GUIDANCE DOCUMENT: RECRUITING POTENTIAL PARTICIPANTS AND OBTAINING TELEPHONIC CONSENT FOR RESEARCH PARTICIPATION

1. INTRODUCTION

This document sets out guidelines for recruiting potential participants and/or obtaining telephonic consent from individuals for participation in research.
It is important, from the outset to state that the ideal is an in-person consenting process which provides opportunity for potential participants to engage with the researcher, seek clarification of any aspects that are not understood, and to physically sign the consent form. As such, obtaining telephonic consent represents a variation to the current HREC SoP guidance that "Written informed consent should always be obtained unless an alternative process is adequately justified and approved in advance by HREC" (11.1.5, p. 53). Even when a telephonic consent process is conducted, participants should still be sent a copy of the information and consent sheet to review and sign.

Given the current context of the COVID-19 pandemic and supported by the evolution of telephonic and virtual methods for obtaining consent for participation in research, HREC will consider study protocols proposing telephonic consent on a case-by-case basis with due consideration of the following aspects:

a) Whether the study is minimal risk or higher than minimal risk. Telephonic consent is not advisable for moderate to high-risk studies or where the type of research is contentious or of a sensitive nature.
b) To what extent the rights of the participant may be adversely affected.
c) In emergency research situations, if the participant is not able to provide informed consent (IC) due to seriousness of his/her medical condition, a legally authorised representative, who is able and willing to, may provide telephonic consent which is then followed by consenting the participant at a later stage. [The inherent challenge is to determine and confirm online the identity of the consenter and the relationship with the participant.]
d) Whether the study is regulated, such as a clinical trial (SAHPRA, etc.) as telephonic consent might not be acceptable to the regulator; however, this situation will provide an opportunity for researchers to be innovative in how a tiered consenting process could be managed in order to ensure regulatory compliance.
e) Whether the consent process is staged in order to truly represent an informed and deliberated process of consenting. This would require due consideration of POPIA compliance in terms of how the telephone numbers of potential participants are obtained and managed.

2. PROTOCOL REQUIREMENTS

At a minimum, the study protocol should include the following:

2.1 In terms of protocol submission, this would essentially imply that the researcher includes a request for *a waiver of <u>in-person</u> consent* and clearly outlines the circumstances and rationale for such.

2.2 The protocol will need to include how researchers will identify potential participants and plan an initial contact with potential participants by telephone. It is important keep in mind POPIA compliance with regards to accessing contact details of potential participants. Therefore, the protocol should address: i) how and from whom telephonic contact details will be obtained; ii)

who will make the initial contact call (together with their affiliation with the clinical environment); iii) how POPIA considerations are adhered to. Seeking advice from the SU Division for Information Governance during the planning of the study is advised. Such advice can be appended to the submission for ethics approval; and iv) how the cost of telephone calls will be covered (budget provision).

Kindly consider aspects of positionality (that is, the relationship of the researcher with the individual) and what plans can be put in place to address and or mitigate potential therapeutic misconception or potential undue influence when treating clinicians are conducting research. In such cases, it is considered best practice for a third party from the same clinical environment (or similar delegated person as per the study informed consent SOP) to undertake the consenting process for the research study.

2.3 A telephonic consent script/standard operating procedure (SOP) would need to be submitted with the protocol for review. In this script/SOP, all components of informed consent (see "Components of Informed Consent" and Sample of such scripts in section 9 of the document) need to be included.

2.4 Note that the process of obtaining telephonic consent includes screening for eligibility, thus it is important to outline the study's inclusion criteria and include how this will be fulfilled prior to proceeding with the consent process.

3. ETHICS & GENERAL PRINCIPLES

In recruiting participants telephonically, the following ethical principles should be borne in mind:

a) Respect for persons,
b) the right of individuals to refuse participation and to withdraw at any stage, and
c) the right to full information related to the study.

Additional considerations:

- The capacity to consent should not be assumed but independently and carefully assessed by the researcher. Safeguards should be built into the process to protect the incapacitated patient while balancing the risk of harm with the proposed research benefits.
- Researchers should note that any form of telephonic consent carries some degree of risk in terms of authenticating identity or misunderstandings about the purpose of the research.
- It is important that aspects such as the type of study, the nature of the research question, its potential risks and feasibility for telephonic consent are carefully considered.

4. DOCUMENTING TELEPHONIC CONSENT

4.1.1 When obtaining telephonic consent for research, the researcher needs to clearly document the consenting process in the protocol in the form of a Standard Operating Procedure (SOP) which should be included in the study protocol. Kindly refer also to section 6.6 for further pointers.

4.1.2 A witnessed audio recording of the informed process (by an impartial witness), from the time the study is introduced to the participant to when the participant confirms willingness to participate, should be kept as evidence of the consent process. Potential participants should be given details about the presence and identity of the witness and informed that the call will be audio recorded and their consent for both should be obtained.

4.1.3 The recorded audio interaction should be supplemented by a signed written consent document, wherever possible. For example, in a minimal risk study participants can be sent the Participant Information Sheet (PIS) via electronic means and consent can be recorded

verbally and verified via an electronic message confirming participant consent. However, it must be reiterated that telephonic consent is not advisable for moderate to high-risk studies or where the type of research is contentious or of a sensitive nature.

4.1.4 Authenticating the identity of the participant is important, as is checking with the participant that they are able to have the conversation in a private place.

The researcher should describe the following:

a) How the consent process will be documented (such as recording the consent process, logging the date, time, and name of caller, how the consent process will be witnessed and by whom, and so forth);
b) How signing of documents will be managed as would be the case for obtaining face-to-face consent; for example, will participant sign the written document and return to the researcher, or in the case of minimal risk studies – will verbal consent or an electronic indication such as an SMS, be sufficient if recorded and witnessed. Each option would need to be motivated in the protocol and be congruent with the study's risk category;
c) Include a note that the HREC approved script was used.

5. PROCESS FOR TELEPHONIC CONSENT

By implication, obtaining telephonic consent ethically would involve a staged consent process. Due to the potential for this process to be perceived as coercive, it is essential that the process allows time for the potential participant to consider the information regarding the study before consenting to participate.

Importantly, it should be noted that most international guidelines mandate that a copy of the participant information sheet/letter be sent to the participant and that such is then carefully discussed point by point over the phone/online virtual facility/WhatsApp to ensure true informed consent. [To minimise data costs for participants, it might be helpful if content of the participant information is copied into the body of the email or WhatsApp message.]

A staged consent process will typically take the following route:

a) The first contact would be to establish that the individual meets the inclusion criteria and would be willing to engage in discussion about the study after a copy of the study information/Participant Information Sheet has been supplied to the potential participant.
b) The second contact is set up to discuss the study details as per the aspects outlined in the telephonic consent script and the participant information sheet.
c) The final contact would be to follow up to discuss the study information shared with the potential participant further, where a potential participant has been provided the study information and where additional time for deliberation might be required.
d) Obtaining informed consent via electronic platforms (e.g., electronic mail, WhatsApp, and other virtual platforms), could be considered, provided there is adequate motivation to use this alternative and provided that any costs to participants (i.e., data costs) are anticipated and remuneration for such included in the study budget. Electronic signatures may also be considered, where applicable, provided that security and authentication measures are in place. This method of consent, however, has the potential to exclude participants with no access to electronic platforms or electronic signatures and researchers should outline how such issues would be addressed.
e) Compliance to POPIA should be observed and outlined in the study protocol.

6. COMPONENTS IN TELEPHONIC CONSENTING

The telephonic consenting process essentially follows a similar process to obtaining consent from potential participants as would be the case in a face-to-face consenting interaction.
These components are summarised below.

6.1 Provide the participant with all the required information about the study

(i) After initial telephonic contact, a copy of the consent document should be sent to the participant via email, mail, fax or suitably accessible mode (to be motivated in the protocol) so that individuals are fully informed about study procedures and do not feel coerced into participating.
(ii) Cover each of the sections of the study information in the telephonic discussion.

6.2 Provide information in a language the participant understands

a) As is the general expectation in face-to-face consenting, language used in telephonic consent should in layman's terms usually pitched at the Grade 8 level (depending on the study target group). Secure an interpreter for the telephone conversation, if needed.
b) Neutral language should be used during the telephonic discussion to ensure that the individual does not feel guilted or coerced into giving consent.

6.3 Give the participant an opportunity to ask questions before providing consent

a) Ensure the individual has enough time after receiving the consent form to read it before the scheduled follow-up telephone call for the purpose of obtaining telephonic consent.
b) If the individual has questions about the study, the study team should ensure an appropriate individual is available to answer those questions.

6.4 Give the participant enough time to consider participating in the study

a) Inform the individual that if they would like to take more time to consider the study, another telephone call can be scheduled.

6.5 Do not use exculpatory language in the consent process (i.e., language that absolves the researcher of liability of the risks inherent to a study)

a) Acknowledge potential risks of the study.
b) No informed consent, whether oral or written, may include any exculpatory language through which the participant is made to waive or appear to waive any of their legal rights, or releases or appears to release the researcher, the sponsor, the institution, or its agents from liability for negligence.

6.6 Document that the participant's consent was obtained before beginning study procedures

a) Ask the individual if they would like to participate. If yes, have the participant sign and date the consent form, then return it to you (via method as motivated in the protocol e.g., email, WhatsApp, fax).
b) Record-keeping of all aspects related to the telephonic interaction is vital, including :

- When/how the consent form was sent
- When the telephone call was made and by whom
- What was discussed during the phone call
- When the partially signed consent form (signed by participant) was received
- When the partially signed consent form was signed by the person obtaining consent
- When/how a copy of the fully signed consent form was given or sent to the participant

- When you receive the partially signed consent form, the person obtaining consent should sign the form, indicating the date that the form was signed, not the day the phone call was made.

6.7 Provide a copy of the signed consent form to the participant

- Send a fully signed consent form as described and motivated in the protocol, or an acknowledgement from the participant for the record of consent to participate via email, SMS, WhatsApp, as applicable. The participant can then send a confirmatory response to the researcher.
- The researcher/party engaging the participant may also agree to provide a copy to the participant in person, if the participant will be coming in for a study visit.

7. COMMENCING STUDY

Study procedures may only begin once the signed copy or written indication of agreement, as motivated for in the protocol, is received.

8. SUMMARY OF PROCESS

a) Send document to participant via email or online facility (not always possible but always preferable, provided that data costs borne by the participant are remunerated).
b) Read script over the phone/online facility in carefully delineated sections, with pauses for clarification, and in a language understood and preferred by the participant.
c) Discuss any questions the participant may have.
d) Document consent as provided telephonically, co-signed by a witness that hears/ listens in on the instance of providing informed consent or recorded evidence of participant consent and witnessing.
e) Make a formal statement (in the consenting documentation log) that research was initiated after informed consent was obtained telephonically or via an online or virtual mechanism/facility.

9. SAMPLES OF TELEPHONE CONSENT SCRIPTS

The following sample text is outlined to help researchers structure a telephone script which can be adapted as it applies to the specific study and its various components. [Kindly refer also to section 6.]

SAMPLE TELEPHONIC CONSENT SCRIPT

A. First contact

Hello, my name is_____. I am a (student/faculty member/staff member) from Stellenbosch University NAME OF DEPT/SCHOOL.

I am calling to invite you to participate in a research study. I obtained your details from <**insert details on how individual's contact details were accessed>.** Are you happy for me to continue and to give you more information on my/our research project? ***(If yes, proceed; if no thank them for their time and end the call)***.

I also need to inform you of the following:

(a) that our conversation will need to be recorded for record purposes and to ensure that your rights as a research participant are protected; and

(b) that this conversation is being witnessed by <Insert name> to protect us both.

Are you comfortable with our discussion being recorded?

My/our research project is about _____. Your participation in this study would be completely voluntary and you can decide to withdraw at any time even after you have agreed to participate, with no negative consequences. This means that you do not have to participate in this study unless you want to. INCLUDE HERE THE STUDY PURPOSE, WHO IS CONDUCTING THE STUDY, WHO IS FUNDING THE STUDY, WHAT YOU ARE ASKING THE PARTICIPANT TO DO, HOW LONG IT WILL TAKE, RISKS AND BENEFITS. (*See Components of Telephonic Consenting, section 6 above*).

Would you be willing to answer some questions to help me determine if you are eligible for this study? ***(If yes, proceed; if no thank them for their time and end the call)***. Thank you.

I will read a list of questions. If your answer to any of them is yes, please wait until I am done and then we can confirm when I have finished reading the list that you meet the criteria for taking part in the study. It is best that you do not answer each question but rather wait for me to complete the list. (Include a list of the exclusion criteria that you need to know about for this person but getting individual answers might be an issue if recorded anywhere with the name of the person being called).

Is your response to any of these questions "yes?" (If person says yes, discuss and assure them why they are not eligible, and thank them for their time and interest. If the individual answers "no", proceed)

Do you have any questions at this stage?

Read the participant information to the individual <u>with pauses</u> to check understanding of the study and study procedures and what is expected of the participant.

- I will e-mail or send the information via <*WhatsApp/SMS/email*> I have just read to you in a format that would be accessible to you.
- Can we kindly set up another appointment for me to call you to hear whether you are willing to participate in my/our study, and to conclude the process of your consenting to take part in the study. [Discuss how participant information will be sent and also when would be convenient for follow-up call.]

- Thereafter, if you are happy to proceed with the <interview/survey> we can go ahead once you have confirmed your participation via <*WhatsApp/SMS/email*>

If you have any additional questions about this study, you can contact **<Principal Investigator/Research Supervisor as applicable to your study>** at **<telephone and email>**. If you have questions about your rights as a participant in this research study or any complaints about how this study is being conducted you may contact (anonymously if you wish) **Dr Blanche Pretorius, Head: Health Research Ethics Office, Stellenbosch University, which is the office that protects the rights of study participants. You can contact her at e-mail: blanchep@sun.ac.za or at telephone number: 021- 938 9075**.

B. Second contact

Hello, my name is_____. **Thank you, once again, for giving of your time and allowing me to speak further with you about my research. To recap:**
As stated during our previous contact on <DATE of first telephonic contact> I am a (student/faculty member/staff member) from Stellenbosch University NAME OF DEPT/SCHOOL. I called you to invite you to participate in a research study and sent you a copy of the study information as well as a copy of the consent form. [CONFIRM that the participant has received the information.]

As discussed previously, the purpose of this call you is to hear whether you are still willing to participate in my/our study, and to hear if there are any questions you have regarding the information that was sent to you. [If the potential participant has any questions or points of clarification, address these in full.]

If you do not have any questions, can we kindly proceed to conclude the process of your consenting to take part in the study. If you are happy to proceed, we can go ahead to have you confirm your participation by returning your signed consent form via <*WhatsApp/SMS/email*>.
[Provide a recap of details of when study procedures will commence, confirm communication mechanisms in case of participant wishing to contact researcher/study team, and provide any further information that the participant may need.]

Thank you, I will await your return of the signed informed consent document that was sent to you. Please let me know if you have any further questions. Please feel free to contact me at <**insert phone number, and email**>. My research supervisor is <**insert name**> and he/she can be reached at <**insert phone number and email**>.

You will recall that the information I sent to you previously has all the contact numbers for me, the **Principal Investigator/Research Supervisor as applicable to your study>** and the **Health Research Ethics Office, Stellenbosch University,** should you require additional information or to raise a complaint.

Final step

Discuss/recap how ICF will be sent and returned and logistics for interview or survey etc. If a signed copy of the ICF is required (based on study risk category) arrange for hard copy to be signed at study site.

Thank you for your interest and willingness to take part in the research study on <Confirm date>.