**TOPIC2 Healthcare Professional Information Study and Audio-recording Consent Form**

In order to improve the delivery of information within the informed consent process, there is a qualitative research intervention (The ‘QRI’) incorporated into the TOPIC 2 study. This aspect of the study will evaluate information delivery for study patients and will help to identify specific issues that are affecting recruitment.

We would like you to provide consent to audio-record all conversations that you have with patients for TOPIC 2.We may also ask you to complete an audio-recorded in-depth interview with one of the *qualitative researchers involved in the study.* Your participation in this qualitative research is voluntary.  *The aim of the audio-recordings is to understand and* improve the recruitment process. Analysis of the audio-recordings will be undertaken by the qualitative research team from University of Bristol. You may receive personal confidential feedback or you may receive more general anonymised feedback at a centre, or study level.

All information that is collected about you during the course of the research will be kept strictly confidential. Access to this data will be restricted to members of the research team at Bristol University. The recordings will be made on an encrypted device (password protected) and saved using a study ID and not your name. You will never be identified in any publications but we may quote your words. All audio-recordings will be kept for 10 years after the end of the study. With your consent, we would like to keep audio-recordings indefinitely to help us with future training, teaching and research into RCT recruitment.

All information collected about you for this study will be subject to the General Data Protection Regulation and Data Protection Act 2018 for health and care research and will be kept strictly confidential. University of Birmingham is the Sponsor for this study. The University of Birmingham will act as the data controller for this study. This means that the University of Birmingham are responsible for looking after your information and using it properly. University of Birmingham and will keep identifiable information about you for at least 25 years after the study has finished, to allow the results of the study to be verified if needed.

All information collected by the Sponsor will be securely stored at the Trials Office at the University of Birmingham on paper and electronically and will only be accessible by authorised personnel. The only people in the University of Birmingham who will have access to information that identifies you will be people who manage the study or audit the data collection process. In the Trials Office, you will be identified by a unique study number.

Under no circumstances will you be identified in any way in any report, presentation or publication arising from this or any other study. All individuals who have access to your information have a duty of confidentiality to you.

You can withdraw your consent to our processing of your data at any time. Your rights to access change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. Under the provisions of the General Data Protection Regulation (GDPR) 2018, you have the right to know what information the Trials Office has recorded about you. If you wish to view this information, or find more about how we use this information, please contact Legal Services at the address below. Please note that a small fee may be payable to retrieve this information.

Legal Services

University of Birmingham

Edgbaston

Birmingham, B15 2TT

If you are worried about any part of this study or have a complaint, you should ask to speak to the researchers who will do their best to answer your questions. If you wish to complain formally, then the normal National Health Service complaints mechanisms will be available to you: please ask to speak to [insert local details of independent advice service as per local trust policies] or you can contact the trial office at [topic2@trials.bham.ac.uk](mailto:topic2@trials.bham.ac.uk) or telephone 0121 415 9133.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| ***This form should be completed by the participant.*** | | ***Please initial each box:*** | | | | | |
|  |  |  | | | | | |
| 1. | I confirm that I have received enough information about this research and have had the opportunity to ask questions. These questions have been answered clearly and satisfactorily. |  | |  | | | |
|  | | | | | |
|  |  |  | | | | | |
| 2. | **[if involved in recruiting patients to trial]** I agree to audio-record consultations with patients eligible for TOPIC 2 and to transfer my audio-recordings and relevant data to the QRI team at the University of Bristol for analysis. |  | |  | | | |
|  | | | | | |
|  |  |  | | | | | |
| 3. | I agree to take part in an in-depth audio-recorded interview about recruitment to the TOPIC 2 study ***(not all people will be asked to have an interview)*** |  | | |  | | |
|  |  |  | | | | | |
| 4. | I understand that I am free to withdraw from the study at any time without giving a reason and that withdrawing from the study will not affect my legal rights. |  | | | |  | |
|  |
|  | ***For Statement 5 please tick Yes or No:*** | **Yes** |  | | | | **No** |
| 5. | I agree for my data to be retained for training, teaching and research purposes, now and in the future, with personal identifiers removed. |  |  | | | |  |

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of participant Signature Date

1 copy for participant; 1 for research team