

## NATIONAL HEALTH ACT: IMPLICATIONS FOR RESEARCH

HAVEG [www.saavi.org.za/haveg.htm](http://www.saavi.org.za/haveg.htm)

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The table below sets out the changes that will be introduced when s71 of the National Health Act (2003) is implemented, and the implications for research.

| PROVISIONS IN THE NHA (2003) s71   | HOW THE PROVISIONS WILL CHANGE THE EXISTING SITUATION  | IMPLICATIONS FOR RESEARCH  |
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| <p>S 71 (1) (b) Consent<br/>Consent must be <b>“written consent”</b></p>   | <p>Currently RECs may be permitting enrolment into research with <i>verbal consent</i> (e.g. for low risk research, or research where written consent constitutes a threat to confidentiality, or for certain methodologies like telephone interviews)</p> <p>Currently RECs may also be permitting <i>“passive consent”</i> from parents for research of a certain risk with children (i.e. sending consent forms home and if no objection is received, the researchers proceed to enrol minor-participants)</p>  | <p>When s71 is implemented, consent will have to be obtained in writing for all health research with human subjects</p> <p>The protocol will have to specify written consent, plus procedures for the signing of illiterate participants</p>   |
| <p>S 71 (2) Research with minors for a <i>“therapeutic purpose”</i></p> <p>Research must be in the <b>“best interests”</b> of the minor</p> <p>Research must be conducted with the <b>consent of the parent</b> or legal guardian of the child</p> | <p>The courts have generally held that the principle requires a wide range of factors to be considered to promote a child’s physical, moral, emotional and spiritual welfare during decision-making affecting the child (<i>Mc Call v Mc Call</i> 1994 (3) SA 201 (C) at 204). Recently the <i>“best interests”</i> principle is defined in section 7 of the Children’s Act, no 35 of 2005. However, the list of factors to be taken into account in establishing a child’s best interests are of little or no assistance when applied to research</p> <p>Currently there is no law that sets out when children may consent independently to <i>“therapeutic research”</i>. As the Child Care Act (1983) allows children to consent independently to treatment at 14, some scholars have argued that children may consent independently to TR at 14; and this position is upheld in the MRC (2001) <i>General Principles</i>. (Some scholars</p> | <p>RECS will have little guidance on the factors to be taken into account, and will need to establish their own guidelines on when <i>“therapeutic research”</i> is in the best interests of children</p> <p>When s71 is implemented, children (even older adolescents) may not consent independently to health research; even for research that holds out the prospect of direct benefit; or is of a low risk nature (i.e. parental consent will be required)</p> <p>The protocol will have to spell out that consent from a parent</p> |

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| <p>If the minor is capable of understanding, the minor should also <b>consent</b></p>  | <p>argue, however, that treatment and research cannot be likened). National guidelines for health research (DOH, 2004) also allow <b>independent consent</b> from older adolescents for low risk research. Therefore currently, some RECs are permitting independent consent from adolescents for research that may hold out benefit (or is of a low risk). Some RECs also allow for <b>consent from care-givers or custodians</b>. The future law will change this situation</p> <p>Currently, ethical guidelines allow that when parents/ legal guardians give consent for research participation, it is the <i>assent</i> of the minor that is obtained. S 71 will change that situation by requiring that children join their parent in giving formal consent when their understanding meets the higher threshold for consent</p> | <p>will be obtained</p> <p>Where no parent or legal guardian exists, children may not be enrolled in health research. This will endanger research with orphans and other vulnerable children</p> <p>The protocol may have to spell out how it will be established that adolescents enjoy the higher standard of competence to be able to consent, rather than assent</p> |
| <p><i>S 71 (3) (a) Research with minors for a “non-therapeutic purpose”</i></p> <p>The Minister must give consent</p> <p>As for TR, parental/ LG consent required plus consent of the child if they are capable of understanding</p> | <p>Currently, there is no additional procedural requirement for non-beneficial research with minors (only REC review). S 71 will require that when the research holds out no prospect of direct benefit, the Minister must review/ approve such studies. The exact definition of “NTR”, the scope of research that will fall into NTR, the sequence of the approval process, and the body to which this task may be delegated is not known</p>  | <p>When s71 is implemented, for NTR, the protocol should deal with:</p> <ul style="list-style-type: none"> <li>• Scientific necessity of the research</li> <li>• How it will benefit minor-participants directly or minors as a class</li> <li>• How the research is not contrary to public policy (i.e. meet acceptable risk standards)</li> </ul>                      |
| <p><i>S 71 “in the prescribed manner”</i></p> <p>Norms in the regulations for human subjects research must be complied with</p>  | <p>Currently the regulations are in a draft form</p>  | <p>Not clear yet</p>   |