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To Whom It May Concern,

**RE: UNIVERSITY OF THE WITWATERSRAND, HUMAN RESEARCH ETHICS COMMITTEE: (MEDICAL) – GUIDANCE DOCUMENT ON HOW TO DEAL WITH PREGNANCY TESTING, CONTRACEPTION, MANDATORY REPORTING AND ASPECTS OF CONSENT/ASSENT FROM A LEGISLATIVE AND STATUTORY PERSPECTIVE, IN RESEARCH INVOLVING MINORS (BY: ADV JANET EARLY):**

**1. INDEPENDENT ADOLESCENT CONSENT FOR VARIOUS HEALTH-RELATED INTERVENTIONS:**

In terms of the various provisions of the Children's Act, 2010, adolescents can independently, with the proviso being, *if they have sufficient capacity and maturity*, which legally is a subjective test, consent to:

- 1.1 HIV testing: from age 12, under 12's if they have sufficient capacity: s130 of the Children's Act;
- 1.2 Medical treatment from age 12, including for STI's and HIV, in terms of s 129, provided sufficient maturity exists, this being mental capacity to understand the benefits, risks, social and other implications of treatment;
- 1.3 Contraceptives and contraceptive advice, including emergency contraceptives from age 12 (s 134);
- 1.4 Termination of Pregnancy at any age in terms of the s5 of the Termination of Pregnancy Act, however providers must, (so a mandatory obligation exists) advise the participant to consult with their parents, guardian, family members before termination.
- 1.5 In all instances, adolescent participants should be reminded that, while they have the right to self-consent and independently so in respect of health interventions – adolescents should involve trusted adults for support and decision-making including parents. This aligns with the 'best interest of the child' criterion that drives the purpose and the spirit of the Children's Act and the views of the child must be heard, this is commonly deemed the 'voice of the child' interview. In my opinion, it would be unethical, potentially illegal and a conflict of interest if the researchers undertook this enquiry. This is where the involvement of an independent social worker, psychologist or as the Children's Act deems it, a suitably recognised professional be employed as an independent consult to ensure not only that the minimum requirements for capacity and maturity are determined but also that the minor research participant's view and opinions are independently sought.
- 1.6 It is also important for researchers to note that adolescent participants should be linked to appropriate service organisations by researchers, especially when the study population is vulnerable or may experience distress and/or as with all research involving minors that a mandatory reporting obligation exists. As per 1.5 above this function could also be undertaken by a social worker/psychologist.

- 1.7 In my opinion and as with all studies with minors, the greatest hurdle in respect of self-consent to various health -related interventions by adolescents in research is who will determine if the said adolescent has sufficient capacity and maturity in terms of the provisions of the Children's Act, with due noting that this determination must be undertaken with each participant, based on each participation's particular circumstances.
- 1.8 A minimum requirement for consideration and approval by the Wits HREC will be for the development and implementation of a SOP for managing distressed participants and also to assist in determining what would be recognised as sufficient maturity and capacity as it required by the Children's Act.

## **2. CONFIDENTIALITY/PRIVACY**

- 2.1 Minors have a right to privacy if there is an expectation of privacy that society regards as reasonable. The right to privacy is constitutionally entrenched in the Bill of Rights and in common law and in the case of minors based on the legitimate expectation test.
- 2.2 Adolescents can lawfully engage in sex at age 16 (Sexual Offences Act (s15, Criminal Law (Sexual Offences and Related Matters) Amendment Act 2007).
- 2.3 Furthermore provided the sexual relationship is not deemed statutory rape or/and exploitative, which would then override confidentiality in terms of mandatory reporting, the adolescent and by implication his/her sexual partner be that singular or multiple should enjoy confidentiality for their sexual risk data and have an expectation of privacy which would hold as reasonable. This in addition imposes a difficulty for the researcher who may want to follow the participant's pregnancy which will then require the disclosure of the partner(s) identity. With due consideration of not only the Constitution, common law privacy provisions and POPI, the participant would have to first obtain consent from his/her sexual partner to disclose the pregnancy and a refusal will not be deemed unreasonable. The researcher's will need to clearly anticipate that this could have a significant impact on the study.
- 2.4 Although a child's right to confidentiality regarding their health status can be limited where it is in their best interest to do so (s13(1)(d) Children's Act 2005. This limitation requires an evaluation, weighing and balancing of the child's physical, moral, emotional and spiritual welfare and also requires the child's wishes to be taken into account. There is no automatic override, just because the minor has consented to being a research participant and the parents/or legal guardian would have to be involved in the process.

## **3. MANDATORY REPORTING**

- 3.1 A broad range of persons have a mandatory obligation to report any child that has been sexually abused, deliberately neglected or abused in a manner causing physical harms. This would include a Principal Investigator/and or Sponsor.
- 3.2 In addition, any person who is aware of a sexual offence having been committed against a child must report this to SAPS as per the provisions of the Criminal Law [Sexual Offences and Related matters] Amendment Act 2007.
- 3.3 Reportable sexual offences are:
  - 3.3.1 All instances of commercial sex work or rape (including all sex with persons under 12, even if consensual);
  - 3.3.2 Where 16-17 years olds have sex/or sexual activity with 12-15-year olds if there is more than a 2-year gap between them;

- 3.3.3 Where persons older than 18 have sex/sexual activity with a child between the ages of 12-15 years even if consensual.
- 3.4 Although it is often argued that a nuanced approach should be taken in respect of mandatory reporting, these obligations are onerous and require a proactive stance with criminal sanction if not adhered to.
- 3.5 It must also be noted that when adolescent participants between the ages of 12 and 15 years report consensual sexual activity with an adult (over the age of 18 years) **this is statutory rape and must be reported within 48 hours of disclosure, in addition to the relevant HREC.**
- 3.6 Finally the consenting party or parties should understand what information about the enrolled adolescent will be kept confidential and what will be disclosed to another party, especially in terms of mandatory reporting.
- 3.7 Consent materials and discussions should clarify that parents will not be informed by the study team about adolescent's medical tests, contraception and risk behaviour even where a parental consent approach is adopted. However, adolescents should still be encouraged to make their own disclosures to trusted persons, which might include parents.
- 3.8 Consent materials and discussions should clarify that certain categories of sexual activity will be reported to authorities as well as underage consensual sex deemed to be exploitative.
- 3.9 All research involving minors must also include a SOP to manage the process of mandatory reporting and must be submitted to the HREC for consideration. In addition, were a mandatory reporting issue has arisen this must be reported to the HREC in addition to the continuous monitoring of the reporting until such time as the matter has been resolved.
- 3.10 With regards to consent/assent of minors in research, South African law does not recognise a "legally designated representative". Section 71 of the National Health Act permits only parents/legal guardians and in very limited instances alternative proxies which will mostly require legal recognition in the form of a court order.

#### 4. RECOMMENDATIONS

- 4.1 Protocols must align with South African legislation by considering the aspects contained in this guidance document, and ensure protocols adequately deal with these issues.
- 4.2 A SOP for distressed participants, mandatory reporting and ongoing monitoring and reporting back to the HREC, needs to accompany a submission.
- 4.3 The study staff should engage key stakeholders, including the employment of a statutory and independent social worker to secure expertise in making determinations about abuse, neglect and to provide services to affected adolescents as well as reporting back to the relevant HREC for monitoring purposes and to manage the Mandatory Reporting Requirements.
- 4.4 The services of a social worker or psychologist would also assist the study staff in determination of sufficient capacity and sufficient maturity which is a requirement for own consent in respect of health-related interventions or where conflictual or sensitive issues arise.
- 4.5 Guidance can be provided but the onus will remain on the applicants to anticipate the issues at hand with clear understanding of the legal provisions and mandatory reporting obligations.