health
Department:
Health
REPUBLIC OF SOUTH AFRICA

AIDE MEMOIRE

MEETING OF THE NATIONAL HEALTH RESEARCH ETHICS COUNCIL (NHREC), HUMAN RESEARCH ETHICS COMMITTEES (HRECs), ANIMAL RESEARCH ETHICS COMMITTEES (ARECs)AND OTHER INTERESTED PARTIES

18 MAY 2017

CIVITAS BUILDING,IMPILO BOARDROOM

NATIONAL DEPARTMENT OF HEALTH, PRETORIA

NATIONAL HEALTH
RESEARCH ETHICS COUNCIL

ATTENDEES:

See Annexure 1.

1. Opening and Welcome

Ms T Zondi, Cluster Manager: Health Information, Research Monitoring and Evaluation, opened the seventh joint meeting of the National Health Research Ethics Council (NHREC) and the Health Research Ethics Committees (HRECs), Animal Research Ethics Committees (ARECs) and other interested parties. Ms Zondi welcomed the new NHREC Chairperson, Deputy Chairperson and members of the National Health Research Ethics Council to the Department of Health. She further welcomed representatives of the different Research Ethics Committees from across the country. Ms Zondi expressed awareness that attendees include Provincial Health Research Committees (PHRCs), the National Society of Prevention of Cruelty to Animals of South Africa (NSPCA) and the South African Veterinary Council (SAVC) and the Medicines Control Council (MCC).

Ms Zondi mentioned that the NHREC plays an advisory role to the Department and the Minister. Ms Zondi drew attention to the South Africa Demographic and Health Survey (SADHS) 2016 Key Indicator Report that was recently completed. She mentioned that the new integrated National Strategic Framework (2017-2022) of the Department is in place to strengthen health research in the country. The NHREC plays an important role in the ethics and research field. She reported the National Development Plan (NDP) 2030 sets out the overarching goals for the health sector.

Ms Zondi concluded by saying that the Council has achieved considerable progress and she expressed the Department's gratitude for the work. Finally, she wished attendees fruitful deliberations and a successful meeting.

2. Chair's overview of beginning of new term '2016' to 2019

Professor Pope (Chairperson) explained that Human RECs and Animal RECs from all over the country had sent attendees to the meeting. In addition, there were other interested parties in attendance.

She explained that the current NHREC term had started late. The previous NHREC term ended in August 2016 but the new Council was appointed only in November 2016 as the process was delayed. This meant that a period of some three months elapsed without a NHREC in place. Some members from the previous Council helped to complete outstanding matters in the interim period. However, the implication of the delay in appointment is that an unavoidable break in continuity has occurred. All members are familiarising themselves with their new roles and work is beginning to pick up.

Professor Pope explained that appointment to the NHREC has nothing to do with representation of universities. While it is true that many members of the NHREC are from tertiary institutions, none is appointed *because* she or he is from an institution. Instead, the process of nomination, application and selection by the Minister follows the statutory provisions of the National Health Act. Interested people who are appropriately qualified may apply, submitting supporting documentation including nominations and a motivation that sets out the eligibility and expertise of the applicant. The Department of Health selects the NHREC members in terms of the categories for appointment, as spelled out in the Regulations governing the NHREC. She reminded the meeting that members of the NHREC contribute independently to the NHREC, rather than representing their home institution.

Professor Pope pointed out that five members of the new Council served on the previous NHREC. The term of office is three years. Any appropriately eligible member from any institution may apply for the next NHREC. The new NHREC held its induction meeting in December 2016.

Professor Pope concluded by reminding everyone that the term ‘REC’ is used inclusively to indicate both HRECs and ARECs.This is consistent with the fact that the principles of ethical research apply to all researchers across the board and that this forum (the joint meeting) provides the opportunity to speak to as many role players as possible.

3. Explanation of organization of day’s proceedings

Dr Ncanana explained that after the initial plenary session, separate programmes will address HRECs and ARECs respectively. HRECs will focus on SA GCP topics, while ARECs will discuss Animals in Research WG business & other topics.

4. Separate programmes for HRECs & ARECs

To facilitate more focused discussion, two venues were arranged so that HREC and AREC topics could be addressed simultaneously but separately. It is important to note,however, that the NHREC does not support conceptual separation of HRECs and ARECs, since, by definition, all members of RECs have similar responsibilities and professional expectations. For this reason, a complete separation between HRECs and ARECs for purposes of meetings with the NHREC will not be encouraged. The approach remains that all REC members should see themselves as subject to similar research ethics principles while simultaneously they acknowledge that their review of research proposals necessarily draws on different substantive principles relevant to the involvement of humans and animals respectively. In similar vein, these comments apply also to RECs that only review research proposals to use human biological specimens. The importance for enhancing high standard ethics review lies in being open to input from diverse voices, even those not usually engaged on one's area of expertise.

4.1 Human RECs discussions (Prof Pope & Dr Ncanana)

Topic: issues arising from feedback to SA GCP Revised Draft

This topic serves in 2017 to assist with obtaining feedback from all role players on the draft revision of SA GCP guidelines. A draft was circulated to REC Chairs (in early 2016) with the request that these should be widely circulated amongst their committee members and institutional researchers. In early 2017, the draft was circulated to pharmaceutical industry role players for input. Issues arising from input received form the basis of the discussion topics circulated prior to the meeting.

1. *Managing responses to suggested change: e.g. 'Purpose of NHREC is not to rewrite SA GCP'*

Background provided by Prof Pope:

The first issue incorporates how we respond to change. What limitations affect our consideration of change? How do we incorporate change management into our daily professional lives? The comment in the feedback seems to be a pushback against the obvious change of style and format adopted in the revised draft of SA GCP. It question why a revision of SA GCP should include a 'rewrite'?

Most GCP guidelines deal with standard operating procedures for clinical trials, but this does not mean that ethics should be separated from GCP.Without integration of ethics, this might leave huge gaps for researchers who only access GCP and no other guidelines.This is why the NHREC decided to change GCP to a narrative style and to achieve closer alignment between GCP and DoH Ethics in Health Research Guidelines. Narrative GCP Guidelines will facilitate thinking about ethical conduct of research.

Discussion:

It was noted that only a handful of members said they had received the current revised draft GCP guidelines; also that only a handful of members are new Chairs of RECs.This was very disappointing as the revised GCP guidelines were circulated to Chairs of RECs with the request that they be circulated widely: to all REC members as well as researchers.

This outcome reflects a major issue with dissemination of information. In turn this presents a big problem for the NHREC. How is the Council supposed to achieve consultation input from the research ethics community if the information it sends out is not disseminated by those who receive the emails? A suggestion from the floor was that general apathy to requests for comments on revised guidelines exists; further, that emails received with documents attached are sometimes insufficiently uninformative as to what is required by way of response. It was noted also that RECs do not communicate changes regarding who is the Chair and what the updated contact details are to the Secretariat. This means that when the mailing list is used in good faith by the Secretariat, emails are not reaching the appropriate people. It is very important that these 'housekeeping' matters are addressed urgently. The NHREC cannot communicate effectively with RECs if it does not have accurate contact details. Attendees were requested to notify the Secretariat of changes to contact details and identity of Chairpersons. The NHREC will do its best to communicate, but RECs must take responsibility for ensuring that communication channels are effective.

Prof Pope:

Some dissension is evident from the feedback regarding the role of the NHREC, especially that the NHREC should not enter (perceived) domains of other bodies. The nature of research ethics requires us to be collegial and to collaborate and work together.It is important that we work together to minimise or ensure no harm to participants, researchers and institutions. We

need to work jointly to achieve these goals. Important, though, is that the NHREC is mandated by the National Health Act to determine the norms and standards for research ethics, including for clinical trials.The MCC sets standards for how to implement best practice in running a clinical trial, but they do not determine ethical norms. A complementary relationship between the MCC and the NHREC will facilitate the appropriate revision of the GCP Guidelines.

2. *Relationship between DoH 2015 and revision of SA GCP: why does the revision of SA GCP refer to DoH 2015; why are ethical issues relevant to GCP*

Discussion:

The revised GCP highlights the importance of ethics and of following guidelines to address ethical issues.

3. *Why revise structure and format? Why could the old format not just be updated; the language of the revision is too difficult e.g. equipoise, and full of legal writing; why a totally new title; SA GCP should only have information that is not in ICH*

The Hospice Palliative Care REC reviewed the revised draft GCP:no problems were identified with structure or format; the 'read' of the new GCP was much improved. A related query concerns the content of GCP training, specifically whether adequate input on research ethics is included in the training.

New title of GCP guidelines was questioned – the explanation is that the change aligns the formal with the name commonly used by researchers and RECs.

4. *Responsibilities of HRECs and MCC regarding clinical trials: looking after the ethical issues of clinical trials is for the HRECs and the MCC*

Prof Pope: having clarity on the roles of the regulatory oversight bodies and the reviewing bodies allows us to be confidentin the correctness of the assigned roles. The NHREC has regulatory oversight and a determinative role in formulating norms and standards. In fulfilling these roles, the approach of the NHREC has been consultative, seeking input from all role players to ensure that the norms and standards are feasible and effective. The MCC has a similar oversight role and a determinative role in formulating the best practice standards. The HRECs apply the norms and standards and implement the best practice standards set by the

regulatory bodies. The revised GCP guidelines are an important component of this framework.

5. *Why is 'vulnerable populations' not specifically mentioned in SA GCP revision? (refer to 3.2-3.5 in DoH 2015)*

Discussion:

This issue is fully addressed in the 2015 Research Ethics Guidelines; it is not necessary to repeat information in the GCP Guidelines when it is readily available in the complementary guidelines.

6. *Payment for participants: Time, Inconvenience, & Effort (TIE) method of calculation; is a flat rate preferable? How to be fair and ethical and avoid being over-paternalistic?*

The DoH 2015 Ethics in Health Research Guidelines provide guidance on how to calculate the amount of reimbursement for participants. Several issues arise when PIs and RECs consider reimbursement for participants. The most important issue seems to be a general lack of clarity about the meaning of the terms 'reimbursement', 'incentive', and 'payment'. First, the casual tendency is to use 'payment' when properly either 'reimbursement' or 'incentive' should be used, depending on the context. In principle, research participants are NOT paid to participate. Each participant decides voluntarily whether to participate. Having chosen to participate, a participant is not expected to pay or to incur costs to participate, which means that travel and subsistence costs incurred by participants should be reimbursed by the researchers. Some research projects may struggle to attract appropriate participants, which means that an incentive (usually money) may be used to attract them. The difference between 'reimbursement' and 'incentive' should be clear: reimbursement is for expenses incurred by participants, while an incentive serves to attract participants.

To calculate a fair rate of reimbursement requires an accessible standard for comparison. The Time, Inconvenience & Effort (TIE) method explained in the guidelines provides the standard. The *basic recommended unit* for calculating the hourly rate for a study is based on sectoral guidelines for manual labourers in the construction industry from the Department of Labour, i.e. R25-R30 per hour. Importantly, if the time, inconvenience and effort expected of participants is negligible, then no reimbursement is necessary. This point appears to be misunderstood by many. The notion that some 'payment' is due despite no expenses being

incurred is not compatible with voluntary participation in research. It becomes paid participation, which is not ethical.

It seems that many researchers would prefer a flat rate (e.g. the rate of R150 previously recommended by the MCC). A flat rate raises several ethical dilemmas, not the least of which is that, without a calculation of TIE, the amount bears no resemblance to reimbursement but becomes a payment. This approach may suit researchers as it is convenient and regarded as 'fair'. But if researchers do not apply their mind to the amount of reimbursement, there is no justification for the amount, which means that the participants in that study are not in mind. Instead, expedience and study efficiency are elevated above the interests of the study participants.

Furthermore, when the MCC originally recommended a *minimum* rate of R150 per visit, the nuances of this recommendation very quickly faded and it became seen as a mandatory payment rate. Ethically, this approach is doubtful. Recent discussions show that there are concerns about the flat rate failing to reflect changes in inflation. A rough calculation of an increased amount shows it should increase to R300 per visit. This amount provokes concerns for many REC members and researchers about participants being unduly influenced to participate by the prospect of R300 per visit. Respect for persons and for autonomy require RECs and researchers to avoid paternalism. Some REC members and researchers favour not revealing amounts of reimbursement in informed consent documentation. Arguably, however, if the study stands up to ethics review and is approved, then in principle the study is ethical which means that even if a person is attracted by the reimbursement amount, that cannot by itself make the study unethical. The idea that reimbursement amount might be unduly attractive relies on there being no proper calculation using the TIE method.If the outcome of the calculation is the amount of the proposed reimbursement, then this is fair. It is important to recognise that this amount is not a payment. When a reimbursement is proposed, does the amount match the 'work' a participant will to do? The PI should justify the amount for the REC to review.

Whether a distinction between commercially sponsored clinical trials and other clinical trials is relevant for reimbursement calculations was raised but not conclusively answered. However,

the TIE method of calculating provides a guide for any clinical trial. The realistic minimum amount is R0, i.e. if there is no TIE implicated, then no reimbursement is necessary.

Multinational clinical trials – comments from the floor mentioned that transport costs are generally easy to mention, but that inconvenience and effort are seldom addressed. The role of the local PI (and especially the National PI) includes seeing to the fairness and appropriateness of these latter aspects being included in the calculation. That currency exchange rates may result in differences between local payment rates in ZAR and others paid USD was raised as a matter of concern based on fairness. But reimbursement is about actual costs; thus exchange rate fluctuations and vagaries are not relevant. Confusion about this point arises when 'payment' is in mind, rather than 'reimbursement'. There is no obligation to give reimbursement if it is not warranted. Participants are not being paid for taking part in research studies. It is very important that the participants are not seen as employees getting payment for 'working'; they are voluntary participants in research studies. It is essential that reimbursement is considered in terms of the TIE method. And that the consent process addresses reimbursement and the TIE calculation for the specific research context.

The TIE method is not difficult to implement. Inevitably, however, there is a tension between what is reasonable for the researcher and what is fair and ethical for the participants. Time is considered in terms of the commitment required of participants that is more than standard of care. While time is relatively easy to calculate, inconvenience and effort may require more thoughtfulness. The level of risk of harm, the complexity of procedures and the invasiveness of interventions affect inconvenience. Effort includes how many public transport modes must be used to arrive for study visits, whether additional child care must be paid for, etc. The local context is directly relevant.

The MCC is currently deliberating on the issue of reimbursement and is considering changing its recommendation to R300. Input from the NHREC to the MCC is that the TIE method is preferable to a flat rate, which suggests that *everybody* is *entitled* to the minimum rate and does not consider the ethical and contextual issues.

7. *Post-trial access (or continued access) to study medicine; how to optimize fair benefitethically?*

Concerns abound about participants who are 'doing well' on study medicine being able to continue after the trial is over. The newest revision of Helsinki Declaration includes a mandatory statement requiring continued access, without providing any guidance regarding phase of clinical trial or otherwise. Many RECs and researchers agree with this call but some advocate caution on ethical grounds. Concerns include that the evidence for shifting from experiment to clinical care may be scant; that the line between research and clinical care is being blurred; that longitudinal information about side effects is seldom available so early; and that appropriate analysis in light of end points is essential to inform decisions. Furthermore, what is the ethical obligation of RECs? To facilitate 'rescue' of participants at end of trial?

Clinical trial design is well established for good reasons – protection of participants is paramount. If continued access is permitted, are they participants? Does this mean imposing extension studies on all trials? Who oversees participants' well being? Who pays for the medicine or for the possibility of medicine related injury? The insurance policy ends when the trial ends. Caution requires that a much more nuanced approach is adopted to ensure that participants can share in fair benefits of the trial, including continue on medicine that has beneficial outcomes.

TEA 11h00-11h30

8. Technical topics: 11h30-12h45

8.1 Electronic CRF & source documents: how should these be described, regulated?

What is an electronic signature?When you deliberately sign your own signature and preserve it in electronic form, sometimes well-protected and sometimes not. It looks just like the handwritten signature.

Other versions of electronic signatures are becoming accepted – e.g. typed in certain font.These latter types of signatures should not be accepted. Importantly, the person whose signature is appended to a document must *know* that this is happening. Also, how do electronic signatures link to mindful/responsible signing off? Security measures need to be

built in. And some process to show that signature is yours. The implications of misuse of signatures are serious.

In the clinical trial context and the research context more generally, applications carry signatures of e.g., HOD, supervisor, etc. For clinical trials, a number of source documents must be retained as *original records* in the study files.What does 'original' signify? Hard copy or electronic?

Several questions were posed but not definitively answered:

- Is it fine that electronic signatures can be used for the source documents?
- What format of signature is 'legally binding'? Depends on what is being signed e.g. email can indicate entering into a contract; but other issues (eg, signing will) require witnessed handwritten signature. Question is not whether electronic signatures are ok, but rather how to incorporate these into the Guidelines. No clear guidance forthcoming yet.
- Electronic documentation brings advantages including easy access to further information. But accessibility to electronic services is potentially an obstacle.

Suggestion: align REC processes with institutional policies. And use established processes in other jurisdictions where these are appropriate for local use. NIH & ICH & FDA documents refer to use of signatures.

- How does this affect the participants signing informed consent?ICF is not a contract. But different implications (fewer) implications for harm as no legal issues.

Nothing that is stated in GCP guidelines would impose – it would permit. This would ensure alignment with institutional policies.

The issue for SA GCP is how to explain issues re electronic vs manual signatures.

8.2 Electronic signatures: how to ensure that the responsible person reads the document before his or her signature is added?

Covered under 8.1

8.3 National PI – how should this role be described, regulated?

A national PI is envisaged particularly for multi-site studies in the country and especially when some sites are not in SA. This is important because the locus of overall responsibility is not clear otherwise.

Views needed on how this role should be described or regulated?

Responsibility – research management, monitoring & record management responsibility would lie with the national PI.There are budgetary implications associated with nominating a national PI.

Would giving status as a national PIresult in other sites being sub-sites? MCC recommends that national PI role is advisory only as part of a study advisory board. MCC is still deliberating on this role.

A related question was asked about review reciprocity between RECs of different institutions. Some perceive there to be a 'lack of cooperation' between different universities' RECs, especially when one study has multiple South African sites. Why must multiple REC reviews and approvals be obtained? A suggestion was that there is need to discuss the role and responsibilities of a national PI. The question also speaks to the issue of *reciprocity*, as discussed in the DoH Ethics in Health Research Guidelines. Several issues are implicated: sites do not necessarily share the same contextual factors; factual information rather than perception should guide RECs. Institutional risk and other related factors should be considered. However, reciprocity of review is permitted. As HRECs are audited and evaluated, the standard of ethics review and administrative processes will become more standardized which in turn will help to boost confidence amongst RECs. It is currently open to any REC to decide to rely on a review of another registered REC and to expedite its own review process. Decisions in this regard should be based on appropriate information supplied by researchers, e.g. review correspondence from the full review REC.

8.4 The need to customise clinical trial design and procedures for SA: E.g. inclusion/exclusion criteria: comment received 'the entry criteria cannot be changed for South Africans and it is irrelevant whether they are appropriate for South Africans – they need to adhere to same entry criteria…

Discussion points:

Is this where the role of a national PI comes in? To customise criteria for a South African population.

The notion of customizing entry criteria may be misunderstood in this comment – it is accurate to state that entry criteria cannot be different for one group. That would introduce a confounding factor which would make the research unfeasible. However, some of the design features, consent processes and other aspects can be adapted to suit local conditions. One commonly criticized feature is the failure of PIs to ensure that the consent documentation is appropriate for the reading age and ability of the local population.

8.5 How to manage discrepancies between 2006 SA GCP and comments made:

The concern is that the revised SA GCP states requirements which certain commentators find contradictory or inaccurate. E.g.

8.5.1 The MCC is responsible for reviewing the study design for scientific validity and safety and to ensure that all <u>legal and ethical</u> requirements have been met.

Comment: It is not within the MCC scope to review the *ethical* aspects of the trial – only scientific aspects and safety of the IP.

It is true that sometimes a guideline reflects a position that may have changed over time in practice. However, it is not possible to separate the ethics from the science (and safety issues) of a protocol – ethics is inherently intertwined with the scientific and safety aspects. An interesting point is that some RECs do not favour the MCC also reviewing the ethics of a study. It is unclear why this is the case. Similar views arise about different entities reviewing 'the science' and ethics of a proposal.

8.5.2 The MCC must ensure that the trial site is licensed.

Comment: Licensed as what or by whom? e.g. what license should research sites have? Is MCC approval for a site considered to be a site license?

This question was not answered directly.

Another issue relating to gatekeeper functions was raised: who should review first? What to do when conflicting reviews are given by the REC and the MCC? The first question is a process question: generally, PIs are advised to submit applications simultaneously to minimise delays. However, final approval from the REC is generally subject to the other permissions being in place. It is also important to note that just obtaining ethics approval doesn't mean that research can just go ahead – gatekeeper role is essential. A study might be ethical, but it might not be practical or feasible to conduct research at a particular site.

The total process of obtaining ethics approval and permissions from the various regulatory authorities and institutional gatekeepers must be considered by the PI and planning should occur accordingly.

How much of this confusion has to do with the content of training that researchers do in order to conduct research?If training is currently only GCP and regulatory in nature, then perhaps training needs to be considered differently.More education and training might assist to address some of this confusion. It is apparent that often PIs do very little preparation before submitting protocols for review, regarding community engagement or stakeholder involvement in the study. Applications often do not contextualise the planned research adequately – it is important that these issues are considered.

What is also apparent from the discussion is that, in this context, perhaps the guidelines need to elaborate a bit more on certain points. Need to consider how to provide extra information to elaborate on points.Clarity needed whether this information should be in the DoH Guidelines or GCP Guidelines.

There is also a lack of clarity re different gatekeeper functions for health-related research nationally and provincially. It would be important to clarify roles.

There is still confusion re functioning of provincial research committees, and the gatekeeper function.Liaison between NHREC and NHRC needs to be stronger to ensure that information regarding the role and function of provincial committees needs to be disseminated.It is also important to consider complexities of stakeholders and sites and combination of regulatory and practical issues in planning of research studies. Health Systems Trust piloting online database to improve links between RECs and provincial research committees.

Given the absence of clarity regarding getting the requisite clearances, how should this be presented to gatekeepers and getting appropriate approvals.Advice to researchers should be to get all necessary approvals and to ensure that due diligence is followed, especially considering different timing of different review processes.Submissions can occur in parallel. RECs can provide provisional clearance, pending MCC and institutional approval.Guidelines highlights that one cannot commence research until all appropriate approvals have been obtained.Any letter from RECs **must** state this clearly.

8.6 Guidance on how to determine level of risk

Harms can be physical, social, emotional, third party, psychological, etc.National and international guidelines refer to minimal risk, more than minimal risk and high risk.

Risk is generally measured in accordance with every day risk encountered by the person. For example, taking part in a cycle race. There is inherent risk of harm associated with taking part in a cycle race. Does one include these inherent risks when evaluatingthe risk of harm for the study? I.e. that which would exist around you – how should this be considered? E.g. measuring heart rate during the cycle race. Risk of harm from this measurement is minimal, but the context of the cycle race is potentially risky.

Another example is vulnerable adult participants suffering from serious illness or socioeconomic deprivation. The everyday risk of harm might be that participants are hungry and so this is not a study related risk of harm but it is relevant that this deprivation might affect potential participants' ability to make decisions, including a voluntary informed choice about whether to participate.

An example of a lab-based study where participants are subjected to cycling intervention. The risk evaluation for this study would be different compared to taking part in an established cycle race.Indeed it would. Appropriate screening can facilitate safe participation in the research.

Regarding the established cycle race, should the REC ask availability of first aid, traffic control, etc. in terms of event? Important to consider whether the study would add to risk of harm or create a context for increased risk of harm.It is important for RECs not to 'mission creep' i.e. to go beyond the bounds of their proper mandate; they should notimpose undue burdens on researchers, which have the effect of limiting research.

A request was made for a checklist for evaluating minimal risk. A checklist should be well-underpinned by ethical considerations. Subjectivity in checklist approach should also be considered. What does it mean in context? How is vulnerability assessed in within the appropriate context? Some RECs have devised such lists. Perhaps they are willing to share with others. Those that are willing are requested to forward them to the Secretariat for posting on the website (with appropriate acknowledgements of course).

Training of researchers in risk evaluation important. Important for researchers to justify and motivate. Sometimes checklists can provide an 'out' and do not encourage researchers to think about their research context. But, checklist can also stimulate thinking and facilitate understanding context. Prop Pope also highlighted risks or harms associated with social sciences research. Being thoughtful and mindful and being guided by checklists is very valuable in terms of appropriate identification of risk.

If the understanding of minimal risk is improved, what are the implications for high risk studies? Is an effective mitigation plan acceptable or does it mean that a high risk study cannot be approved? Understanding the level of risk of harm does not hold out necessary implications for whether research can be approved. Rather, it assists the REC and researchers to plan appropriate mitigation measures. It also permits potential participants to understand what is envisaged and what will be done to minimize the harm from occurring.

8.7 Open access to research data – how to regulate ethically and fairly?

Attendees want better clarity regarding how open access to research data works and what makes it work well.There are many processes to consider (ethical issues, institutional processes, etc.) and to engage with.We also need more information about what ethical aspects of open access should be considered and prioritised.

LUNCH 13h00-13h40

Plenary session

Questions:

1. Status of research ethics committees – what is the timeline for the accreditation process; and is provisional accreditation the same as full accreditation?

Please note South African does not have an 'accreditation' process; instead the National Health Act provides for 'registration' of audited RECs. There are no specific timelines for the registration process.Once application documents are submitted, an assessment visit takes place; this is followed by an audit process. As soon as any queries or gaps are addressed, full registration is achieved. Between the initial assessment and full registration, provisional registration is noted. Only after full registration, does the REC receive delegated Ministerial authority regarding approval of 'non-therapeutic research with minors'. Apart from the delegated authority, the work of the REC remains the same for provisional and full registration. However, recognition by others e.g. regarding reciprocal review, depends on full registration. The purpose of the assessment and audit processes is to strengthen the review process and to achieve a high standard both procedurally and substantively across the board.

Re current timelines, there has been a lag for some provisionally registered RECs.The NHREC apologises for this. The reasons include logistical matters and access to funding. The backlog is being addressed: several audits are taking place in May and June 2017.

2. What if two ethics committees are in close geographical proximity – one is fully registered and other is provisionally registered. What happens if a researcher bypasses the fully registered committee and approaches the provisionally registered REC? Is there a choice between committees?

The registration status should not influence the quality of review. However, if a newly established committee is approached, that committee should be able to consult with the more experienced committee. In general terms, an institution does not permit 'forum shopping' i.e. permit researchers to look for a favourable landing place. There will be institutional policies which should be adhered to. Where an institution has more than one equivalent RECs, there should be a procedure to prevent inappropriate forum shopping e.g. shared lists of applications received or agendas etc.

4.2 Animal RECs discussions (Dr Mohr and Prof Brink)

1. Welcome and introductions

Thirty-six delegates attended the AREC session, representing ARECs from across South Africa.

Dr Bert Mohr (session Chairperson) introduced the NHREC Animals in Research Working Group and provided an overview of the NHREC's mandate for ARECs, which include to determine guidelines for the functioning of health ARECs, to register and audit health ARECs, and to set norms and standards for conducting research on animals, as per Section 72 (6) of the National Health Act No 61 of 2003.

2. NHREC audit of ARECs – key findings and recommendations

Dr Mohr presented key findings and recommendations from the NHREC Final Report of 6 Oct 2016 on AREC audits, with a focus on moving forward constructively as a national animal ethics community.

The purpose of auditing the 17 ARECs was to ensure objective, independent, quality oversight so that the public is assured that ARECs meet optimal standards of ethical practice and that humane requirements for the care and use of animals are met. It was emphasised that it is through auditing processes that the NHREC can identify ways in which to build greater capacity in ARECs.

The auditing standards were based on the South African National Standard for the Care and Use of Animals for Scientific Purposes (SANS 10386:2008) and the National Department of Health's (NDoH) publication Ethics in Health Research: Principles, Processes and Structures, 2015.

In terms of best practice, the message was positive overall with most ARECs being well established, resourced and functioned well, e.g. all had SOPs (though not always complete) with 94% meeting regularly to review protocols. The composition of the ARECs was largely compliant, e.g. 88% had a veterinarian, 76% had a community representative and 82% had a legally trained member.

Areas for improvement included that only 53% of ARECs had documented animal research ethics training for their members; 47% of ARECs did not have clear guidelines on post-

approval monitoring and evaluation of approved protocols; and registration of research animal facilities with the SAVC and inspection by the NSPCA or other welfare organisations was considerably lower than expected.

Recommendations included the need for formal documented training of ARECs, including prioritised induction training of new members; AREC membership should include all required categories and reflect the South African population's demographics; AREC members should be given appointment lettersthat specify assurance that their organisation or institution will provide legal protection in respect of liability that may arise in the course of bona fide conduct of their duties; AREC Terms of Reference and SOPs should be clearly separated and aligned with the relevant standards; Post-approval monitoring and evaluation of approved studies must be conducted and documented by ARECs; ARECs should inspect research animal facilities and produce inspection reports, with recommendations implemented and clearly documented to be readily available to auditors; facilities should be registered with the SAVC and inspected by animal welfare organisations; and guidelines concerning the responsibilities of researchers and teachers should be made available.

Dr Mohr reiterated that the audits identified ways in which to build greater capacity in ARECs, rather than being punitive. A supportive environment for nurturing ethical animal research will include development of the national animal ethics community. Together everyone achieves more.

A key message from Dr A Motsoaledi, Minister of Health, in the report highlighted how the NHREC's work contributes significantly to the enhancement of dignity in South Africa. Reference to the dignity of animals can be found in modern international legislation regarding the care and use of animals.

The meeting was reminded that all registered ARECs are required to submit an annual report to the NHREC. Annual report templates are available on the NHREC webpage. The report template will be further refined in future in order to be more specifically applicable to ARECs.

3. The education and training needs of ARECs in South Africa – SAALAS survey feedback

The need for education and training of ARECs was discussed in light of the NHREC audit report. The NHREC's mandate does not extend to provision of education and training for ARECs. Given the importance of education and training in achieving the required standards of AREC functioning and animal research, it was agreed that the topic should receive dedicated attention in the day's agenda.

Prof Tiaan Brink (session Vice-Chairperson) presented an overview of the interim results from the national online survey (anonymous) of AREC Chairpersons that was conducted in 2017 by the South African Association for Laboratory Animal Science's (SAALAS) Working Group (WG) for Animal Ethics Committees (AECs). The survey was aimed at identifying education and training needs of AECs.

The survey received 22 responses, representing diverse scientific areas and ranges of animal species. Highlights of findings included: The preferred mode of training was workshops at own institution, followed by online learning (self-pace courses or assigned readings), workshops at other institutions and conferences. Gauteng was the preferred site of training, followed by the Western Cape.

The main challenges for AEC training include funding (for travel and registration fees), insufficient human resources to provide training (i.e. number of staff and their professional time), insufficient clarity regarding the type of training required, and limited time of AEC members to attend training.

Preferred training topics included how to perform effective ethical review, laws and regulations, South African National Standards 10386, requirements for inspections of animal facilities, moral philosophy, compassion fatigue, practical application of the Three Rs and care of specialised species.

4. Education and training of ARECs in South Africa – practical solutions

The meeting considered how to implement the education and training of ARECs. No comprehensive national platform currently exists. As a community, we can support each other and share resources.

Several institutions shared their experience on in-house training for AREC members, some consisting of short or informal sessions and others more structured. Often institutional training

is aimed mainly at researchers, rather than AREC members. Some ARECs receive formal animal ethics training from private service providers. Associations are increasingly playing a role, e.g. the SAALAS conference near Cape Town (1-3 Nov 2017) will include sessions on effective animal ethics review, as well as a session dedicated to education and training of AREC members by the SAALAS WG for AECs, which will address topics identified in the survey. Other associations, e.g. SARIMA, play a role for administrators, while the newly constituted REASA may play a future role. A proposal was to develop online training courses and to develop a database of existing online training resources.

How to make efficientuse of limited resourceswas considered i.e. to reach as many ARECs as possible in a single national training event. A proposal was to hold a training event for AREC members on the day after the 2018 NHREC Annual Joint meeting in Pretoria. This would save travel costs for many registered AREC members, which are a major expense. It was proposed that the SAALAS WG for AECs could consider hosting the event at a separate venue to achieve clear separation from the NHREC meeting. Delegates were in broad agreement that this proposal should be pursued.

It was agreed that training should cover theoretical principles and knowledge, as well as practical implementation of the principles (e.g. effective ethical review of animal research proposals). Training should be offered on various levels, e.g. induction training for new members (how to function effectively on an AREC), continuing professional development and refresher courses for existing members, as well as more specialised training for subsets of AREC members, e.g. veterinarians, administrators, facility managers and lay persons. There was general agreement that animal species covered should include agricultural animals and wildlife, since many registered ARECs evaluate these and the same standards should apply; ethical standards should not depend on the animals' location.

Concerns were raised regarding perceptions of lack of institutional support for AREC training in some instances. It should be emphasised to the institutional official who bears ultimate responsibility for animal research that education and training of ARECs is a requirement for NHREC registration.

Other aspects raised include that a simple method to build capacity for newly constituted ARECs is for members to attend AREC meetings of nearby institutions that have established

capacity and experience. It was discussed that lay members (Category D) can be difficult to find and retain, though some institutions have had good success with this. Training of lay members is critical. The point of openness and development of trust between ARECs and the scientific community they support was also emphasised, as this is the way to further interests of ethical practice in animal research.

5. Cooperative animal ethics oversight and monitoring agreements for inter-institutional animal research in South Africa – proposal for the development of national best practice guidelines

Multi-institutional and contract-based animal research is becoming common in South Africa. Several institutions shared examples. Animals are often transferred between institutions (e.g. for imaging). Resource constraints support the development of regional collaboration and resource sharing. The meeting considered this contemporary topic in the context of AREC oversight of approved protocols.

Inter-institutional animal research presents advantages, but also carries the potential for increased institutional reputational or legal risk, which should be managed. In collaborative studies, ethical obligations may extend to animals housed or subjected to procedures at other institutions' facilities. Collaborations may also raise additional requirements by funders for welfare assurance. Examples were cited how such complexities can increase in cases when international companies are involved.

The meeting concurred that it is essential to have formal agreements between institutions prior to the initiation of collaborative animal studies, which clearly outline the responsibilities of the various parties, including during animal transport. The ownership of animals should be specifically defined, since this has legal implications, including details of any transfer of ownership. Agreements may take substantial time to finalise and this should be factored into project timelines. Legal opinion should be sought, with intellectual property and confidentiality components appropriately considered.

It was considered that such cooperative agreements are based on trust and mutual understanding. Components for the establishment of trust include openness, compliance, facility standards, animal welfare and ethical oversight systems. There was agreement that it should be ensured that oversight and animal welfare meets appropriate standards at all

institutions where animals will be housed. Reporting requirements should be clearly defined in agreements, as well as access to animals. In this context it was discussed that reporting requirements should not be seen as policing exercises.

It was proposed by several delegates to inspect the facilities of other (collaborating) institutions, before the collaboration is initiated, in order to confirm animal care standards. The availability of veterinary care and response times in emergencies should also be considered. NSPCA inspections are required and recommendations in inspection reports must be addressed. The NSPCA is however not currently resourced to enable inspection of all animal facilities on a regular basis.

The competence of AREC functioning and oversight, including post-approval monitoring (of protocol adherence), should also be established. Some institutions have discussions with other institutions' ARECs during initial facility inspections. ARECs may also be asked to complete questionnaires. There was broad agreement that all ARECs involved should be registered with the NHREC, with SANS 10386-compliant review and oversight. Ethical review and approval should be conducted by the ARECs of all institutions involved, unless this function is formally delegated, as per SANS 10386.

There was agreement that it would be efficient to have national guidelines for cooperative animal ethics oversight and monitoring agreements for inter-institutional research. The NHREC Animals in Research Working Group would work towards the development of national best practice guidelines. It was proposed that some principles of multi-site GLP studies might be relevant.

6. Update on revision of the South African National Standard for the Care and Use of Animals for Scientific Purposes (SANS 10386:2008)

Sr Erika Vercuiel (NSPCA Animal Ethics Unit) informed the meeting that the revision of the SANS 10386:2008 is in an advanced stage. First drafts will be circulated later in 2017, working towards publication of the revised standard anticipated for Dec 2018.

7. New national Animal Welfare Act under development by DAFF

Limited information was discussed. Drafting of the Act is expected to take a few years. It is understood that the care and use of animals for scientific purposes would be included in the Act.

8. Regulating standards for performance-based functioning of ARECs in South Africa

ARECs with non-compliance issues identified in the 2016 NHREC audits will be followed up soon, in order to establish compliance with required standards and to enable full registration. Thereafter, the NHREC will perform quality-assurance audits in around 3-5 year cycles, in order to ensure that the functioning of ARECs and the conduct of animal research continue to meet relevant standards.

9. Other matters

The point of NHREC registration of Animal Ethics Committees that do not oversee health research was queried. Are these AECs eligible for NHREC registration? The answer includes that there are non-health related research ethics committees that have registered with the NHREC on a voluntary basis. The approach taken is that the guidelines represent the minimum national benchmark to encourage high standards. In essence, NHREC registration provides a quality-control mechanism for institutions to maintain public confidence, enable high quality science and safeguard animal welfare.

National regulation of practical competence of persons who perform procedures on animals was raised insofar as knowing which professional Council oversees such functions,e.g. regarding wildlife; which procedures on animals are regulated by the South African Veterinary Council (SAVC); and which procedures by the South African Council for Natural Scientific Professions (SACNASP (http://www.sacnasp.org.za/). Since this information falls outside the mandate of the NHREC and is defined in other regulations, it was advised to approach with the relevant Councils directly, if institutions require guidance.

5. Plenary session – Educative discussion topic:

On being a member of a research ethics committee: *An educative interaction amongst all attendees about the 'optimal REC'* **(Prof Pope)**

- Five things an active member should do
- Three things a member should **not** do
- Four things a chairperson should do
- Two things a chairperson should never do

Suggestions from the floor:

Five things an active member should do:

- Review proposals
- Be properly trained
- Attend meetings
- Apply minds properly to review process – thoughtful and responsible way
- Engage with proposals from a PI perspective
- Keep updated with national legislation and/or guidelines
- Balance scientific, regulatory and ethical requirements – examine merit of protocol
- Deliver timeously – review and submission of reports
- In review – constructive, avoid re-writing, give adequate advice
- Promote positive image of RECs

Three things a member should not do:

- Arrive late (unless unavoidable)
- Indulge in bias
- Breach confidentiality of review process
- Be obstructive and reject proposals that are less well formulated; rather provide constructive feedback
- Breach confidentiality generally

- Hide a conflict of interest
- Bypass formal channels of communication to contact applicant directly just because she knows her
- Not judge merit of proposal merely on basis of language skills

Four things a chairperson should do:

- Listen well
- Manage consensus and collective decision making
- Commitment – first to arrive and last to leave
- Effective management of committee meetings
- Balance hawks and doves
- Work closely with secretariat& support staff
- Keep members informed and updated re research ethics developments – is this a member responsibility too?
- Liaise with research ethics community and feedback to committee
- Represent REC on other committees
- Protect committee members
- Ensure that conflict of interest and of commitment are managed appropriately
- Ensure committee works efficiently

Two things a chairperson should never do:

- Never tolerate incompetence
- Should not defend protocols from their department
- Should not postpone or delay meeting merely because he cannot attend
- Never lose patience with committee members
- Never undermine or disrespect members
- Never influence change when consensus has been achieved
- Never impose own views

Prof Pope's points gleaned from her research

- Five things an active member should do
  - Prepare before the meeting
  - Be punctual & meet deadlines
  - Listen actively
  - Keep an open mind
  - Understand your role on the REC

Active listening – [1] concentrate fully on person speaking; do not try to formulate a response while the person is speaking; if you find yourself doing this, you are not focused properly; [2] listen carefully to what is said, how it is said, body language etc; [3] Give positive encouragement – nod, smile, etc; [4] feedback your understanding by paraphrasing what has been said in a coherent statement or question.

- Three things a member should **not** do
  - Dominate discussions
  - Start arguments
  - Engage in distracting behaviour

- Four things a chairperson should do
  - Ensure a good sense of humour
  - Set and manage etiquette rules
  - Listen actively
  - Ensure the agenda can be effective and lead to desired outcomes

- Two things a chairperson should **never** do
  - *Talk more than anyone else*
  - *Make people feel foolish or useless*

6.Wrap up and closure

Prof. Pope thanked everyone for attending the meeting and closed the meeting at 15h30.

7. Additional questions

These questions or suggestions were either submitted before the meeting on 18 May 2017 but could not be accommodated on the agenda or raised at the meeting where time constraints did not permit discussion. As was indicated at the meeting, they are included here.

1. *To what extent should the H3Africa guidelines on informed consent, data sharing, etc., be accepted and used by the NHREC and RECs? It will impact on the approval of consent forms for specimen storage and genetic research.*

The DoH 2015 Ethics in Research Guidelines explicitly endorse the H3Africa Initiative as indicated in the excerpt pasted below.

> 1.8.3 These Guidelines further endorse the ethical principles laid down in
> - The Belmont Report: www.edu/irb/pdfs/BelmontReport.pdf
> - Declaration of Helsinki 2013:www.wma.net/e/policy/pdf/17c.pdf
> - Medical Research Council: Guidelines on Ethics for Medical Research:HIV Preventive Vaccine Research: www.sahealthinfo.org/ethics/ethicsbooks5.pdf
> - The Singapore Statement on Research Integritywww.singaporestatement.org
> - Human Heredity and Health in Africa (H3Africa) Initiativehttp://h3africa.org/

Then in 3.3.6 further reference is made to H3Africa guidelines. The H3Africa initiative relies on input from many role players across the continent. As is evident on the document, many of those role players are from South Africa, which means that South African RECs should be confident to consider using them.

The vision of the H3Africa Initiative and its recommendation is that consent should be

> 'broad enough to allow for future and secondary uses of data, in line with the opportunities to use such data in advancing knowledge to improve health. The consent processes need to be appropriate for the cultural contexts in which the research takes place and tailored accordingly'.

By incorporating this information in the DoH Guidelines, the Department of Health indicates its endorsement of the vision. Consequently, RECs are permitted to adopt the H3Africa guidelines, as the DoH 2015 Guidelines indicate. It does not mean that RECs *must* adopt them. Local conditions under the jurisdiction of a particular REC may require a slightly different approach.

Importantly, however, when a claim is made that local conditions preclude use of the H3Africa approach, the claim must have a *factual* basis and not rely on REC members' opinions only. This means that local information must have been gathered to inform the claim.

2. *Is consent by caregivers to enrol minors in research permissible? How to manage the tension between the text of s71 of the NHA and the DoH 2015 Guidelines?*

The DoH 2015 Guidelines address research involving minors at 3.2.2

The text of s71 does not mention 'caregiver', while the DoH 2015 Guidelines make provision on pragmatic grounds for substituted parental permission. This is perceived by some as 'illegal' or 'contrary to law'. Literally, this technical argument about the law may be correct but the consequence is a severely negative effect on the scope of research amongst a category of minors. If a minor cannot be enrolled in research unless a biological parent or guardian gives permission, then a very large number of South African minors are excluded from research on a technical legal basis rather than on an ethical basis.

> '**Caregiver**' means a person who factually cares for a child (s 1 Children's Act, 38 of 2005 (defined as '…any person other than a parent or guardian, who factually cares for a child and includes – a) a foster parent; b) a person who cares for the child with the implied or express consent of a parent or guardian of the child; c) a person who cares for the child whilst the child is in temporary safe care; d) the person at the head of a child and youth care centre where a child has been placed; e) the person at the head of a shelter;f)achildandyouthcareworkerwhocaresforachildwhoiswithout appropriate family care in the community; and g) the child at the head of a child-headed household'); a caregiver is obliged (in terms of s 32(1)) to safeguard the child's health, well-being and development; and to protect the child from abuse and other harms. Further a caregiver may exercise the parental right to consent to medical examination or treatment of the child (interms of s 32(2))

There are complex social challenges in South Africa when it comes to research with minors without biological parental/legal guardian representation. The National Health Act 61/2003 in s 71 stipulates that only parents or guardians may provide consent for minors to participate in research. However, the NHREC noted that it is not ethical to exclude from research participation those minors who do not have parents or legal guardians (either court-appointed or appointed in terms of the Children's Act). In other words, s 71 in its current format is unethical. To insist on a strictly literal following of s 71 results in manifest unfairness to a group of minors whose situation may benefit from being research participants.

For this reason, the DoH Ethics in Health Research guidelines (2015), par 3.2.2.3 provides clear guidance and justification for use of parent substitutes in circumstances where ethically

this is justifiable. The Guidelines were signed off by the Minister of Health and came into effect on 1 March 2015, indicating acquiescence with the formulation in the Guidelines.

Whether community involvement is necessary before deciding that caregivers may consent depends on the context. If the situation involves minors in a formal structure such as an orphanage, researchers would probably not need community involvement, but if it involves minors nested within a community, community involvement would likely be required. A Research Ethics Committee (REC) should be able to deliberate on the circumstances of the minor(s) and approve the research proposal and protocol, provided the recommended processes are followed to identify parent substitutes, and that the risk/benefit assessment complies with what is permitted by the DoH 2015 guidelines.

A REC would need to also consider:

1. Participation of the minors in the study should be essential, in other words, could the minors not be 'substituted' with children whose parents can readily be located?
2. Engagement with the community, depending on the research settings, context, etc.
3. The level of foreseeable risks associated with minors' participation in the study.
4. The process of obtaining informed consent from the legal guardians, and where not possible, from the caregivers after an attempt is made to trace the legal guardians.
5. The risk-benefit ratio and the mechanisms identified to minimise potential discomfort.
6. A monitoring and safety plan to ensure early identification of any adverse events.

The question of granting a waiver of consent is not relevant to this situation. Consent from a parent or substitute may be waived only in the circumstances outlined in the Guidelines when (older) minors are considered more likely to participate if they can choose to do so independently.

3. *Definition of 'health research' and implications for ethics review: A challenge for many RECs is how to determine whether research e.g. in the context of education, non-health care facility work with children, work within communities must be reviewed and approved by a registered REC to be 'properly approved'.*

This challenge usually arises in tertiary institutions where faculties of Humanities, Social Sciences, Education, or Commerce do not wish to register with the NHREC on ideological grounds, including that the DoH cannot have jurisdiction over them since they are not concerned with health-related work. The DoH has clear jurisdiction over health faculty and

health facility RECs which must all be registered. The question is then whether approval from an unregistered REC is invalid?

The discussion in DoH 2015 Chapter 1 provides some guidance on how to think about these matters but it deliberately does not provide a Standard Operating Procedure. It is up to each institution to determine how it will ensure that all research conducted under its auspices is ethical. It is helpful if the RECs do register because the compliance assessment and auditing processes provide guidance and assistance but the status quo is that not all RECs will register. The consequence of this is that ethical review should not be seen as dependent only on registration with the NHREC.

4. *Clarify hierarchy of approval structures to be followed when conducting research at different levels of the Department of Health i.e. national, provincial, district and hospital/clinic level. Confusion whether approval from national level makes further at provincial, district rf hospital/clinic level unnecessary. Department of Health officials are also confused.*

Extract from 2016 Report of Joint Meeting where the same questions were asked:

> (b) Prof J Mekwa (NHRC) briefly explained the structure and mandate of the National Health Research Committee. She clarified that the mandate of Provincial HRCs is neither scientific nor ethics review, but rather to perform gate keeping for research that takes place in the provinces within public institutions. A few PHRCs are fully registered RECs and do review proposals as well; e.g. KZN & NWPHRCs.
>
> (c) Prof Pope also added that PHRCs and RECs are meant to work together to promote research and to build capacity in the country.
>
> (d) Experiences were shared on the review of research proposals by different PHRCs. Some processes were said to be faster than others; however some still take as long as six months to authorize access to public facilities for research purposes, which is not reasonable. A request was made to the KZN PHRC to provide a written description of the challenges encountered so that they can be addressed.
>
> (e) Prof Ruff of MCC CTC highlighted that the multiple processes have potential to destroy research in the country. Especially given that the PHRCs serve public institutions, the MCC would like to see capacity building there. He said they are not seeing much capacity building currently.

5. Which office is responsible for approval of MTAs? Research Ethics or Legal Office?

The Material Transfer Agreement (MTA) is not an ethical requirement. This means it is not the business of the REC. The MTA is a logistical requirement of the DoH for use when a researcher wishes to use research facilities outside of SA to analyse biological materials or data, or when collaboration between researchers includes sharing of biological samples or data as part of the research contract between them.

This means that,in principle, at institutional level, the PI is responsible for ensuring that the MTA is completed appropriately for onward transmission to the DoH. Whether institutional approval of the MTA is required, will depend on institutional policy and whether there is infrastructure for research contract scrutiny and approval including MTAs. In the absence of institutional research administration capacity, the DVC for Research (or equivalent person) should advise.

ANNEXURE 1

CHAIRPERSON: Prof.A Pope, Chairperson, NHREC

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Professor CB Brink
Dr T Burgess
Professor P Engel-Hills
Dr J Gardner
Professor M Greeff
Dr B Mohr
Ms T Sebata
Dr M Sekhoacha
Dr Y Sikweyiya
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