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Deferred Consent in Emergency Care Research: A Comparative Perspective of South African Regulations

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Abstract
Obtaining informed consent from potential research participants can be fraught with difficulty at the best of times. In emergency care research, consent procedures are particularly controversial as research subjects are usually unable to voice their wishes and unable to consider the material benefits and risks of the medical procedures, treatment and research. And, an added level of difficulty is the unique nature of the emergency situation, where time is of the essence and obtaining proxy consent from a legal representative or family member is not always logistically possible. This article will consider the deferred consent procedures and regulations of emergency care research in South Africa. A comparative overview will then be provided of the relevant procedures and regulations on emergency care research in the UK, continental Europe, and the USA. The important oversight role of Research Ethics Committees and Institutional Review Boards in emergency care research will be emphasized in terms of the difficult ethical and legal concerns that must guide them in their decision-making responsibilities.

Introduction
Voluntary informed consent for clinical research participation is the cornerstone of health research ethics. Yet, in many situations it is not possible for research subjects to give their full and informed consent, for example when they are under the age of 18 years, severely ill or when they suffer from a mental disability. Obtaining voluntary and informed consent for research participation under these conditions can be extremely difficult and even more so in the context of emergency care research (ECR), where potential research participants are unconscious or otherwise temporarily incapable of voicing their express wishes. In addition to the ethical concerns in the consent procedures of ECR, a real risk also exists that such patients' health may be adversely affected if the consent is not obtained timeously and treatment is not provided immediately. Obtaining consent in the context of ECR can therefore rightly be described as a '…real tension between the need for health-care workers to fulfil their duty of care by providing evidence-based treatments and the right of patients to be accorded respect for their autonomy'.[1]

In an attempt to overcome these obstacles, various approaches have been suggested to act as a surrogate for the subject's consent in ECR: While some researchers suggest that an independent physician should provide consent on behalf of the patient, others submit that the subject's deferred consent should be obtained at a time when the subject is able to provide it. Or, that the subject's legal representative should give his/her deferred proxy consent as soon as the representative had been located and been informed of the material benefits and risks of the study. Yet, many researchers submit that these approaches are opportunistic at best and that consent should rather be waived completely for the purposes of ECR.[2]

This article will only focus on deferred consent practices in ECR and will not consider the requirements for informed consent practices, the exceptions to obtaining informed consent, and the safeguards for patient autonomy in other emergency care settings. The focus will furthermore be on the legal and ethical considerations of deferred consent in ECR from a South African perspective, while comparisons will also be made with standard practices and recent developments in other jurisdictions, particularly in the United Kingdom, the USA and continental Europe.

Deferred consent and emergency care research in South Africa

Deferred consent refers to the randomization at the investigator's discretion according to criteria that have been made explicit during the ethical review of the protocol, followed by the deferred consent of the patient/subject or the deferred proxy consent of the patient's legal representative at a later stage when the patient is able to provide such consent or when the legal representative has been located, informed and is able to provide the necessary consent.[3]

The following South African guidance documents were considered for this article:

- ICH GCP (International Conference on Harmonization: E6 Consolidated Guidelines for Good Clinical Practice, 1996);[4]
- SA GCP (South African Good Clinical Practice guidelines 2nd edition Issued by the Department of Health in 2006);[5]
- Ethics in health research: principles, structures and processes (Issued by the Department of Health in 2004 and referred to as ethical guidelines for the purpose of this article);[6]
- Guidelines for good practice in the health care professions. Seeking patients' informed consent: the ethical considerations. Booklet 9. 2008. (Issued by the Health Professions Council of South Africa in Pretoria and referred to as HPCSA guidelines for the purpose of this article);[7]

These guidance documents acknowledge that there may be instances where it is impossible to obtain informed consent from either the prospective research subject or his/her legally accepted representative. Provision is therefore made for the special and reinforced protection of research subjects from such vulnerable populations. However, none of these sources make specific provision for the process whereby informed consent is obtained in an emergency care setting. A teleological interpretation (value-coherent interpretation) of existing statutes and the Constitution should therefore be applied when considering what the legally appropriate process should entail.

With regard to informed consent in a clinical research setting, the South African Constitution (1996)[8] underpins the right to autonomy when it requires in section 12(2)(c) that no person may be subjected to medical or scientific experiments without that person's informed consent. Chapter 9 of the National Health Act 61 of 2003[9] furthermore makes provision for research or experimentation on human subjects and section 71 of this chapter deals with informed consent in health research and specifically requires that written informed consent is obtained. The requirements with regard to consent in medical research are therefore clearly stated, stringent and must be adhered to at all cost.

Section 7(1) of the National Health Act provides for instances when first-person consent is not possible. In terms of this provision, a surrogate mandated in writing by the person not being able to give informed consent or a legally acceptable representative (such as a spouse, partner, parent, grandparent, adult child or a brother or sister of the person (in this specific order)) may give informed consent. And, in section 7(1)(e) it is stated that where a delay in the provision of the health service to the user may result in his/her death or irreversible damage to his/her health and the user has not expressly, impliedly or by conduct refused that service, then the health service may be provided without that user's informed consent. Section 5 of the National Health Act furthermore states that emergency medical treatment may never be refused.

Section 9.4.2 of the HPCSA, similar to section 7(1)(e) of the National Health Act, emphasizes the importance of a patient's known wishes and requires that health care practitioners first find out whether the patient has previously mandated another person in writing to make decisions on his/her behalf in advance statements such as a living will. Such valid advance pronouncements by a patient (which is known or drawn to the attention of the health care provider) must always be respected. If an advance statement is not available, the patient's known wishes should be taken into account and section 8.1 of the HPCSA guidelines furthermore require that medical treatment is provided but limited to what is immediately necessary to save a life or to avoid significant deterioration in the patient's health.[10]

Other than these foundational principles with regard to informed consent in the delivery of health care services, no specific mention is made of the appropriate consent procedures to be followed in ECR. However, sections 11, 72 and 73 of the National Health Act, read together with principle 29 of the Declaration of Helsinki (2008) (Issued by the World Medical Association at the 59th WMA General Assembly, Seoul 2008)[11] provides some insight and guidance. Principle 29 of the Declaration of Helsinki (2008) makes provision for ECR and requires that the relevant Research Ethics Committee (REC) consider the circumstances for alternative options if no legally acceptable representative is available to consent. The 2008 Declaration also allows enrolment to proceed without informed consent on condition that the REC has approved the research protocol. When first-person consent from the prospective participant is therefore not possible upon arrival at the emergency room, the best interest of the research subject is wholly placed in the hands of a REC and the researcher. It is then presumed that the research subject would have agreed to participate in the study if he/she was able to do so, and deferred consent is only obtained at a later stage when the research subject is indeed able to give such consent.

The central role that the REC should play in this regard is also reflected in the provisions of the National Health Act. First, in section 11 of the Act, provision is made for those unique instances where a health service is provided for experimental or research purposes. Here, it is mandated that before a health establishment provides such a health service for experimental or research purposes that the user must be informed, in the prescribed manner as per the protocol, and that such a service may not be provided if the user, the health care provider primarily responsible for the user's treatment, the head of the health establishment and the relevant REC or any other person to whom the authority has been delegated has not given their prior written authorization for the provision of health service in question. The roles of the REC as gatekeeper and overseer of research projects are also emphasized in sections 72 and 73 of the National Health Act. Provision is furthermore made for the RECs actions to be policed and reviewed by the National Health Research Ethics Council (NHREC) of South Africa (section 72(6)).

With regard to the central role that RECs play in emergency care research, note should also be taken of the new draft revised version of the Declaration of Helsinki dated April 2013.[12] In terms of paragraphs 19 and 20 of the proposed new version of the Declaration of Helsinki, RECs may authorize emergency research where there is no direct benefit to individual patients but where the research is responsive to the health needs and priorities of the specific vulnerable population or community, or where the population or community stand to benefit from the knowledge, practices or interventions that may result from the research.[13] In terms of paragraph 23, investigators must also submit to the REC a final report containing a summary of the study's findings and conclusions. However, Kompanje questions what the use of such a report would be and what actions will be available to RECs if the results of the study are not in line with the protocol, are unethical, or do not provide any benefit for the study population or community.[14]

Deferred consent and emergency care research in the United Kingdom

In the United Kingdom, the written and informed consent of the research participant or his/her legal representative is required before that participant can be enrolled in ECR. And, while written informed consent can be waived under specific circumstances – e.g. where the patient is unconscious, the treatment is urgent and no relative or other legal representative is available - it is usually still required despite the delays to treatment that may result.[15]

The oversight role of the REC in those instances where a potential research participant is unable - due to a physical or mental incapacity - to provide informed consent, is also emphasized in section 14(3) and 15(5)(g)-(h) of the Medicines for Human Use (Clinical Trials) Regulations 2004.[16] In section 15(5)(g) of the Act is it explicitly provided that the REC shall be approached for, and must provide, an opinion on the adequacy and completeness of the written information to be given and the procedure to be followed for the purpose of obtaining informed consent to the subjects' participation in the trial. Compared to its South African counterpart, more detailed and stringent requirements are, however, included in the Act. Section 15(7) requires, for example that where a potential research subject is unable to give his/her full and informed consent, and the REC does not have a member with professional expertise in the treatment of the disease to which the trial relates as well as a member with professional expertise on the patient population suffering that

disease, that the ethics committee must obtain advice on the clinical, ethical and psychological problems in the field of that disease and patient population which may arise in relation to that trial before giving its opinion.

Part 5 of Schedule 1 of the Act sets out further conditions and principles which will apply in relation to an incapacitated adult in the context of health research participation. These conditions and principles emphasize the role of a legal representative for the research subject and state that the informed consent given by a legal representative on behalf of such an incapacitated adult shall represent that adult's presumed will (Principle 12).

Deferred consent and emergency care research in continental Europe

In continental Europe, the European Clinical Trial Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2011[17] allows for two main categories of patients who are not able to give full and informed consent for participation in health research: the first category deals with minors and the second category with participants with an impairment of cognitive functions and who are for that reason unable to give informed consent. In terms of this directive, for incapacitated participants to partake in research, deferred consent is required according to the approval of a REC.[18] And, similar to the UK Medicines for Human Use (Clinical Trials) Regulations 2004 the role of the research participant's legal representative is also emphasized (article 3) as well as the oversight role of the REC (article 6). It is furthermore required in article 5(g) that the REC must have expertise on the relevant disease and the patient population concerned or must take advice on the clinical, ethical and psychosocial questions in the field of the relevant disease and patient population before endorsing the protocol.

Country specific regulations and differences do, however, exist. In Austria, for example, patients are only allowed to participate in ECR if deferred consent is obtained and where participation of such patients are coupled with the prospect of a potential direct benefit which exceeds the risks involved in the study. In Austria, the prospect of a group benefit or general beneficial outcome of the research is therefore not sufficient and, where the participant's will is known and documented it must be respected.[19] And countries like Belgium, France, The Netherlands, Spain and Germany continue to authorize the waiver or deferral of consent in emergency care situations despite the provisions of the directive.[20]

Another important and recent development is the new regulation that was proposed by the EU Commission in July 2012. The primary objective of this new regulation is to simplify and speed up the process of authorization and conduction of clinical trials on medicines.[21] Although this regulation is not yet in effect, it is important to take note of as it explicitly makes provision for deferred consent procedures in emergency care research. Article 32 of this new regulation allows for informed consent to be obtained after the start of a clinical trial subject to the following conditions:

- The urgency of the situation makes it impossible to supply the research participant with information and gain his/her prior informed consent;
- No legal representative is available;
- The research participant has not, to the best knowledge of the investigator, expressed any prior objections to participating in the research;

- The research relates directly to the medical condition that is causing the impossibility to supply the research participant with full information and obtain his/her informed consent;
- The clinical trial poses a minimal risk to and minimal burden on the research participant.

The new regulation furthermore requires that full information on the clinical trial be provided to the research participant's legal representative as soon as reasonably possible, and that his/her informed consent be obtained on behalf of the research participant until the research participant is him-or herself able to give informed consent.

While it is important for the European Clinical Trial Directive 2001/20/EC to be amended to specifically provide for ECR, Matei warns that article 32 of the new proposed regulation will limit the use of deferred consent in ECR as the requirement that the clinical trial must pose a minimal risk to and burden on the research participant will effectively mean that only authorized medicines be used in ECR and clinical trials on new and innovative drugs in ECR will no longer be possible.[22]

Deferred consent and emergency care research in the USA

In the USA, the Food and Drug Administration (FDA) issued non-binding recommendations on the permissible exceptions from informed consent requirements in emergency research in March 2011.[23] This guideline, entitled *Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research*, together with regulations 21 CFR 50.24 and the conforming amendments contained in 21 CFR Parts 5, 312, 314, 601, 812 and 814 provide a comprehensive overview of ECR and the unique obstacles which researchers in this area face.

Similar to the European and UK counterparts, these recommendations also emphasize the role of the legally authorized representative in giving proxy consent and deferred proxy consent (questions 38 to 43). It is furthermore recommended that the clinical investigator must attempt to contact the research subject's legal representative and thereafter a family member and only after reasonable attempts have been made and before the therapeutic window for the administering of the test drug or medical treatment has been exhausted may the clinical investigator continue with the medical procedure.[24] It is also explicitly stated that the effect of delaying treatment should be taken into consideration when determining the portion of the therapeutic window devoted to seeking informed consent from the research participant's legal representative.[25]

Further protection of research subjects is provided in terms of 21 CFR 50.24 which requires *inter alia* that the condition of informed consent may only be deviated from if the research subject is '…in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions'.[26] It is also required that participation in such research be of direct benefit to the research subjects since the research subjects face a life-threatening situation that necessitates intervention, appropriate animal and other preclinical studies have already been conducted and shows support of the potential direct benefit of the

treatment/medicine to human subjects, and the risks associated with the investigation are reasonable given the particular emergency situation.[27] (Compare with the new Declaration of Helsinki (April 2013) referred to above in which paragraphs 19 and 20 recommend that RECs may now authorize emergency research where there is no direct benefit to individual patients but where the research is responsive to the health needs and priorities of the specific vulnerable population or community, or where the population or community stand to benefit from the knowledge, practices or interventions that may result from the research.)[28]

Similar to the ethical guidelines of the other jurisdictions discussed above, the Institutional Review Board (IRB) also has an important policing and reviewing function in the context of ECR (questions 44 to 51 and 21 CFR 50.24 (a)(7)(v)(b)). It is emphasized, for example, that due to the controversial nature of ECR, that the meeting minutes and all decisions taken by the IRB with regard to the particular research protocol be carefully noted. One of the important oversight functions of an IRB in terms of ECR and as set out in these recommendations is that the IRB must ensure that adequate procedures are in place to ensure that the clinical investigator will make every attempt possible to contact the research subject's legal representative and family members (question 96 and 21 CFR 50.24 (a)(7)(v)(b)). Comprehensive recommendations are also provided on how to obtain deferred consent from a legal representative or family member after the research medical treatment had been administered (questions 103 to 115 and 21 CFR 50.24 (a)(7)(v)(b)-(e)).

Deferred consent in emergency care research: A comparative perspective of some pertinent issues

A number of pertinent ethical concerns with regard to deferred consent in ECR will now be considered in terms of the above overview of the different ethical guidance documents and legal imperatives on deferred consent in ECR in South Africa, the USA, the UK and Europe. It will be evident from this discussion that the South African guidance documents and relevant statutes are vague and wholly insufficient in addressing these pertinent concerns.

First, with regard to the question of *when* the deferred consent should be obtained from the research subject's legal or other authoritative representative, the South African guidance documents and legislation do not make mention of the appropriate consent procedures to be followed in ECR. The research subject's best interest is rather wholly placed in the hands of the relevant REC and the researcher. If the REC approved the research protocol, the research subject may be enrolled in the study based on the researcher's discretion and deferred consent need only be obtained at a later stage when the research subject is indeed able to give such consent. No timeframe or specific requirements stipulating exactly *when* and *under what conditions* such consent should be obtained, are furthermore provided. The UK position is equally silent on exactly when the deferred consent of the research subject's legal representative must be obtained.

In the USA, in contrast, it is recommended that the clinical investigator must attempt to contact the research subject's legal representative and thereafter a family member and only after reasonable attempts have been made and before the therapeutic window for the administering of the test drug or medical treatment has been exhausted may the clinical investigator continue with the medical procedure. It is

also explicitly stated that the effect of delaying treatment should be taken into consideration when determining the portion of the therapeutic window devoted to seeking informed consent from the research participant's legal representative.

The best practice is found, however, in the new EU regulation that was proposed by the EU Commission in July 2012. In article 32 of this regulation it is required that full information on the clinical trial be provided to the research participant's legal representative as soon as reasonably possible, and that his/her informed consent be obtained on behalf of the research participant until the research participant is him-or herself able to give informed consent. And, with regard to the importance of short timeframes and therapeutic windows, it is only the USA guidelines and the proposed new EU regulations that recognize and emphasize that the therapeutic window for the administering of the test drug or medical treatment and the effect of delaying the treatment should be taken into consideration.

Finally, all the guidance documents and legislation of the different jurisdictions discussed here remain quiet with regard to the question of whether the research results may be retained and used if the research subject passed away before his/her informed consent or the deferred consent of that subject's legal representative was obtained. From a human rights perspective it is paramount that the deferred consent of the subject's legal representative be obtained for the retention and continued use of the research results obtained from the subject. However, Jansen et al. suggest a more flexible approach that take into consideration a myriad of reflections including that article 8 of the European Convention of Human Rights read together with the EU Data Protection Directive and the UK Data Protection Act of 1998 justify the use of private medical information if the processing thereof is necessary and proportionate for the protection of health, if sufficient safeguards apply, or if it is necessary and proportionate for the goals of medical research.[29] In order for this exception to informed consent not to be abused, Jansen et al. also recommend that a time limit of 72 hours apply. If a research subject should die after 72 hours have expired and consent was not obtained within this time period, then the data should not be used.[30]

Some of the most important similarities and differences between the deferred consent practices in ECR in the jurisdictions discussed above are summarized in the table below.

	South Africa	United Kingdom	Europe	USA
Provision is *explicitly* made for ECR	No	No	Yes, but only in the new proposed July 2012 regulations. Note that country specific regulations re ECR may apply.	Yes
Recognize deferred consent explicitly	No, but can be inferred from sections 11, 72 & 73 of the National Health Act read with principle 29 of the Declaration of Helsinki (2008).	Yes, but consent by a legally acceptable representative is preferred. (See the Medicines for Human Use Clinical Trials Amendment (no. 2) Regulations 2006 no. 2984 and 2004 no. 1031)	Yes, but consent by a legally acceptable representative is preferred (See European Clinical Trial Directive 2001/20/EC)	Yes, but all reasonable attempts must first be made to contact the research subject's legal representative.
Conditions for exception to informed consent	• Research subject unable to consent • No legal representative present • REC/IRB approved the research protocol	• Research subject unable to consent • No legal representative or relative present • REC/IRB approved the research protocol and procedure under which action is taken • The treatment or situation is urgent • The nature of the clinical trial requires urgent action • It is not reasonably possible to meet the conditions in paragraphs 1 to 5 of Part 5 Schedule I (Regulations 2004 no. 1031)	<u>In terms of the new July 2012 proposed regulations</u>: • Research subject unable to consent • No legal representative present • REC/IRB approved the research protocol • The treatment or situation is urgent • The research subject has not (to the best knowledge of the researcher) expressed a prior objection to participating in the research • The research relates directly to the condition that is causing the	• Research subject unable to consent • No legal representative present • REC/IRB approved the research protocol • Participation in the research is of direct benefit to the research subject • Appropriate animal and other preclinical studies shows support of the potential direct benefit • The research subject faces a life-threatening situation that necessitates an intervention • The risks associated with

			subject's inability to give full and informed consent • The trial poses a minimal risk or burden to the research subject	the investigation are reasonable given the particular emergency situation
Makes specific provision for a timeframe when, and/or specific procedures how deferred consent must be obtained	No	No	Yes, in terms of the new proposed regulations (dated July 2012) it is required that full information on the clinical trial be provided to the research subject's legal representative *as soon as reasonably possible*, and that his/her informed consent be obtained on behalf of the research subject until the subject is him-or herself able to give informed consent. Due regard must furthermore be had to the limitations of the relevant therapeutic window.	Yes, all reasonable attempts must first be made to contact the research subject's legal representative, family or relatives with due cognizance of the limitations posed by the relevant therapeutic window. The REC/IRB must also ensure that adequate procedures are in place after the treatment/medication has been administered to ensure that the research subject's legal representative is found and deferred consent obtained.
Specific provision is made for procedures to be followed when the research subject passes away before his/her informed and/or deferred consent is obtained	No	No	No	No
Role of the REC/IRB	• Central to ECR • REC/IRB must have approved the research protocol • Best interest of the research subject placed wholly in the hands of	• Central to ECR • REC/IRB must have approved the research protocol and the procedure under which action is taken • The REC/IRB must have	• Central to ECR • REC/IRB must have approved the research protocol and the procedure under which action is taken • The REC/IRB must have	• Central to ECR • REC/IRB must have approved the research protocol and the procedure under which action is taken • The meeting minutes

	the REC/IRB and the researcher.	a member with professional expertise in the treatment of the disease to which the trial relates or must obtain advice on the clinical, ethical and psychological problems in the field of that disease and patient population which may arise in relation to the trial.	expertise on the relevant disease and the patient population concerned or must obtain advice on the clinical, ethical and psychosocial questions in the field of the relevant disease and patient population before endorsing the protocol.	and all decisions taken by the IRB with regard to the research protocol must be noted • The REC/IRB must ensure that adequate procedures are in place to ensure that the researcher will make every attempt possible to contact the research subject's legal representative and family/relatives

The important role of the Research Ethics Committee in the consent procedures of emergency care research

A common theme across all the ethical guidance documents and legislation of different jurisdictions discussed in this article is the important oversight role of the REC/IRB. It was also evident that the REC/IRB must tread carefully in a minefield of legal and ethical considerations when exercising their responsibilities in evaluating and monitoring the consent procedure in ECR. This is anomalous as 'consent' in emergency care research rarely reflects the true and real autonomous decision/wishes of the research participant or that of his/her legal representative.[31]

- Consent obtained for ECR is usually based on presumptions about the choices that the participant may have made, on the basis of a general theory of human goods, or of the rational will of a person.[32]
- Deferred consent cannot be regarded as 'informed' since the participant was not informed of all material aspects of the research, nor was the participant offered the opportunity to weigh potential risks and benefits before participating in the research.[33]
- And, it is also questionable whether the vulnerable and constraint position in which research participants find themselves can ever be regarded as conducive of true informed consent. It is even said that the validity of proxy consent in such situations is questionable as proxies tend to make decisions on what they hope will happen and they don't take into consideration the real possible non-benefit and/or research-related burdens.[34]

Berger therefore questions whether a research subject's deferred consent can be regarded as proper retroactive authorization for research initiation. And he also questions whether it can be said that the RECs policing role adequately protects such participants' best interest .[35]

RECs and IRBs should be sensitive to these concerns and objections especially as courts will also be responsive to arguments questioning whether the self-imposed regulations applied by RECs in determining whether consent procedures for ECR is adequate to sufficiently protect a participant's statutory, common law or constitutional rights. This places researchers at a real risk of liability even though the research protocol was approved and carefully followed.[36] And, this risk is further exacerbated where scant or no national norms, standards or regulations are available on which RECs can base their review process and consummate decisions. Researchers should therefore also be sensitive to these concerns and try and address the logistical challenge of obtaining informed consent in ECR in terms of the available ethical and legal standards, and with due cognizance of processes and developments in other jurisdictions.

Conclusion

Despite these ethical and legal concerns with regard to decision-making and consent procedures in ECR, such research remains important and necessary in improving the safety and effectiveness of emergency care.[37] However, given the dangerous inroads

that ECR can make in the personal autonomy of research participants, careful scrutiny and review by an oversight body in terms of national standards and guidelines is certainly pivotal. The current absence of standards and guidelines in South Africa is problematic and the National Health Research Council should definitely address this in terms of their mandated responsibility to set norms and standards for health research and clinical trials (section 72(2)(c) of the National Health Act). Guidance is also required on how the restored autonomy of such a research participant ought to be respected, especially where the participant refuses participation in the research project ex post facto. Questions furthermore remain whether the research results of a participant who refused consent ex post facto, or who had passed away before being able to give the requisite consent may be retained and used.

In addressing these *lacunae*, the relevant South African authorities may, and should, consider the norms and standards applied in other jurisdictions with regard to deferred consent in ECR. In the proposed new version of the Declaration of Helsinki this is, in fact, obligatory in terms of general principle 10 which states that "Physicians must consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards".[38]

About the Author

Dr. Andra le Roux-Kemp's primary interest is in Medical and Health Law, focusing on the intersection between the law and other disciplines (specifically medical sciences) and how different perspectives and research methodologies (specifically medical anthropology and bioethics) can inform the law. This interest in the interaction and interstices between the law, other disciplines and its social contexts has also informed her work in Forensic Law. She is currently residing in Berlin where she is completing a book 'Foundational Principles of Forensic Law in South Africa', and working on a second PhD entitled 'A moral evaluation of Universal Health Coverage by means of National Health Insurance Plans in South African and Ghana'.

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