UNIVERSITEIT•STELLENBOSCH•UNIVERSITY
jou kennisvennoot • your knowledge partner

Health Research Ethics Committee (HREC)

Material Transfer Agreement (MTA) and Data Transfer Agreement (DTA) HREC requirements and processes

There has been some confusion recently after the National Department of Health (NDoH) MTA that was gazetted in July 2018. Clinical trial sites and other research PIs, in earnest attempt to remain within these published regulatory requirements, have been asking for our HREC to review and/or sign MTAs.

Kindly see below clarity on the **HREC and SU institutional processes and requirements for MTAs and DTAs:**

1. A material transfer agreement (MTA) or data transfer agreement (DTA) is required to move research materials and/or data between institutions and/or countries;

2. If material or data transfer is anticipated in a project, the research applicant completes the **HREC MTA Term Sheet** (Available at http://www.sun.ac.za/english/faculty/healthsciences/rdsd/Pages/Ethics/Forms-Instructions.aspx) and submits this completed term sheet along with their HREC application;

3. The specific terms of the MTA term sheet are reviewed by the HREC to ensure that they match the commitments in the protocol and the promises made to participants in the informed consent document;

4. Once the project, including the MTA/DTA term sheet, is approved by HREC the research applicant sends the MTA term sheet to the University's contracts office. The contracts office uses the MTA term sheet to prepare an MTA which is appropriate for transferring materials as part of and in accordance with the protocol;

5. Recent communication from our National Health Research Ethics Council (NHREC) confirms that the HREC should not sign the MTA nor should they be responsible for the final review and approval of the full MTA contract (further details in Prof Pope's email below). At Stellenbosch University the approval of MTA'S lies with SU's Research Contracts Office at the Division for Research Development and in the case of FMHS the final signatory is our Vice Dean: Research.

From: Nhrec NHREC Secretariat <nhrec@health.gov.za>
Subject: Re NDoH Gazetted MTA - queries and concerns

Dear Colleagues

Many of you responded to the call from the NHREC in November / December 2018 for input regarding your concerns and questions about the MTA that was gazetted in July 2018.

Recently a workshop meeting with the relevant stakeholders from the NDoH and other entities met to discuss the concerns and to find a way forward.

It was agreed that there were textual and conceptual matters that required clarification and revision.

It was further agreed that those present at the workshop would have the opportunity to provide written input on the document or under separate cover. The due date for receipt of this input by the NDoH is 2 May 2019. After this the input will be collated and a revised version will be circulated to those who were present at the workshop.

In my capacity as Chair of NHREC, I and two other members of the NHREC (Dr Mamello Sekhoacha - Deputy Chair of NHREC and Dr Theresa Burgess) were present to raise the input and concerns raised by yourselves. We are currently engaged with the revision as described.

A couple of points to clarify matters in the interim: most of those who raised concerns included these two matters. I can confirm that these were discussed.

The MTA was intended as a guideline to show what elements an appropriate MTA should include. The language is being revised to make this clear. The guideline will also be revised to make it obvious that customisation is acceptable provided the core elements are present.

The involvement of the HREC was discussed at length. It was strongly disputed by HREC members that HRECs should perform the role as described in the MTA. While it is evident that some institutions may follow this practice, it is not appropriate for the HREC to become involved in being a party to a legally binding contract about sharing access to samples and/or data. Consequently, it is likely that the link between ethics approval process and the need for the MTA will be explicit, eg the application form for ethics review should include relevant provisions that probe whether access to samples and/or data will be shared and, if so, that a MTA must be completed via the relevant institutional authorities. Because this agreement is a legally binding contract, the signatories must be authorised to sign. The HREC is not so authorised and should not be given this responsibility.

The NHREC will communicate further on the matter when there is substantive information available.

Best wishes

Anne Pope

Emeritus Associate Professor

Private Law Dept., UCT