

SOP 5: Research Involving Minors

The South African College of Applied Psychology Review Ethics Committee (SACAP REC)	
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1. COMPILATION AND AUTHORIZATION

Action	Designated person	Date	Signature
Compiled for SACAP by	Dr Malesa Kgashane	6 August 2021	
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Checked by	Academic Manager	10 November 2021	C.E. Ford
Authorised by	Academic Dean	18 January 2022	J.O. Lotter

2. DOCUMENT HISTORY

Date	Version no	Reason for revision
July 2021	1	Development of the document

3. DEFINITION OF TERMS AND ABBREVIATIONS

Abbreviation/ Term	Definition
SACAP REC	The South African College of Applied Psychology Research Ethics Committee

SOP	Standard Operating Procedure(s)
Adolescent	A child between the ages of 12 and 17 years of age (ICH Topic E 11 Clinical Investigation of Medicinal Products in the Paediatric Population. 2000 [http://www.emea.eu.int/pdfs/human/ich/271199EN.pdf])
Caregiver	A person who factually cares for a child (Children’s Act, 38 of 2005). A caregiver is obliged (in terms of section 32(1)) to safeguard the child’s health, well-being and development, and to protect the child from abuse and other harms. Furthermore, a caregiver may exercise the parental right to consent to medical examination or treatment of the child (in terms of section 32(2)).
Child	A person under the age of 18 years (section 28, SA Constitution; section 1 Children’s Act 38 of 2005).
Child-headed household	Where there are no adult carers available and children live on their own. An older child will often care for siblings, cousins, nephews or nieces. A household as defined in section 137 Children’s Act 38 of 2005.
Guardian	A person appointed by a court to look after the financial and welfare interests of a minor, or a person appointed by a parent with sole responsibility for the minor in terms of the parent’s will.
Harm	Refers to physical, emotional, psychological, social or legal harm.
Minor	A person (child) less than 18 years (section 17 Children’s Act 38 of 2005).
Neonate	A new-born child, including an infant less than a month old.
Orphan	A child who has no surviving parent caring for him or her (section 1 Children’s Act 38 of 2005).
Parent	Includes an adoptive and Foster parent (as per Children’s Act 38 of 2005).
Therapeutic research	Research that includes interventions that may hold out the prospect of direct health-related benefit for the participant (Regulation 135).
Non-therapeutic research	Research that includes interventions that will not hold out the prospect of direct health-related benefit for the participant but may produce results that contribute to generalizable knowledge (Regulation 135)

4. PURPOSE OF THE SOP

Research involving children requires additional ethical, regulatory and legal protections. The purpose of this SOP is to outline general and specific ethical, regulatory and legal requirements for conducting research with children and adolescents.

5. SCOPE

The scope of this document covers the ethical issues when conducting research with children and adolescents. It covers the responsibilities and procedures to be followed for research activities with the aforementioned group.

6. RESPONSIBILITIES

The SACAP REC must determine whether the risks to minors are sufficiently minimised, informed consent and assent are appropriately obtained, and that privacy and confidentiality protections are adequate.

7. PROCEDURE(S)

7.1. Minimum Conditions for Research Involving Minors: The SACAP REC in reviewing research with child and adolescent participants, must include members with appropriate child and adolescent research experience. The following considerations are critical when the SACAP REC reviews proposals to involve child and adolescent participants:

- 7.1.1. Children should participate in research only when their participation is scientifically indispensable to the research. The research should investigate a problem of relevance to children. The protocol should provide sufficient information to *justify clearly why children should be included as participants*, and the research could be deemed to meet the best interests of the child criteria.
- 7.1.2. The following is the criteria which must be considered when determining a child's 'best interests':
 - 7.1.2.1. age, maturity and stage of development;
 - 7.1.2.2. background;
 - 7.1.2.3. the child's intellectual, emotional, social and cultural development;
 - 7.1.2.4. any disability a child may have; and
 - 7.1.2.5. any chronic illness from which a child may suffer.
- 7.1.3. Children should participate in research only where such research poses acceptable risks of harm. That is, research involving minors should be approved only if the research, including observational research, is not contrary to the best interest of the minor.
 - 7.1.3.1. The research, including observational research, places the minor at no more than minimal risk of harm (i.e. the 'everyday risks standard' which means the risk of harm is equal with daily life in a stable society or routine medical, dental, educational or psychological tests or examinations; or
 - 7.1.3.2. The research involves greater than minimal risk of harm, but provides the prospect of direct benefit for the minor. The degree of risk of harm should be justified by the potential benefit; or
 - 7.1.3.3. The research, including observational research, involves greater than minimal risk of harm, with no prospect of direct benefit to the minor, but has a high probability of providing significant generalizable knowledge.

- 7.1.4. The SACAP REC will consider the degree of risk of harm should be justified by the risk-knowledge ratio, meaning that the contribution to knowledge outweighs the risk associated with conducting the research with minors.
- 7.1.5. The SACAP REC will evaluate the consent process for research involving minors, as research involving children must respect their evolving capacity to give consent. Children should participate in research only where the proper written permissions have been obtained. The consent process for a minor's participation in research requires:
- 7.1.5.1. Permission in writing from parents or legal guardian for the minor to be approached and invited to participate (in accordance with section 10 of the Children's Act 38 of 2005);
 - 7.1.5.2. Assent from the minor in writing (i.e. agreement to participate) if he or she chooses to participate.
 - 7.1.5.3. Children's privacy and confidentiality interests should be addressed in the assent form, respecting their right to not be identified in the research findings unless they and their parents or legal guardians provide written consent for identifying details to be included in the research findings.
 - 7.1.5.4. Limits of confidentiality, such as when the researchers have a legal obligation to report child abuse and neglect. They should report under the Children's Act 38 of 2005 (as amended by Act 41 of 2007) in instances where the child discloses to the researcher any experiences of physical abuse causing injury, deliberate neglect sexual abuse that includes sexual offences. Further to this. the researchers must disclose to the relevant authorities if children disclose experience of rape and sexual assault, statutory rape and sexual assault, and sexual penetration or other sexual activity as per the Criminal Law (Sexual Offences and Related Matters) Amendment Act No.32 of 2007.
- 7.2. Parental or Legal Guardian Permission for Research Involving Children:** Parents or legal guardians may not decide whether their minor child should participate in research without the minor's contribution to the decision. The parent or guardian is requested to give permission for the minor to be approached and to be invited to participate in the study. The parental permission and minor's decision must be consistent. The parents or legal guardians should be used in descending order, as listed.
- 7.2.1. The minor chooses whether to participate and thus expresses their will after;
 - 7.2.2. The parent gives assistance with understanding (so the minor makes an informed choice);
 - 7.2.3. If no parent, the guardian, either court-appointed, or as indicated by the parent in a will (section 27 Children's Act);
 - 7.2.4. If no guardian, then foster parent (per order of Children's Court). Note that social workers should request that the authority to give permission should be included expressly in the court order authorizing foster care;
 - 7.2.5. If no foster parent (per the point above), then caregiver (section 1 Children's Act: defined as "...any person other than a parent or guardian, who factually cares for a child and includes – a) a foster parent; b) a person who cares for the child with the implied or express consent of a parent or guardian of the child; c) a person who

cares for the child whilst the child is in temporary safe care; d) the person at the head of a child and youth care-centre where a child has been placed; e) the person at the head of a shelter; f) a child and youth care worker who cares for a child who is without appropriate family care in the community; and g) the child at the head of a child-headed household”); or

- 7.2.6. If a minor is a caregiver in a child-headed household and no supervisory adult (section 137 Children’s Act), then a trusted adult nominated by minor, including but not limited to social worker, community worker or teacher (*See Annexure A of SOP 5: Research Involving Minors for Parental/Legal guardian consent for child to participate in research template*).
- 7.3. Minors’ Independent Consent:** In certain conditions, e.g. for reasons of sensitivity, such as discussion related sexual activities, substance abuse, etc., it may be necessary and ethically justified for minors (especially older minors, i.e. 16 years and older) to choose independently, i.e. without parental assistance, whether to participate in research. Generally, only minimal risk research is suitable for independent consent by minors. An ethical justification for independent consent by minors may be made in the following conditions:
- 7.3.1. By prior engagement with participating community role players, the researcher can request, but needs to justify explicitly to the SACAP REC waiver of the parental (or substitute) should be permitted. Engagement could include outreach to relevant role players such as canvassing the opinion of a representative body of parents, e.g. via schools.
- 7.3.2. Factual evidence of such engagement must form part of the researchers’ justification in the protocol. Factual evidence may be in the form of a letter from a relevant role-player (like a community leader or school principal) that confirms the view that independent consent by minors is acceptable to the parents.
- 7.3.3. If the SACAP REC finds the ethical justification and the factual evidence of parental support for independent choice by their minor children acceptable, the SACAP REC may grant a waiver of the requirement of written parental permission and will document both the decision and the process followed carefully.
- 7.4. Guidelines for Drafting an Assent Form:** *“Assent is an interactive process between a researcher and child participant involving disclosure of cognitively and emotionally appropriate information regarding, at minimum, why the child is being asked to participate, a description of the procedures and how the child might experience them, and an understanding that participation in the study is voluntary. Children should understand that they can decline participation or withdraw from the study at any time. Assent requires that the child explicitly affirm his or her agreement to participate in a manner that reflects their age-appropriate understanding and that is free of undue influence or coercion. In the absence of an explicit agreement, mere failure of the child to object cannot be construed as assenting”.* For younger children, the document should be limited to one page if possible. Illustrations might be helpful, and larger font types make a form easier for young children to read. Studies involving older children or adolescents could include more information, but this information must be in simple, non-technical language (*Annexure B of SOP 5: Research Involving Minors includes an assent form template*). Researchers should draft a form that is:
- 7.4.1. Brief;

- 7.4.2. Contains simplistic language written at the appropriate age level;
- 7.4.3. Study specific;
- 7.4.4. Takes into account the typical child's experience;
- 7.4.5. Treats the child respectfully; and
- 7.4.6. Conveys the essential information about the study.
- 7.4.7. The assent form should:
 - 7.4.7.1. Tell why the research is being conducted;
 - 7.4.7.2. Describe what will happen and for how long or how often;
 - 7.4.7.3. Say that it is up to the child to participate and that it is okay to say no;
 - 7.4.7.4. Say what the child's other choices are;
 - 7.4.7.5. Describe any good things that might happen;
 - 7.4.7.6. Say whether there is any compensation for participating; and
 - 7.4.7.7. Ask for questions.

8. REFERENCE DOCUMENTS

- Children's Act 38 of 2005 (as amended by Act 41 of 2007)
- Constitution of the Republic of South Africa, 1996
- Sexual Offences and Related Matters Amendment Act No.32 of 2007
- ICH. (2000). *Clinical investigation of medicinal products in the paediatric population* (Topic E 11). <http://www.emea.eu.int/pdfs/human/ich/271199EN.pdf>
- Department of Health. (2015). *Ethics in health research: Principles, processes and structures*.
- Trait, A.R, & Geisser, M. E. (2017). Development of a consensus operational definition of child assent for research. *BMC Medical Ethics*, 18(41). <https://doi.org/10.1186/s12910-017-0199-4>

ANNEXURE A:
**PARENT/LEGAL GUARDIAN INFORMATION SHEET AND CONSENT FOR CHILDREN TO PARTICIPATE
IN RESEARCH**

We/I would like to invite your child to take part in a study conducted by (names of researchers) for the purposes of obtaining a (name of degree) at the South African College of Applied Psychology (SACAP). Your child will be invited as a possible participant because (explanation of why the child will be invited to participate).

Purpose of the study

(Briefly describe what the study is about in simple, non-technical language. Remember this consent form is for the parent to request their permission to approach their child to gain assent to take part in a research study)

What will be asked of my child?

If you consent to your child taking part in this study, the researcher will then approach the child for their assent to take part in the study. If the child agrees to take part in the study, they will be asked to (Briefly describe in simple, non-technical language all the research-activities the child-participant will be involved in for this study, detailing what they will be asked to do, the length of time estimated for each activity, the frequency of activities, and the location where activities will be done, etc.).

Possible risks and discomforts

(State any actual, potential, or perceived foreseeable risks, discomforts, inconveniences, and discuss how you will address or manage these risks to protect the child-participant, e.g. referral for counselling or therapy, etc.)

Possible benefits to the child or to the society

(State any direct or indirect benefits to child-participants that could be expected from their participation in the study. If the child-participant will not benefit directly, this should be clearly stated.)

Payment for participation

(State whether the child and/or parent will receive payment for participation or whether they will be compensated for any expenses paid to take part in the study, e.g. compensation for transport costs, entry into lucky draws, etc. If not, state so clearly. If participants will receive payment, state the amount, state when payment can be expected, and describe the pro rata schedule should the participant decide to withdraw.)

Protection of your and your child's information, confidentiality and identity

Any information you or your child will share with me during this study and that could possibly identify you or your child will be protected. This will be done by (Describe the measures or steps you will take

to ensure confidentiality and/or anonymity, where and how data will be stored, who will have access to it, etc.)

(If the information will be released to or shared with any other party/agency for any reason [e.g. translator, transcriber, language editor], please mention this here and identify the person/agency to whom the information will be furnished, the nature of the information, and the purpose of this disclosure. State whether the participant has the option to opt-out of their information being shared.)

(If activities will be audio-recorded, photographed or videotaped, mention this here and state whether the participants will have the opportunity to review/edit the tapes, who will have access to these recordings, if they will be used for educational purposes, and when they will be erased.)

(State whether the information collected for this study will be used for future publications and/or used for other purposes in the future. If you plan on publishing the results of the study, describe how confidentiality and/or anonymity will be maintained in the publication.)

Participation and withdrawal

You and your child can choose whether to be part of this study or not. If you consent to your child taking part in the study, please note that your child may choose to withdraw or decline participation at any time without any consequence. Your child may also refuse to answer any questions they don't want to answer and still remain in the study. The researcher may withdraw your child from this study if (Describe the anticipated circumstances under which participation may be terminated without regard to the child's assent or parent's consent.)

Researchers' contact information

If you have any questions or concerns about this study, please feel free to contact (names of researchers) at (researchers' contact information), and/or the supervisor (Supervisor's name and surname) at (Supervisor's contact information).

Rights of research participants

Your child may withdraw their consent at any time and discontinue participation without penalty. Neither you nor your child are waiving any legal claims, rights or remedies because of your participation in this research study. If you have questions regarding your or your child's rights as a research participant, contact the REC Office on rec@sacap.edu.za.

DECLARATION OF CONSENT BY THE PARENT/LEGAL GUARDIAN OF THE CHILD PARTICIPANT

As the parent/legal guardian I confirm that I agree to the following: (Please circle the relevant options below)

I have read the above information and it is written in a language that I am comfortable with.	<input type="radio"/> Yes	<input type="radio"/> No
The research study was explained to me, including the aim of the study, procedures, potential benefits and anticipated inconveniences of participation.	<input type="radio"/> Yes	<input type="radio"/> No
I understand what this study is about as explained in the Parent/Legal Guardian Information Sheet and Consent Form for Children to Participate in Research.	<input type="radio"/> Yes	<input type="radio"/> No
I agree that I had sufficient opportunity to ask questions and have received satisfactory answers to all of my questions.	<input type="radio"/> Yes	<input type="radio"/> No
All issues related to privacy, and the confidentiality and use of the information have been explained.	<input type="radio"/> Yes	<input type="radio"/> No
I understand that my child can volunteer to take part in the study, that I am free to withdraw his/her data at any time without consequence, and his/her data may be withdrawn prior to publication.	<input type="radio"/> Yes	<input type="radio"/> No
I understand that my child may refuse to answer any questions he/she would prefer not to.	<input type="radio"/> Yes	<input type="radio"/> No
I agree that my child may be audio recorded, video-recorded or photographed – as relevant to your study.	<input type="radio"/> Yes	<input type="radio"/> No
I understand that the audio and transcripts/completed questionnaire/survey will not be seen or heard by any person at any time and will only be processed by the researcher.	<input type="radio"/> Yes	<input type="radio"/> No
I understand that my child's responses on the questionnaire/survey will be only looked at in relation to all other responses, and that feedback given to the organisation/company/institution will be in the form of group responses and not individual perceptions.	<input type="radio"/> Yes	<input type="radio"/> No
I agree that direct quotations from my child's interview/focus group/other activity may be used by the researcher in their research report/ manuscript/book chapter.	<input type="radio"/> Yes	<input type="radio"/> No
I agree that my child's participation will remain anonymous and his/her responses will remain confidential (my child's name and any personal information will not be used by the researcher) in their research report/manuscript/book chapter/conference proceedings), unless authorised by myself.	<input type="radio"/> Yes	<input type="radio"/> No
I understand that all audio-recordings/video-recordings/photographs of my child will be destroyed after the research is complete.	<input type="radio"/> Yes	<input type="radio"/> No

I agree that the researcher may approach my child to take part in this study.	<input type="radio"/> Yes	<input type="radio"/> No
I understand I will be provided with a copy of this form for my records.	<input type="radio"/> Yes	<input type="radio"/> No

By signing below, I agree that the researcher may approach my child to take part in the research study.

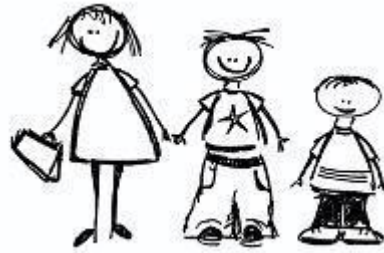
Child's Name and Surname	
Full Name and Surname of Parent/ Legal Guardian	
Signature	
Date	

DECLARATION BY THE RESEARCHER(S)

- As the researcher/s, we/I hereby declare that the information contained in this document has been accurately explained to and understood by the parent/legal guardian of the child named above, and that consent to approach the child to participate in this study was freely given by the parent/legal guardian of the child named above.
- We/I also declare that the parent/legal guardian was encouraged and given ample time to ask any questions.

Full Name of Researcher	
Signature	
Date	
Full Name of Researcher	
Signature	
Date	
Full Name of Researcher	
Signature	
Date	

ANNEXURE B:
CHILD PARTICIPANT INFORMATION SHEET AND ASSENT FORM FOR CHILDREN



Adult: A person who has attained the legal age of majority in the country where the research is to take place.

Children: Persons who do not have the legal age for consent to participate in research, usually being individuals who are under 18 years of age.

Assent (for children of 7–17 years): is a child's agreement to participate in research.

Guidance for child participant information sheet and assent form:

- Children with the ability to understand the basic concepts of research must assent to a research study. This is generally possible for children between the ages of 7 to 17 years of age, but these ages are not a fixed rule and some children younger than 7 years of age may also have sufficient insight and understanding to give assent for a study.
- If children refuse assent their refusal should be accepted, even if the parents have consented, although there are exceptional cases where this rule may not apply. The SACAP REC should be made aware of these instances, which will be evaluated on a case by case basis.
- This template is specifically developed for 7-12 year olds and should be adapted for adolescents, who may expect more adult type use of language.
- If the age range of children potentially involved in research are wide, you will need 2 different versions of assent, one for younger children and a more detailed one for adolescents.
- Adapt this template to suit the needs of your specific project.
- This minor assent form must be used in conjunction with a parental/legal guardian participant information sheet and consent form.
- Assent forms can be made more child friendly by the use of appropriate pictures.
- The language used in an minor assent form should be in layperson's terminology, and non-coercive. A practical guideline is that the content should be understandable to a 14-year-old. Sentences should be short and concise, with all initials and abbreviations explained.

CHILD PARTICIPANT INFORMATION SHEET AND ASSENT FORM FOR CHILDREN

Title of the research project	
Insert the title of your research project in simple, non-technical language.	
Researchers' name(s)	
Researcher's contact number	

What is research?

Research is something we do to find new knowledge about the way things (and people) work. We use research projects to help us find out more about children and the things that affect their lives, their schools, their families and their health. We do this to try and make the world a better place!

What is this research project all about?

Explain in simple child friendly language. Adapt the information according to the age range of child participants that the research targets.

Why have I been invited to take part in this research project?

Answer this question in simple, non-technical language.

Who is doing the research?

Identify yourself and explain who you work for and/or why you are doing the project.

What will happen to me in this study?

Describe what the participant will be expected to do. Describe all procedures using simple terms and explain any technical or medical term.

Can anything bad happen to me?

Use simple terms to explain any possible risks to the child. State if something might be painful or scary to the child. Explain to the child that they must tell his/her parents if they are sick or in pain during the course of the study.

Can anything good happen to me?

Only describe known benefits to the child. You may describe any possible future benefits for other children with similar conditions or in similar positions. State if there are no known benefits.

Will anyone know I am in the study?

Explain in simple terms that the child's participation in the study will be kept confidential, but certain information about him/her might need to be disclosed to authorities as required by law.

Who can I talk to about the study?

List those individuals the child can contact, including their contact details, if they have any questions or have any problems related to the study.

What if I do not want to do this?

Explain to the child that they can refuse to take part even if their parents have agreed to their participation. Explain that they can stop being in the study at any time without getting in trouble.

Do you understand this research study and are you willing to take part in it? (Tick appropriate box)

<input type="checkbox"/> Yes	<input type="checkbox"/> No
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or draw a circle around the face that shows me how you feel about talking to me.



Has the researcher answered all your questions? (Tick appropriate box)

<input type="checkbox"/> Yes	<input type="checkbox"/> No
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or draw a circle around the face that shows me how you feel about talking to me.



Do you understand that you can STOP being in the study at any time? (Tick appropriate box)

<input type="checkbox"/> Yes	<input type="checkbox"/> No
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or draw a circle around the face that shows me how you feel about talking to me.



Please print your name here _____

Full Name of Minor	
Signature or printed name for children	
Date	