal consent because “the paper

50 will not mean anything to me.” However, the study also highlighted that written documents  
51 can serve as a reminder for respondents that they participated in the study, and that  
52 community leaders play an important role as gatekeepers in rural research.

53 More generally, researchers and research ethics guidelines agree that verbal consent can be an  
54 alternative to written consent where (a) the research carries only minimal risks, (b) literacy and the  
55 cultural context make signatures and thumb prints problematic for equal participation in research,  
56 and (c) the consent process is documented adequately [1 2 10-12]. For example, the Nuffield Council  
57 on Bioethics [13] and the National Bioethics Advisory Commission [14] appreciate that signing  
58 documents can over-formalise the relationship between the researcher and the participant, thereby  
59 undermining trust and discouraging participation. The same concerns can apply when using thumb  
60 prints to document consent [15 16]. At the same time, Marshall [2] maintains that, “in many cultural  
61 settings, agreements based upon trust do not require a signature.” Altogether, these reports suggest  
62 that alternative arrangements to written consent are possible but require “safeguards” like an audio  
63 recording of the respondent’s consent, or a signed statement by the researcher that the study had been  
64 explained and that the participant had given her or his consent. Bhutta [12], who reviewed various  
65 research ethics guidelines, seconds this argument and states that, “Using the improved technology of  
66 video and audio recordings during the consent process may carry the dual benefits of documenting  
67 consent as well as acting as a mechanism for oversight by ethics review committees.”

68 In light of the varying levels of literacy in our rural field sites, the risk of alienating participants who  
69 are only very infrequently requested to sign documents, and the low-risk nature of our social survey,  
70 we substituted the written consent process with audio-recorded and documented verbal consent.  
71 Following permission of village leaders to conduct our survey, we approach the sampled households  
72 and select the respondents accordingly. For the selected respondents, the fieldworker reads an oral  
73 consent script, containing the same information as the Participant Information Sheet (the respondent  
74 receives a printed copy). The script and PIS are available in Thai and Lao and include information on

75 the exact nature of the study; what it will involve for the participant; the implications and constraints  
76 of the protocol; data sharing arrangements; and the risks and benefits involved in taking part. The  
77 fieldworker thereby explains that the participant is free to withdraw from the study at any time for  
78 any reason without prejudice to future care, and with no obligation to give any reason for  
79 withdrawal. The reading of the script is audio recorded in order to document the consent process.

80 The participants are allowed as much time as they wish to consider the information, and they have  
81 the opportunity to question the field investigator to decide whether they will participate in the study.  
82 Verbal Informed Consent is then obtained by the respondent confirming that they wish to take part in  
83 the study, stating their name and confirming whether the project has been explained to them, whether  
84 they have received the information sheet, whether they give the interviewer the permission to survey  
85 them, and whether they agree with the study's data sharing arrangements. The survey fieldworker  
86 then stops the recording and completes and signs the record of oral consent.

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