



The Director-General: Health
(for the attention of the Director: Health Systems Research)
Private Bag x828
Pretoria
0001

29 July 2013

Submission on the 'Regulations Relating to Research on Human Subjects'

1. Context:

The National Health Act (Act 61 of 2003) was enacted in 2004 and provides the basic framework for health care in South Africa. Segments of the Act have been progressively implemented since 2004, while a number of sections in the Act require Regulations to operationalize its requirements.¹ Section 71 of the National Health Act, entitled "Research on or experimentation with human subjects" was proclaimed with effect on 1 March 2012.²

¹ Gray, A. and Jack, C. (2008), "Health Legislation and Policy" *South African Health Review 2008* Health Systems Trust.

² Section 71 of the National Health Act 61 of 2003 reads as follows:

71. (1) Notwithstanding anything to the contrary in any other law, research or experimentation on a living person may only be conducted-

(a) in the prescribed manner; and (b) with the written consent of the person after he or she has been informed of the objects of the research or experimentation and any possible positive or negative consequences on his or her health.

(2) Where research or experimentation to be conducted on a minor for a therapeutic purpose, the research or experimentation may only be conducted-

(a) if it is in the best interests of the minor; (b) in such manner and on such conditions as may be prescribed; (c) with the consent of the parent or guardian of the child; and (d) if the minor is capable of understanding, with the consent of the minor.

(3) (a) Where research or experimentation is to be conducted on a minor for a non-therapeutic purpose, the research or experimentation may only be conducted- (i) in such manner and on such conditions as may be prescribed;

(ii) with the consent of the Minister; (iii) with the consent of the parent or guardian of the minor; and (iv) if the minor is capable of understanding, the consent of the minor.

(b) The Minister may not give consent in circumstances where- (i) the objects of the research or experimentation can also be achieved if it is conducted on an adult; (ii) the research or experimentation is

On 29 May 2013, proposed “Regulations Relating to Research on Human Subjects” were published, inviting public input.³ The draft Regulations set out a range of principles of health research with human subjects as well as concomitant researcher obligations.

2. Background to this submission

This submission is made on behalf of the Southern African HIV Clinicians Society.⁴ It has been endorsed by a number of organisations that work on health research, programmes and policy, with a focus on HIV/AIDS. The list of endorsements is attached as Appendix A.

This submission is grounded in our experience as health researchers. We are all involved in different ways in research with human participants primarily in the field of HIV prevention and treatment. HIV research in South Africa has a long and proud history of grappling with the dynamics and complexities of HIV prevention, treatment and care in a southern African context and includes biomedical, socio-behaviourial, legal and policy research responses to the epidemic. These activities have been underscored by a strong commitment to both ethics and robust evidence-based interventions to combat HIV/AIDS.

As researchers, clinicians and/or programme-implementers we are particularly concerned about the on-going high rates of HIV infection amongst young people where 17% of 15-49 year olds are infected with HIV.⁵ Furthermore, HIV incidence rates peak in women between

not likely to significantly improve scientific understanding of the minor’s condition, disease or disorder to such an extent that it will result in significant benefit to the minor or other minors; (iii) the reasons for the consent to the research or experimentation by the parent or guardian and, if applicable, the minor are contrary to public policy; (iv) the research or experimentation poses a significant risk to the health of the minor; or (v) there is some risk to the health or wellbeing of the minor and the potential benefit of the research or experimentation does not significantly outweigh the risk.

³ Government Notice 378

⁴ This submission was drafted by Ann Strode (HIV/AIDS Vaccine Ethics Group (HAVEG), UKZN), Jacintha Toohey (HAVEG, UKZN), Melissa Wallace (Desmond Tutu HIV Foundation, UCT) and Marlise Richter (International Centre for Reproductive Health, Ghent university and African Centre for Migration & Society, Wits) following a consultative meeting with HIV researchers and programme implementers on 19 July 2013 convened by the Southern African HIV Clinicians’ Society. This submission benefitted from a range of comments and input from workshop participants and colleagues.

⁵ Rehle T. M., Hallett T. B., Shisana O., et al. (2010) A decline in new HIV infections in South Africa: estimating HIV incidence from three national HIV surveys in 2002, 2005 and 2008. *PLoS One*. 5(6):e11094.



15-24 years of age,⁶ with modelling estimates suggesting that 45% of all heterosexual transmission of HIV in South Africa occurs in this group.⁷ In view of the fact that young people, and young women especially, are at high risk of HIV infection, research among these groups is particularly vital to enable appropriate health and socio-legal responses. Equally important is a research focus on 'Key Populations' as set out in South Africa's AIDS Plan – the National Strategic Plan on HIV, STIs and TB 2012-2016.

We also note that the global trend is to be more inclusive in research practice and to facilitate research in minors whilst recognizing that minors need to be protected as a vulnerable population.⁸ By withholding them from research, we may in fact infringe their right to excellent health care and appropriate responses to unique challenges they may face.⁹

Accordingly, we respectfully submit for consideration the following written comments which are based on our practical experience in the field. We have made submissions on (a) our concerns with the current normative framework for health research with human subjects as set out in the National Health Act of 2003 (NHA); and (b) the draft regulations on human subjects.

3. Broader context: Concerns with the norms underpinning the regulation of health research with children and other groups

⁶ *ibid*

⁷ Johnson L. F., Dorrington R. E., Bradshaw D., et al. (2009) Sexual behaviour patterns in South Africa and their association with the spread of HIV: insights from a mathematical model. *Demographic Research*. 21: 289-340.

⁸ Sandy Fraser (ed.) *Doing Research with Children and Young People* SAGE, 2004

⁹ See for example the WHO: "There are no clear ethical justifications for excluding from research adolescent subjects below the age of legal majority. If there are reproductive health problems that are restricted to, or occur also in, adolescents which cannot be solved with existing knowledge, there is an ethical duty of beneficence and justice to conduct appropriate research to address these problems." World Health Organization Scientific and Ethical Review Group "Reproductive health involving adolescents" Available http://www.who.int/reproductivehealth/topics/ethics/adolescents_guide_serg/en/ [Accessed 23/07/2013] Also see Zuch et al. "Changes to the law on consent in South Africa: implications for school-based adolescent sexual and reproductive health research" *BMC International Health and Human Rights* 2012, 12:3 and Singh JA, Abdool Karim SS, Abdool Karim Q, Mlisana K, Williamson C, et al. (2006) Enrolling Adolescents in Research on HIV and Other Sensitive Issues: Lessons from South Africa. *PLoS Med* 3(7)



There have been many concerns and criticism articulated on the norms established in sections 11 and 71 of the NHA.

Key concerns about these provisions include the following:

- a.) They conflict with other laws such as the Children's Act.¹⁰ For example, the Children's Act allows children to consent to a range of health interventions before the age of 18 whilst the NHA prohibits any independent consent to research before adulthood;¹¹
- b.) In some instances they are diametrically opposed to the norms established in the National Health Research Ethics Council (NHREC) ethical guidelines.¹² For example, the national ethical guidelines allow in certain instances the waiver of informed consent or verbal consent to be obtained however the NHA requires written consent in all instances;¹³
- c.) They conflict with other parts of the NHA. For example, section 73 of the NHA provides that Research Ethics Committees (RECs) must grant approval to research that they deem ethical. However in some instances given that section 71 conflicts with many ethical norms, a study that is ethical will not necessarily be legal, effectively placing RECs within a quandary in choosing between their obligations in section 73 and those in section 71;
- d.) The rationale for a number of provisions such as ministerial consent is unclear and it offers limited additional protection for child research participants.¹⁴
- e.) The new norms in section 71 of the NHA do not address many of the pre-existing concerns and issues that had been raised about the previous ethical-legal framework where the norms were largely established within ethical guidelines.¹⁵

¹⁰ Children's Act 38 of 2005 and Stobie M, Strode A and Slack C 'The dilemma of enrolling children in HIV vaccine research in South Africa: what is in 'the child's best interests'?' in A van Niekerk and L Kopelman (eds) *Ethics and AIDS in Africa* Cape Town. David Philip Publishers (2005) 190 – 207.

¹¹ Strode A, Slack C and Essack Z 'Child consent in South African law: Implications for researchers, service providers and policy makers' (2010) Vol 100(4) *South African Medical Journal* 247 – 249.

¹² Stobie *op cit*

¹³ Ethics in Health Research: Principles, Structures and Processes, Department of Health (2004) <http://www.doh.gov.za/docs/factsheets/guidelines/ethnics/editors.pdf> [Accessed: 23 July 2013].

¹⁴ Strode AE, Slack CM, Wassenaar DR and Singh JA 'One step forward, two steps back – requiring ministerial approval for all forms of non-therapeutic health research with minors' (2007) Vol 97(3) *South African Medical Journal* 200 – 202.



f.) In some cases, provisions within the NHA are based on out-dated concepts such as the division of research into 'therapeutic' and 'non-therapeutic' protocols.¹⁶

Some of the far-reaching implications of the current framework of the NHA for our work include the following:

- (a) Mandatory parental consent in all instances means that it will no longer be possible to undertake certain forms of health research.
 - i.) For example, adolescent Men who have Sex with Men (MSM) are still highly stigmatised in South African society. If adolescent MSMs are approached to be research participants, they may face social harms if it is required of them to seek parental consent on their behalf to participate in research focusing on their sexuality or sexual practices;
 - ii.) Likewise, research into terminations of pregnancy with young girls will also be hindered or deemed impossible. It is foreseeable that very few teenage girls would be willing to approach their parents for consent to a study on a decision they had made individually to terminate a pregnancy, of which parents may not be aware. This anomaly is particularly striking in view of the fact that the Termination of Pregnancy Act provides specifically for terminations of pregnancy without parental consent for young girls, clearly recognizing their rights, as well as the community and national interest in preserving their health. This choice by parliament was held to be constitutionally valid by the High Court;¹⁷
 - iii.) Studies with children who do not have parents or legal guardians will no longer be possible due to the current limitation of the authority to provide proxy consent. Furthermore, such children may not volunteer for health research as they do not have an adult with the legal capacity to provide proxy consent. This principle may also apply to mothers under

¹⁵ Slack C, Strode A, Grant K and Milford C 'Implications of the Ethical-Legal Framework for Adolescent HIV Vaccine Trials: Report of a Consultative Forum' (2005) Vol 95(9) *South African Medical Journal* 682 – 685.

¹⁶ Stobie *op cit*

¹⁷ *Christian Lawyers Association v Minister of Health and Others (Reproductive Health Alliance as Amicus Curiae)* 2005 (1) SA 509 (TDP).

the age of 18 who have lost parental support, yet who are at particular risk of both HIV acquisition and transmission. This will also have far-reaching implications for research with child-headed households, orphaned and vulnerable children (OVCs) and undocumented migrant children in particular, as by 2015, some **5 700 000** children would have lost one or both parents to AIDS.¹⁸ OVCs are increasingly recognized as a special population in terms of HIV risk and transmission.¹⁹ OVCs and child-headed households are a unique and contemporary issue placing many South African institutions (including government) under tremendous pressure. Innovation and responsiveness are key factors to counter these challenges. While the children require protection, the area can ill afford to be neglected by research. Not including this population would be detrimental to participants who may benefit from it, but also in terms of HIV prevention and treatment as a significant proportion of the population will be excluded from having interventions researched for them;

- iv.) Studies into current illegal practices or people, such as adult drug use, sex work or undocumented migrants will also be complicated by concerns that the documenting of written consent may place participants at risk of criminal prosecution; and
- v.) Health research regarding private medical interventions provided to children over the age of 12 such as contraceptive studies or those relating to treatment for sexually transmitted infections will be hindered again by the parental consent requirement.

¹⁸ Holborn, L. & Eddy, G. (2011). *First steps to healing the South African family*. South African Institute of Race Relations. Johannesburg: South Africa.

¹⁹ Cluver, L., Orkin, M., Boyes, M., Gardner, F. & Meinck, F. (2011). "Transactional Sex Amongst AIDS-Orphaned and AIDS-Affected Adolescents Predicted by Abuse and Extreme Poverty". *Journal of Acquired Immune Deficiency Syndromes*: 58(3) p336-343



It is worth noting that in all of the above examples, adolescents in these circumstances are likely to be considerably more vulnerable and at risk than their peers, and research and consequent evidence-based intervention with these groups may be particularly pertinent. Likewise, as access to highly active antiretroviral therapy (HAART) improves globally, the population of vertically infected adolescents is expected to grow.²⁰ While youth aged 10-19 accounted for 1% of the total number of patients receiving HAART in South Africa in 2008, this proportion is expected to grow to approximately 5% by 2020, mainly as a result of vertically infected children surviving into adolescence.²¹ This population is accessing healthcare services en masse and we are ill equipped to manage the distinct nuances of treating them; research is urgently required if we are to curb the tide of new infections and managing the current prevalence in adolescents.

Given the principled nature of many of the concerns set out above, we *understand that they cannot be addressed merely through the issuing of regulations*. Regulations are subordinate legislation and the Minister of Health does not have the authority to amend the principles in the NHA in this manner. Nevertheless, we would like our concerns noted, and submit that the Ministry of Health must as a matter of urgency initiate a longer term law reform process to address these concerns.

4. Comments on the draft Regulations

We wish to turn to the draft Regulations and our responses to these.

i. Useful provisions within the draft Regulations

There are a number of areas in which the draft Regulations have provided clarity and will assist in the full implementation of sections 11 and 71 of the NHA.

²⁰ Ferrand, R.A., Corbett, E.L., Wood, R., Hargrove, J., Ndhlovu, C.E., Cowan, F.M., Gouws, E. & Williams, B.G (2009). "AIDS among older children and adolescents in Southern Africa: projecting the time course and magnitude of the epidemic". *AIDS*, 23, pp2039-2046.

²¹ Jaspan, H.B., Li, R., Johnson, L., & Bekker, L.G. (2009). "The emerging need for adolescent-focused HIV care in South Africa." *The Southern African Journal of HIV Medicine*, Dec, pp9-11



We submit that the following sections should be retained in the final draft of the Regulations:

- (a) The definitions in Regulation 1 of ‘best interests’, ‘council’, ‘human subjects’, ‘Medicines Control Council’, ‘minimal risk’, ‘non-therapeutic research’, ‘research ethics committee’, ‘significant risk’, ‘therapeutic research’ and ‘vulnerable persons’;
- (b) The protection of special classes of persons as set out in Regulation 4;
- (c) Other types of research that require special attention as set out in, Regulation 5;
- (d) Informed consent as set out in Regulation 6;
- (e) Review of research proposals by an REC as set out in Regulation 7; and
- (f) Details set out for ministerial consent for non-therapeutic research with minors, Regulation 8. This section of the Regulations paves the way for the Minister of Health to *delegate the authority to consent for such research to REC registered with the National Health Research Ethics Council* – the strategy that the NHREC has recommended as per its correspondence with REC Chairs in December 2012 (see Appendix B). This is a helpful addition to the Regulations, and will offset many of the concerns identified with the overly broad wording of the ministerial consent requirement in the NHA.²² Whilst we are pleased that attempts are being made to mitigate the impact of this provision, we would like to re-iterate our concern regarding the assumption underlying the legislative framework that research with children are inherently exploitative.

ii. *Areas in which the draft regulation should be revised, amended or supplemented*

There are some areas in the draft regulations where further clarity is required or gaps should be filled. We would like to propose the following amendments:

a) *Terminology.*

It is submitted that there ought to be synergy between the terms used in the Regulations and those in the NHA. Currently, although the term ‘health research’ is generally used in the Regulations there are times when just the word ‘research’ is employed. Given that the term ‘health research’ is used and defined in the NHA, it

²² See Strode *et al op cit*



would be more appropriate to use this phrase throughout the document. In Regulation 4(3)(b) the term ‘patient’ is used, but we submit that this be replaced with the term ‘user’ which is used and defined in the NHA. Likewise, in this same section the words ‘health care professional’ are found rather than ‘health care personnel’ or ‘health care worker’ which are the terms used in the NHA.

b) *The word ‘condition’ needs a broader meaning if it is to give effect to section 71(3).*

The draft Regulations define the word ‘condition’ which is used in section 71 of the NHA. The Act provides that the Minister of Health may not give his/her consent to non-therapeutic research with minors unless, amongst others, it can be demonstrated that the study will result in a significant improvement in the understanding of the minor’s condition or disorder. This term is not defined in the Act and some academics questioned whether this factor was implementable as participants in a so-called non-therapeutic study are likely to be healthy and may not have a disorder as such.²³ The draft Regulations attempt to rectify this concern by defining ‘condition’ broadly - as the ‘physical and psycho-social characteristics shown to affect health’. Although defining this term could assist in the full implementation of section 71(3), it is submitted that this particular definition fails to address the core issue – that of the need for the term to be used broadly so that it includes conditions to which the participant may be at risk of acquiring. Therefore we recommend an even broader definition be inserted into the Regulations.

c) *The term ‘research stakeholder’ should be defined.*

Regulation 3(g) refers to an obligation to disseminate research results to all “research stakeholders” without defining what this term means.

d) *The lack of clarity between Regulation 2 (principles underpinning health research) and Regulation 3 (obligations on researchers) should be addressed.*

²³ *ibid*

There does not appear to be any clear distinction between what is considered to be a “principle“ which underpins the way in which research is conducted, and the obligations on researchers. A “principle” has been defined as ‘a fundamental truth or proposition that serves as the foundation for a system of belief or behaviour or for a chain of reasoning’²⁴. Conversely, an obligation has been defined as an ‘an act or course of action to which a person is morally or legally bound; a duty or commitment’.²⁵ These definitions seem to suggest that Regulation 2 ought to set out the broad propositions which give rise to various obligations in Regulation 3. For example, a principle would be the need to respect the autonomy of research participants. This could be translated into the dual obligations of ensuring that participants are well informed and participate in health research only after having provided consent. In Regulations 2(a) the language used seems to refer to obligations rather than ‘fundamental truths’ which guide the way health research is conducted.

It is recommended that the following provisions in Regulation 2 are principles and should be retained:

- i.) the need for research to be relevant,
- ii.) the importance of a valid methodology,
- iii.) effective management of studies,
- iv.) the importance of individual autonomy, and
- v.) respect for rights,

It is recommended that firstly all remaining principles should be phrased as principles. Secondly, the principles which are in fact obligations such as the points on obtaining informed consent, fair recruitment, risks, obtaining ethical approval and registering on the South African National Clinical Trials Register (SANCTR) should be moved to Regulation 3. Thirdly, there should be a synergy between the principles and obligations, in other words there ought to be obligations which correlate with each principle.

²⁴ Oxford Dictionary

²⁵ Ibid.

e) *The obligation to disclose the amount and source of the funding of research should be limited.*

Currently, Regulation 3(c) requires disclosure of funding to the REC and participants. It is submitted that this is overly broad and adds unnecessary detail to an informed consent form. It is recommended that the words 'to participants' be deleted.

f) *Clarity regarding research with women.*

Currently, Regulation 4(4)(b) is unclear. It seems to imply that no health research may take place with pregnant women or foetuses unless there have been for example, animal studies. It is recommended that this section be re-worded as this is a particularly bio-medical approach to health research. There may be many social science studies with pregnant women where there is no need for animal studies.

g) *Do not necessarily exclude persons with intellectual impairments from participating in health research.*

Currently Regulation 4(2) excludes persons with intellectual disabilities from any form of research except that which focuses 'strictly' on their disability. It is submitted that this discriminates against people with disabilities and further stigmatises them. There may be a number of studies where the input of people with disabilities would provide valuable insights, and that do not only focus solely on their disability, such as the quality of health care and other services, accessibility of public spaces etc. For example, recently, Phasha & Nyokangi interviewed female learners with intellectual disability about their experiences of sexual harassment or abuse.²⁶ Likewise McKenzie has conducted research on residential facilities for adults with intellectual disability. She has interviewed adults with intellectual disability regarding their needs for housing and support options.²⁷ There are also several examples from the mental health literature

²⁶ Tlakale Nareadi Phasha & Doris Nyokang "School-Based Sexual Violence Among Female Learners With Mild Intellectual Disability in South Africa" *Violence Against Women* March 2012 vol. 18 no. 3, 309-321

²⁷ Judith Anne McKenzie (2013): Disabled people in rural South Africa talk about sexuality, *Culture, Health & Sexuality: An International Journal for Research, Intervention and Care*, Volume 15, Issue 3.

where mental health service users are asked their opinion on service development.²⁸ It is vital that such research continues.

h) *Clarity on the obligation to provide long term care is required.*

Regulation 5(3) requires long term care for vulnerable participants. It is unclear what this entails. For example, is the care to be for the participants' entire lifetime? What ought to be the standard of care for such treatment?

i) *Narrow the wording of Regulation 6(n) so that the obligation is to inform participants that a study has obtained ethical and other forms of regulatory approval, and not that participants must get a copy of such approval letters.*

This requirement will increase the administrative burden on researchers, unnecessarily increase research costs, and increase the complexity of consent forms. We recommend a statement in the Consent Form that the necessary ethics and regulatory approvals have been obtained with the relevant protocol/study numbers, and that copies of such documents could be made available to study participants upon request.

j) *Provide clarity on the phrase 'the reasons for the consent to the research or experimentation by the parent or guardian and, if applicable, the minor are contrary to public policy' which is used in section 71(3)(b)(iii).*

This phrase is used to describe one of the factors that Minister of Health or a person delegated by him/her must take into account when deciding whether to grant consent to non-therapeutic research with minors. Currently, it is unclear as to when research would be contrary to public policy and some factors that could be used in this assessment ought to be inserted into the Regulations.

k) *Ensure that researchers will be provided with the outcome of their application for ministerial consent in writing.*

²⁸Sumaya Mall, Goodman Sibeko, Henk Temmingh, Dan J. Stein, Peter Milligan and Crick Lund (in press) "Using a treatment partner and text messaging to improve adherence to psychotropic medication: A qualitative formative study of service users and caregivers in Cape Town, South Africa" *African Journal of Psychiatry*

Currently, Regulation 8(e) provides that researchers will be informed ‘timeously’ of the outcome of their application. It is submitted that they ought to be informed of the reasons for the decision **in writing** as this has significant implications for a study that they may wish to consider other legal remedies if for example, consent is not granted.

l) *Provide guidance on how to implement section 71(2)(a) of the NHA.*

This section requires all therapeutic research with minors to be in the best interests of the minor. Currently, it is unclear whether this principle must be used in an individual or collective manner and both the NHA and the Regulations are silent on this issue. In other words, whether therapeutic research must promote the best interests of children as a class or the best interests of individual child research participants is open to debate. Clarity in the Regulations on how to apply this principle would be of great value to RECs and researchers. We suggest that the Regulations provide that in establishing whether therapeutic research is in the best interests of children, consideration must be given to the potential impact of the study on **children as a class**; and

m) *Clarify the distinction between the terms ‘children’, ‘minors’ and ‘persons with intellectual impairments’.*

Currently all three terms are used within these Regulations and it is unclear as to whether there is any overlap between them. For example, are persons with intellectual impairments also minors?

We hope that these comments will assist the Department of Health not only in developing robust Regulations to the NHA, but also to critically appraise the current NHA and its implications for health and health research in South Africa.

Please do not hesitate to contact us if we can provide additional material, input or assistance in this process.

Secretariat for this Submission:

Laurie Schowalter

Technical Advisor Policy & Implementation: Southern African HIV Clinicians Society

Email: Laurie@sahivsoc.org

Tel: (011) 728-7365



Appendix A:

Organisational endorsements:

African Gender Institute, UCT

Anova Health Institute

Child and Adolescent Committee, Southern African HIV Clinicians Society

Desmond Tutu HIV Centre

Desmond Tutu HIV Foundation

Empilweni Services and Research Unit (ESRU), Rahima Moosa Mother and Child Hospital

Health Economics and Epidemiology Research Office

HIV/AIDS Vaccines Ethics Group, University of KwaZulu Natal

Ibis Reproductive Health

Lawyers against Abuse

University of the Witwatersrand Research Ethics Committee (non-medical)

Wits RHI

Endorsements from individuals

Peter Cooper (Professor and Head, Dept of Paediatrics, University of the Witwatersrand & Charlotte Maxeke Johannesburg)

Denise Evans (Senior Researcher, Health Economics and Epidemiology Research Office, Wits Health Consortium)

Andy Gray (Senior Lecturer, Division of Pharmacology, Discipline of Pharmaceutical Sciences School of Health Sciences, University of KwaZulu-Natal)

A P MacPhail PhD FCP FRCP (Professor Emeritus and Professorial Research Fellow, Clinical HIV Research Unit, Department of Medicine, University of the Witwatersrand)

Sara Nieuwoudt (Lecturer, School of Public Health, Wits University)

Marlise Richter (International Centre for Reproductive Health, Ghent University and the African Centre for Migration and Society, Wits University)

Justine van Rooyen (Media & Communications Officer, AIDS Foundation of South Africa)

Appendix B:

NHREC recommendation to REC Chairs



Private Bag X525, PRETORIA, 0001, Cnr Struben and Andries Street, Tel: +27 (0) 12 395 8125/8113 Fax: +27 (0) 12 395 9249

Dear REC Chairs

December 2012

FEEDBACK ON S71 PROPOSED AMENDMENTS AND HUMAN SUBJECTS REGULATIONS

S71 of the National Health Act: Representatives from the NHREC met with Ms M Matsoso, DG for Health, on 13th July 2012, and with Dr G Ramokgopa, Deputy Minister for Health, on the 17th August 2012, and Dr A Motsoaledi, Minister for Health, on the 18th of October 2012.

At these meetings, the NHREC shared its concerns about s71 of the National Health Act (2003) and the manner in which s71 provisions conflicted with its own provisions, with provisions in the Children's Act and with provisions in current ethical guidelines. The Council was invited to make formal submissions to the DG's office regarding a delegation of power to RECs for low-risk non-therapeutic research with children (as a short-term measure) as well as proposals for law reform to s71 (as a longer-term measure). The Council has done so, and is awaiting feedback from the Department of Health.

Human Subjects Regulations: Subsequent to the implementation of s71 in March 2012, the regulations have again been revised. Revisions include, for example, the possibility that Ministerial Consent might be delegated to RECs, however the NHREC cannot guarantee this outcome, and can merely advise the Minister of this strategy.

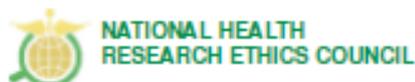
The regulations will be submitted to the Legal Unit and published for public comment again, because substantive comments have been introduced.

A letter will be sent to RECs bringing to their attention the publication of the regulations (when this occurs), alerting them to changes from the draft published in 2007 in response to public comments, and requesting comments.

We will keep you apprised of developments.

Kind regards

Prof. D. du Toit
Chairperson: National Health Research Ethics Council



Prof. D. du Toit (Chairperson), Prof. A. Dhd (Deputy Chairperson), Mrs. F. Buheled, Ms. M. Chetty, Prof. S. Esack, Mrs. M. Hazins, Dr. L. Ham, Dr. N. Khomo, Mrs. G. Loot, Prof. K. Moodley, Adv. L. Nwondwe, Mr. N. Ramuthaga, Prof. W. Shaiba and Ms. C. Sack

