**CONDUCT OF RESEARCH INVOLVING MINORS – WAIVER OF PARENTAL CONSENT**

**Aim:** To provide clear guidance to researchers who are seeking SAMRC HREC approval for parental waiver.

**Introduction:**

1. **Regulatory Framework:**

The National Health Act (“the Act”) 63 of 2003 in sections 71 (2) and (3) provides guidance on the conduct of research involving minors. These sections require that research be conducted with consent of a parent or guardian, and with the consent of the minor if the minor is capable of understanding. At the time these sections were enacted without provision for the recognition of exceptional circumstances.

The result being that they may potentially preclude minors from benefiting from research where they have factual but not legal capacity to consent independently and where the research is sensitive in nature and may incur parental sanction. For example: where minors may be involved in activities that make them vulnerable to parental disapproval or sanction (e.g. drug use), and parental consent for studies of such problems may place minors at risk of harm or impede their enrolment. Minors with no parents/guardians are precluded from research enrolment and such children as a class are precluded from research results that might benefit them.

It is well established that HRECs should only approve consent strategies that deviate from the consent approach set out in section 71 of the Act where this approach is clearly provided for in national ethics guidance. If HRECs are to follow national ethics guidance rather than the Act, they should document their decisions carefully to show that they have made their decision based on the norms and standards of national ethics guidelines and after careful consideration and deliberation.

The responsibility rests on the researcher to provide the HREC with a clearly motivated protocol in terms of section 3.2.2.4 of the Department of Health’s *Ethics in health research: principles, processes and structures* (‘Guidelines 2015’), which states that there are circumstances when it may be ‘desirable’ and ‘ethically justifiable’ for a minor to ‘choose independently’ (without parental assistance)to take part in health research.

These are detailed as three inclusive factors, namely

1. The risks are minimal;
2. The child is ‘older’ (i.e. ≥16 years);
3. Researchers have provided ‘evidence’ of engagement with participating community role players indicating that a waiver of parental consent is acceptable.

Furthermore, researchers need to discuss and provide details on how they will deal with other legal or statutory requirements, for example the provisions of Section 32 of the Protection of Personal Information Act 4 of 2013, when parental waiver is sought.

Mandatory reporting requirements in terms of Section 54 of the Sexual Offences and Related Matters Amendment Act 32 of 2007 must be addressed as to how this will be managed, mitigated, and reported should a parental waiver be granted.

Finally, in accordance with ‘*the best interest of the child’* criterion as contained in the Children’s Act 38 of 2005, a clear referral pathway must be identified and detailed in incidences where the minor may require additional psychological or medical referral.

1. **Procedure**

It is important to note that this waiver is applicable to ***non-therapeutic research*** involving minors. In order for the HREC to consider and approve a parental waiver and the approach taken by the researchers, the following must be clearly identified, discussed and detailed:

1. The protocol must be identified as that of research involving minors and seeking parental waiver;
2. The protocol must include a clearly identified motivation that deals with section 3.2.2.4 of the Guidelines (2015) in regard to risk, the age of the minor and clear evidence of community engagement and/or any other factor that may be relevant for the Committee to consider;
3. A section detailing compliance with section 32 of the POPI Act and how it will be legally managed;
4. Mandatory reporting requirements and how this will be managed and escalated (where relevant);
5. Clearly identified pathway referrals including that of the inclusion of consulting professionals to ensure ‘*the best interests of the minor child’* is protected in accordance with the provisions of the Children’s Act;
6. Furthermore, the HREC may deem it fit to invite the researchers to join a HREC meeting to discuss the protocol and any concerns or clarity the HREC may require prior to approval;
7. A distress protocol needs to be part of the submission, such as Appendix A.

Du Toit sign

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**Chairperson: SAMRC Human Research Ethics Committee**

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**APPENDIX A**

**Procedures for managing distressed participants and mandatory reporting[[1]](#endnote-1)**

Given the nature of this study, there may be instances, where you as a researcher is faced with a distressed participant who you are concerned needs additional or immediate mental health support. For the most part, you can address this by talking to the participant and providing them with a referral to see the mental health nurse or for additional substance abuse services.

1. **What is a distressed participant?**

By “distressed” we mean that a participant shows signs of experiencing negative emotions and by his/her words, expressions, or other nonverbal behaviors or body language indicates that s/he is emotionally upset.

**Possible signs or indications of distress:**

* A participant who is tearful and/or reports that s/he feels badly or is sad
* A participant who shows signs of being considerably more nervous or anxious (e.g. very nervous speech, increased sweating, difficulty sitting still during the appointment) than would be expected during an appointment.
* A participant who seems agitated or aggressive and that you cannot easily calm down.

**1.1 Steps to follow with mildly distressed participants who need additional services**

In most cases of distress, participants may talk about feeling badly but you will be able to manage or contain these feelings and continue with the appointment. They may however, need additional services or support once the counselling intervention has been completed.

In these cases, complete the following steps at the end of the study appointment:

* Indicate to the person that they seem upset or anxious
* Discuss with the participant the importance of additional support
* Ask if they would like to receive additional services to talk more about feelings that came up during the course of the study
* If the participant indicates s/he would like to talk with someone further, ask if they would like you to refer them to an organization
* Complete the referral and release form
* With the participant’s permission, call the agency or the clinic nurse to make an appointment
* Provide the patient with a copy of the referral letter in an envelope and keep one in the participant’s file
* Provide the participant with a copy of the resource guide for additional services
* If the participant indicates that s/he does not want you to make a direct referral, suggest various organizations for him/her to contact on her own and give them a copy of the resource guide.
* At the end of the appointment, document this referral in the Participant’s file

These steps should only be followed if the participant shows signs of distress or expresses a need for more counselling- but ***no suicidal intent or imminent harm is disclosed or suspected***.

**If the person expresses any desire to end their life or hurt themselves or others, follow the steps described in 1.2 and the mandatory reporting procedures described in section 2.**

**1.2 Steps to follow with very distressed participants**

There may be instances where participants are so distressed that you are concerned for their safety and may not be able to continue with the appointment. Remember that we have made it clear in the consent form that there are exceptions to our promise of confidentiality. If participants express the intent to harm themselves or others, or ongoing abuse and/or neglect of children, then we have a duty to report this matter to the proper authorities, e.g. the police, courts or social workers. Field staff will provide information on toll-free hotlines that people can call to talk to someone and seek assistance, as well as local resource information.

If during the course of the study you are concerned that a participant intends to harm him/herself or others, then mandatory reporting procedures need to be followed on completion of the appointment. Immediately inform the project manager and the principal investigator (PI) who will report the incident to the various ethics committees and our project officer within 72 hours.

In these instances, please follow the following steps:

* As far as possible, complete the study appointment
* Indicate to the person that they seem upset or anxious
* Remind the person of the limits of confidentiality as expressed in the consent form, and your duty to report
* Follow the mandatory reporting procedures described below
* Complete the referral and release form
* Call the agency to make an immediate appointment
* Provide the patients with a copy of the referral letter in an envelope and keep one in the participants folder
* Provide the patient with a copy of the resource guide for additional services
* At the end of the appointment, document this referral in the Participant’s file
* Complete an incident report form and immediately send to the project manager and PI who will both keep copies on file and will report the incident to the relevant regulatory bodies.

1. **Mandatory reporting procedures**

It is possible that a participant will indicate during the course of a discussion that s/he is in immediate danger of harm or poses a threat to the safety of others. We want you to feel that you can handle this situation with confidence.

There are essentially three situations in which there may be immediate danger of harm:

1. **Suicidal Intent:** The participant expresses a desire to hurt or kill themselves.
2. **Hurtful Intent to Others:** The participant expresses an interest in hurting or killing someone else (not necessarily someone living in the household).
3. **Child Abuse and Neglect:** Ongoing abuse and/or neglect of children.

The rest of this protocol describes what to do in each of these cases. For each of these cases, you must follow compulsory or mandatory reporting procedures.

These procedures are important to follow because they take away the responsibility of you having to decide what to do. These procedures are in your best interest and in the best interest of the participant- they are to keep the participant safe and unharmed.

**2.1 Suicidal intent**

If a participant expresses an interest in harming or killing him/herself, assess whether the risk is immediate or not immediate by following this procedure:

Ask the following questions:

|  |  |  |
| --- | --- | --- |
|  | **In the past month** | |
| Answer Questions 1 and 2 | **YES** | **NO** |
| 1. ***Have you wished you were dead or wished you could go to sleep and not wake up?*** |  |  |
| 1. ***Have you actually had any thoughts about killing yourself?*** |  |  |
| If **YES** to 2, answer questions 3, 4, 5, and 6. If **NO** to 2, go directly to question 6 | | |
| **3) *Have you thought about how you might do this?*** |  |  |
| **4) *Have you had any intention of acting on these thoughts of killing yourself, as opposed to you have the thoughts but you definitely would not act on them?*** |  |  |
| **5) *Have you started to work out or worked out the details of how to kill yourself?***  ***Do you intend to carry out this plan?*** |  |  |
|  | **In the Past 3 Months** | |
| **6) *Have you done anything, started to do anything, or prepared to do anything to end your life?***  Examples: Collected pills, obtained a gun, gave away valuables, wrote a will or suicide note, took out pills but didn’t swallow any, held a gun but changed your mind or it was grabbed from your hand, went to the roof but didn’t jump; or actually took pills, tried to shoot yourself, cut yourself, tried to hang yourself, etc.  ***In your entire lifetime, how many times have you done any of these things?*** | **YES** | **NO** |
|  | |

If the person answers YES to either questions 4, 5, or 6, this is a red flag and you should consider them at high risk for suicide. Risk is not immediate if the person is expressing some suicidal thoughts to describe how badly they feel but they do not have a plan. In the instance of high risk, follow the script below:

**2.1.1 Procedure: IMMEDIATE or HIGH RISK of SUICIDE**

If you assess that the participant is at **immediate risk** to him/herself, read the following script to the participant:

**Script: Risk of participant suicide or self-injury (immediate danger of harm)**

**Team member reads:**

“When you agreed to participate in this study, I promised that I would tell someone what you told me only if it was necessary to protect you or other people. You told me earlier that you were thinking of harming yourself. I suggest we contact an organization called LifeLine or SADAG and let them know so they can talk to you about how you feel. LifeLine and SADAG offers counseling. You can discuss your problem with one of their counsellors and they may be able to help you. Do you want to call them or should I call them for you?”

**Willing participant:**

* If the participant agrees to contact Lifeline or SADAG, use the project phone to make the call for the participant, hand them the phone and go to another room to give them privacy during the call.
* If the participant asks you to make the call on their behalf, use the project phone to make the call for the participant, and follow the script when speaking to the counsellor
* After the script has been read, hand the phone to the participant and go to another room to give them privacy in the call.

**Script: Risk of participant suicide or self-injury (immediate danger of harm)**

**Team member reads to telephone counsellor**

“We are conducting a research study and during an appointment, the participant expressed s/he was thinking of killing or harming him/herself. The participant has requested that we make this call for him/her.

Please note that this information was obtained through their participation in this research study. We went through appropriate informed consent, including telling the participant that a report might be made if the information s/he provided raised concerns about his/her well-being. I can give you additional information about the research study, if you would like. I can also provide you with the participant’s name.” Would you talk with him/her?

**Unwilling participant**

* If the participant is unwilling to contact the crisis hotline and doesn’t want you to contact them, then you should immediately contact the project manager who should immediately contact a registered psychological counsellor who can assess the situation (e.g., determine reasons why the participant is unwilling to contact the hotline so these issues can be addressed) and who can contact one of the psychologists or the medical doctor in the investigative team for further inputs.
* In the meantime, do not leave the participant by him/herself nor let them leave on their own, as they pose a risk to themselves.
* Ask the participant if s/he has a close family member or friend who can come to sit with them until you receive clear instructions about what to do.
* If the participant remains unwilling to contact the hotline, provide the participant with the referral guide as well as the counselling hotline numbers.
* Make sure you document who you spoke to and the advice provided on the incident form

**Script: Risk of participant suicide or self-injury (immediate danger of harm - unwilling to contact hotline)**

**Read to participant**

“You told me earlier that you had thought about harming yourself, and this concerns me. I have to report this information to the appropriate authorities. I can also take you to the mental health nurse, refer you to the family physician or call LifeLine or SADAG on your behalf. I strongly suggest that you contact LifeLine or SADAG or go and speak to a doctor. Here is information about the telephone hotline that you could call to discuss your problem with a counselor. If you feel that this is an emergency now or later, you should go to a hospital emergency room right away. If you are unable to get to an emergency room without help, you should call the police for assistance."

After giving this information to the participant, immediately contact the hotline and adhere to the following script. The hotline will advise you on next steps.

**Script: Risk of participant suicide or self-injury – to hotline**

“During an appointment for a research project project, a participant expressed s/he was thinking of killing or harming themselves. The participant was encouraged to call LifeLine or SADAG and seek further professional assistance, but we also informed the participant that we have to report the situation. The participant was unwilling to contact anyone for help nor allow us to contact anyone on his/her behalf. S/he is with us now, but we are concerned about her safety.

Please note that this information was obtained through their participation in the study. We went through appropriate informed consent procedures, including telling the participant that a report might be made if the information s/he provided raised concerns about his/her well-being. I can provide you with the participant’s name and residential area. Please can you advise us as to next steps to follow.

**2.2. Hurtful intent to others**

It is unlikely, but someone may spontaneously tell you that they are planning to seriously hurt or kill someone else. If a participant expresses an interest in harming or killing someone else, you should take the following steps.

* As far as possible, complete the study appointment
* Indicate to the person that they seem upset
* If they are expressing a desire to hurt someone else, explore whether there is an immediate risk (i.e. they have a plan and the means to do it)
* If there is immediacy and a plan, remind the person of the limits of confidentiality as expressed in the consent form, and your duty to report.
* Follow the mandatory reporting procedures described below
* Follow the reporting procedures - complete an incident report form and immediately send to the project manager and PI who will both keep copies on file.

**2.2.1 NO IMMEDIATE RISK**

If no immediate danger is perceived, advise the project manager and the PI immediately who will evaluate the seriousness of the issue and give advice on what to do. If the danger of harm is definitely credible, then the authorities will be called to report the incident. If the danger of harm is believed to definitely be credible, you may be advised to contact the police. In this case, please follow the script below.

**Script: Risk of someone being harmed or killed revealed by participant**

**Team member to read to police**

“We are conducting a research study, and during an appointment, a participant expressed an interest in harming or killing someone. I have discussed this situation with my supervisors and we have decided that this person might pose a real threat, so we are alerting you.

Please note that this information was obtained during an appointment that was conducted for this research study. We went through appropriate informed consent procedures, including telling the participant that a report might be made if the information s/he provided indicated that s/he might harm him/herself or others. I can give you additional information about this research study, if you would like. I can also provide you with the contact information for the participant.”

**2.2.2 IMMEDIATE RISK**

If immediate danger is perceived please alert the project manager and the PI immediately and they will report the incident to the authorities. Do not let the participant leave before you have instructions from the police or the trial manager as to next steps to take. Please follow each of these steps.

**Script: Risk of someone being harmed or killed revealed by participant during the appointment**

**Project manager or PI to read to the authorities**

“We are conducting a research study, and during an appointment, a participant expressed that s/he intended to harm or kill someone, so we are alerting you.

Please note that this information was obtained during an appointment that was conducted for this research study. We went through appropriate informed consent procedures, including telling the participant that a report might be made if the information s/he providedindicated that s/he might harm themselves or others. I can give you additional information about the research study, if you would like. The participant is here at the moment.”

It is unlikely that you will be faced with this situation!

**2.3 Child abuse/neglect**

Someone may tell you that s/he has abused or neglected a child or has been/is being abused, if a minor. If a participant reports this, you must report the incident to the authorities i.e Police (if sexual abuse) and Social Services/Childline (if any other type of abuse) after completing the appointment.

Note that, if an adult or even a person over the age of sixteen (in some cases where the age gap is more than two years above the other minor[[2]](#footnote-1)) is having sex with a minor aged 12 to 15 years, even if it is consensual, it must be reported to the police.

Follow these steps:

* As far as possible, complete the study appointment
* Indicate to the person that they seem upset
* If they are reporting abusing a child or is a minor reporting that they or another minor a being abused, remind the person of the limits of confidentiality as expressed in the consent form, and your duty to report
* Follow the mandatory reporting procedures described below
* Follow the reporting procedures - complete an incident report form and immediately send to the project manager and PI who will both keep copies on file.
  + 1. **PARTICIPANT (UNDER 18) BEING ABUSED OR NEGLECTED**

**Script: Minor participant being abused or neglected revealed during the appointment**

Team member to read to authorities:

“*We are conducting a research study, and during an appointment with a participant, who is a minor, certain indications were made that the participant has possibly been physically or sexually abused or neglected. This led us to conclude that it was necessary to contact you to alert you of our concerns.*

*Please note that this information was obtained through the participant’s participation in this research study, with appropriate informed consent procedures which included telling the participant that a report might be made if the data raised concerns about a her well-being. I can give you additional information about this research study, if you would like. I can also provide you with the contact information for the participant.*”

**2.3.2. PARTICIPANT ABUSING OR NEGLECTING A CHILD**

**Script: Child being abused or neglected by participant revealed**

Read to authorities:

“We are conducting a research study, and during an appointment with a participant, certain indications were made that the participant has possibly physically or sexually abused or neglected a minor. This led us to conclude that it was necessary to contact you to alert you of our concerns.

Please note that this information was obtained through the participant’s participation in this research study, with appropriate informed consent procedures which included telling the participant that a report might be made if the data raised concerns about a child’s well-being. I can give you additional information about this research study, if you would like. I can also provide you with the contact information for the participant.”

**3. CONTACT DETAILS**

|  |  |  |
| --- | --- | --- |
| **DESIGNATION** | NAME | CONTACT NUMBER |
| **Principal Investigator** |  |  |
| **Project supervisor/s** |  |  |
| **Clinical Psychologist** |  |  |
| **LifeLine** |  |  |
| **SADAG** |  |  |
| **SAPS** |  |  |
| **Social Services** |  |  |

1. This document was adapted from Myers, B & Carney, T. (2016), *Protocol for identifying and managing distressed participants aged 15 and above*, as part of the project MIND and Women’s CoOp studies. Alcohol, Tobacco and Other Drug Use Research Unit, SAMRC. [↑](#endnote-ref-1)
2. A person aged 12 can consent to sex with someone who is 14 years old, but not someone who is 16. A minor below the age of 16 having sex with a minor below the age of 12 is also a reportable offence. [↑](#footnote-ref-1)