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Boni mores and consent for child research in South Africa

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Consent is required for almost all health research. In order for consent to be valid a number of requirements must be met including that the consent cannot be *contra bonos mores* or contrary to public policy. This principle has its roots in the common law and it is used to ensure that the consent to harm, or the risk of harm, is permitted or ought to be permitted by the legal order. Recently, it has also become a statutory requirement embedded in the consent obligations relating to non-therapeutic health research with minors. Section 71 of the National Health Act provides that the Minister of Health (or potentially his or her delegated authority) must provide consent to non-therapeutic research with minors. However, such consent may not be granted if 'the reasons for the consent to the research or experimentation are contrary to public policy'. Limited work has been done on how to determine when consent to health research with children would be contrary to public policy. This article attempts to begin the debate by describing the *boni mores* principle, setting out some of the general factors that could be used to assess whether consent is consistent with it and suggesting how they could be applied to health research.
The article concludes by stating that simply requiring proxy consent for non-therapeutic health research with children is insufficient as it cannot always be assumed that proxy consenters will act in the best interests of the child. Thus the *boni mores* principle acts as a limit on autonomy in order to protect the child participant. It is further submitted that establishing when consent to health research is consistent with public policy requires an assessment of whether the research is consistent with constitutional values, prevailing legal norms regarding children, and an assessment of the legal convictions of the community.

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It is a well-established international law principle that participation in most forms of health research is dependent on participants or their proxies providing informed consent.[1,2] Likewise, South African law provides that consent is required for almost all health research.[3,4] Section 71 of the National Health Act (NHA) requires that if the participants in health research are minors, proxy consent must be provided by their parent or legal guardian[4] and minors who are 'capable of understanding' may also provide consent alongside their parent or guardian.[4] If participants or their proxies have consented to the health research, the legal maxim *volenti non fit injuria* (to one consenting no harm is done) applies, and this can be used as a defence by researchers or sponsors. However, in order for it to operate as a defence, four statutory and common law requirements must exist:[5]

- the consent should have been provided in writing[4]
- it should have been voluntarily given[6]
- the consent should have been informed by an appreciation of any possible negative or positive health consequences that the research may pose[7]
- the consent may not be *contra bonos mores* (against good morals or public policy)[8]

The fourth requirement for informed consent – that of requiring it not to be *contra bonos mores*, i.e. contrary to the legal convictions of the community or inconsistent with public policy – has its roots in the common law principles which were adopted from Roman and Roman Dutch law.[8] It applies to all forms of consent and is used to ensure that the consent to harm, or the risk of harm, is permitted or ought to be permitted by the legal order.[8]

Recently, it has also become a statutory requirement embedded in the consent obligations relating to non-therapeutic health research with minors.[4] Section 71 of the NHA provides that the Minister of Health (or potentially his or her delegated authority in terms of section 92 of the NHA) must provide consent to non-therapeutic research with minors.[4] However, such consent may not be granted if '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'.[4] Although these sections in the NHA were operationalised on 1 March 2012 they were not accompanied by regulations so some Research Ethics Committees (RECs) did not require compliance with them. However, on 19 September 2014 the Minister of Health published regulations relating to research with human participants.[9] These regulations included a potential delegation of his authority to provide ministerial consent to non-therapeutic research with minors to RECs.[9] This means that further legislative consent requirements have now been introduced and added to the current requirements described above and RECs must comply with all of them.

This article attempts to address the *lacunae* of research into when consent is contrary to public policy by describing the *boni mores* principle, setting out some of the general factors used to assess whether consent is consistent with it and also suggesting how these factors could be applied to the issue of granting ministerial consent for non-therapeutic health research with children. This article does not critique the restrictive nature of current consent norms as that has been done elsewhere.[10,11]

Contra bonos mores

Our courts have long held that consent can only validly operate as a defence if the act being consented to is not *contra bonos mores*.[8] At the heart of this principle is an acceptance that consent – even voluntarily given – must be consistent with public policy. For example, the courts have held that consent to a caning as a form of discipline in the workplace was invalid.[12] Likewise, consent to dangerous car racing in the street was considered *contra bonos mores*.[13] In essence, this principle places a limit on individual decision-making by requiring the reason for the consent to meet an objective legal standard – regardless of voluntariness. In this context, the perception of the consenter regarding the validity of their consent is not relevant.[8]

Key factors used to establish whether the consent is valid include constitutional values, prevailing legal norms and public opinion, discussed in more detail below:

Constitutional values

The constitution is founded on a number of values – including human dignity, the achievement of equality and the advancement of human rights and freedoms, non-racialism, and non-sexism.[3] These values are used as both a tool of interpretation (with courts having to favour an approach which protects the constitutional values) and as an objective standard against which conduct can be measured.[14] The courts have held that the concept of *boni mores* is 'now deeply rooted in the constitution and its underlying values'.[15]

Prevailing legal norms

Consent must be consistent with prevailing legal norms.[12] This requires consideration of the legal norms governing the act being consented to – in order to establish whether the consent is lawful.[12]

Public opinion

In some instances the courts take note of public opinion or morality, in establishing whether consent is *contra bonos mores*. In other words the principle is partially shaped by religious, ethical and moral perceptions of right and wrong. The courts will, however, only consider public opinion when the views of the society strongly require legal sanction for the type of behaviour that was consented to.

Using the *boni mores* principle to establish the validity of consent to health research

There has been limited academic discussion about when health research would be *contra bonos mores*. At a macro level, it has been argued that participants should not be allowed to consent to research if it is likely to result in the discovery of knowledge that is inappropriate for human beings to process,[16] or when such knowledge may be misused in human hands, for example, developing instruments for killing or injuring humans.[16] At a more micro level, it has been argued that research would be *contra bonos mores* if it is not being conducted properly, or the risks to participants are unacceptably large and not sufficiently offset by the benefits to participants or society.[7,17-19] Others submit that if researchers do not comply with substantive and procedural requirements for approving research – for example, if a study does not obtain ethical approval for consent to participation – this would be *contra bonos mores*.[7]

Boni mores and child research

The issue of when research with children would be contrary to public policy has been rigorously debated, with most writers focusing on the vexing issue of non-therapeutic research given that it does not typically offer participants any direct benefit and requires them to act altruistically. Key issues have included:

- Whether parental consent to research investigating illegal activity would be *contra bonos mores?*[19]
- Whether unacceptable levels of risk are illegal?[18]
- Whether proxy consent for non-therapeutic research should be limited?[20,21]

For example, prior to the NHA, Van Wyk submitted that non-therapeutic research with children should only be possible if it was classified as being observational in nature and did not pose more than a minor increase over minimal risk.[18]

We submit that when assessing whether consent to health research with children is contrary to public policy RECs should consider the nature of the study, how it will be carried out and make an assessment of whether consent would be appropriate in the broad circumstances. Possible concerns could include, among others: consent to research investigating illegal behaviours (such as drug use or prostitution) or legal but sensitive behaviour (such as adolescent same-sex activity); or the possible motivation of potential consentors. We argue that the general principles articulated above could form a useful framework for evaluating the validity of such consent. We suggest that these principles could be applied in the following way:

Constitutional values

The consent would need to be consistent with constitutional values. In other words, the research should not violate the basic constitutional and human rights of child participants – including their rights to dignity and equality (especially on the grounds of race and gender). It is hard to imagine research that could be ethical but still violate these constitutional values – given that a core part of an REC's mandate is to protect the rights of participants. National ethical guidelines require RECs to ensure that human subjects are treated with dignity, that their well-being is promoted, and that consent procedures are adequate.[22] Key questions that could be asked to establish if the study is consistent with constitutional values – and hence public policy – would include the following:

- To what extent does the study treat the child participants with respect, and protect their constitutional rights?
- Does the study select potential child participants fairly and avoid the unjustified targeting of a particular sub-group?
- Does the study include appropriate and justified incentives for enrolment of child participants?

Prevailing legal norms

The consent needs to be consistent with prevailing legal norms governing research with children – which are established in the constitution, the NHA, and other relevant legislation such as the Children's Act.[3,4,23]

A key legal norm in this context is the concept of the best interests of the child. Section 28(2) of the constitution states that a child's best interests are of paramount importance in every matter concerning the child.[3] Our courts have generally held that in applying this

principle a wide range of factors should be considered to establish if a decision concerning a child will promote their physical, moral, emotional and spiritual welfare. Section 7 of the Children's Act contains a non-exhaustive list of the factors that ought to be used when applying this principle.[23] None of these principles are research specific but many are broad enough to be useful in this context.

Other relevant legal norms are those in the NHA which provide that both therapeutic and non-therapeutic research with minors is lawful if the requirements in the Act are met.[4] The NHA requires children to be scientifically indispensable to the non-therapeutic study and an obligation is placed on researchers to demonstrate why the data cannot be obtained from adults.[4] It also sets a standard of acceptable risk by stating that the non-therapeutic research with minors must not pose a significant risk to their health.[4]

The other key piece of legislation describing children's health rights is, as mentioned above, the Children's Act.[23] It requires adults to promote a child's well-being and to protect children from discrimination, exploitation and any other physical, emotional or moral harm.[23] It also describes a number of other health rights of children, such as the age at which they may consent for example to medical treatment, HIV testing, and use contraceptives.[23]

It is possible that other legal norms would also have to be considered – depending on the nature of the study. For example, if researchers are investigating child labour, consideration may need to be given to the norms in employment laws. It is worth noting that consent to research that does not comply with legal norms may be inconsistent with public policy if we follow the approach in English law[24] where courts have consistently held that one can never consent to illegal activity as this is by its nature *contra bonos mores*. For consent to health research to be accepted as legal consent it must be permitted by the legal order. The complexity with applying this principle is that the approach to children's health rights in the NHA and the Children's Act are divergent. For example, while the Children's Act recognises the evolving capacity of children to consent independently to certain health interventions the NHA does not.[11]

Key questions that could be used to establish whether consent is consistent with prevailing legal norms include:

- Has the child research met all the procedural requirements established by law – such as ethical approval?
- Will all substantive requirements that need to be met – such as compliance with mandatory reporting requirements – be complied with?
- Is it in the best interests of the child?
- What are the potential risks and harms of research participation, and do they fall below the accepted legal standards?
- Will children be exploited by, for example, asking them to assume an unfair level of risk in relation to the expected benefit for them or the group they represent?

Public opinion or community morals

The consent would need to be acceptable to community morals, as reflected by the community's legal convictions – i.e. its laws. This is a complex factor and it cannot be equated to public opinion. For example, even though public opinion may be opposed to terminations of pregnancy (TOP) below the age of 18, this would not necessarily mean that research into TOP would be inconsistent with public policy. Likewise, research *per se* into illegal or 'immoral' behaviours is not necessarily against public policy – even though the community may disapprove of the behaviour. For example, research exploring factors that impact on risky sexual practices of adolescents might be frowned upon by some stakeholders but this would not mean that research on the topic would be against public policy if conducted in accordance with the legal framework.

Furthermore, ethical guidelines form an important indicator of public policy, as in many instances they reflect the moral convictions of the community. Therefore, if the research complies with current national ethical guidelines it is likely to be consistent with the *boni mores* principle. The complexity with applying this principle is that in some instances research may comply with key ethical norms but not with legal norms, for example, current ethical guidelines allow caregiver consent for certain forms of child research while the NHA prohibits such an approach.

Key questions that could be used to establish whether consent is consistent with community morals include:

- Is it ethical?
- Is the research lawful?
- Will the study violate a child's constitutional rights?
- Would the research be acceptable to the community?

Using the *boni mores* principle to determine whether ministerial consent may be granted for non-therapeutic research in children

Section 71(3) of the NHA provides that ministerial consent for non-therapeutic research with minors may not be given if 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'[4] Form A in the regulations (the application for ministerial consent) simply states that researchers ought to 'explain why consent would be acceptable, for example, that the study poses acceptable risks and promotes the rights of minors'.[9] Although no further detail is provided it would appear from the wording of this section of the NHA that the drafters were concerned about the potential motivations consenters may have for agreeing to research participation.[4] We interpreted this to mean that the minister or their delegated authority should consider possible reasons consenters may have for enrolling children in the study, for example the appropriateness of incentives for study participation, and their potential influence on consent. This assessment cannot be an individual, subjective assessment of each individual consenter's motivation but should rather be a general consideration of possible reasons potential participants may have for joining the study. We would argue further that the general principles articulated above would apply to this assessment. It is, however, a narrower approach because for the purposes of ministerial consent there is no need to establish that the study itself is consistent with public policy, just the reasons for the consent.

Conclusions

Requiring consent to be consistent with the *boni mores* principle or public policy acts as a limit on the personal autonomy of the consenter or proxy consenter. It is not uncontroversial in our constitutional era, as it limits autonomy which is an inherent part of the right to bodily integrity. While it may be argued that the principle is outdated, paternalistic and intrusive regarding adults – such arguments are

less likely to be justified when considering proxy consent to research with minors. There is a constitutional obligation to protect children from harm and to act in their best interests. Simply requiring proxy consent is insufficient as it cannot always be assumed that proxy consenters will act in the best interests of the child when electing whether to enrol them in health research.[25] Hence, it appears that the NHA places the obligation to establish whether the health research is consistent with the *boni mores* in the hands of the regulators of research rather than the proxy consenters as a protective measure. It is submitted that establishing when consent to health research with minors is consistent with public policy requires an assessment of whether the research is consistent with constitutional values, prevailing legal norms regarding children, and the legal convictions of the community. This assessment is inextricably wound up in the review of whether the study is ethical. It is likely that a study judged by an independent REC to comply with prevailing national ethical standards would be consistent with public policy. Also, given that the public policy requirement in the granting of ministerial consent has been limited to a consideration of the potential reasons for consenting, it simply requires an assessment of whether agreeing to be in such a study would be consistent with the legal convictions of the community.

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