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Our ref.: 2013/59

Date: 10.10.13

Concerning dispute over ethical norms of scientific conduct – Anthra and a Norwegian Competence Centre

The National Committee on Research Ethics in Science and Technology (NENT) refers to the letter from GenØk, represented by Acting Director, Anne Ingeborg Myhr of 12 April 2013 and the letter and two supporting emails from Anthra, represented by Director Sagari Ramdas of 5 and 14 July 2013. NENT has also received an internal progress report from the project and the raw data from GenØk, both of which have been forwarded to Anthra.

The committee discussed the case on their meeting of 12 September 2013. Committee member Roger Strand declared a conflict of interest and left the meeting before the discussion.

The parties' contribution to the project and their expectations regarding roles and responsibilities

After their meeting 14 May NENT decided to ask both parties to answer a number of questions. The committee believed it was important to clarify the two parties' expectations regarding their role and responsibilities in the project, and to provide the parties' own description of their actual contribution.

With regard to *the parties' actual contribution to the core elements of the research project*, there largely seems to be a shared understanding between Anthra and GenØk. The formulation of the research problems started with Anthra's field observations and the experiments executed by Anthra in India. The results from these initial investigations were shared with GenØK, and new research problems were discussed in Tromsø in 2008 by a representative from Anthra, Aruna Rodrigues, along with Terje Traavik, Director at GenØk.

Concerning contribution to the design of the project, GenØk emphasizes that they had no chance to influence the experimental design and execution of the sheep field-sampling program, as these were designed and planned before GenØk became involved. Anthra, on the other hand, claims that GenØk became involved in the design after the initial discussions in Tromsø. They express concern as they suspect that the design had serious methodological flaws that should have been corrected by GenØk as they held the greatest scientific experience. NENT assumes that both parties agree on that GenØk became involved in designing the methods and strategies after the sheep field-sampling program.

Anthra carried out the data collection in India, while laboratory analysis was left entirely to GenØk in Tromsø. Furthermore, there does not seem to be any disagreement that the analysis and interpretation of data have been carried out by GenØk alone. Except from an internal progress report written by GenØk in 2011, the project has not resulted in any publications.

Concerning the parties' expectations of their roles and responsibilities in the cooperation, the parties differ substantially. Anthra has repeatedly maintained that they understood "that it would be an active partner in the analysis and interpretation of the data and an active participant in the writing of the study" (letter to NENT 5 July). This was a main premise for taking part in the collaboration from the outset. In particular, Anthra makes it clear that the Government of India granted them permission for sending the samples out of the country on the understanding that Anthra would submit the results of the tests carried out by GenØk to the Government of India. GenØk does not dispute that the analysis and interpretation of data have been handled by them alone.

Ethical evaluation

On their meeting of 14 May, NENT concluded that the case raises several research ethical challenges related to the lack of good collaboration and communication. The committee in particular criticized GenØk's unwillingness to share the data with Anthra, and recommended that the data was made available to them as soon as possible.

Standards of collaboration

The responses from the parties, referred to above, confirm that they had quite different expectations concerning their part in the analysis and interpretation of the data, as well as their part in the writing- and publication process. These diverging expectations and the ongoing conflict only serve to demonstrate the necessity of making a written contract when entering into a research collaboration. Again, NENT finds that GenØk

– being the party holding the greatest research resources – had a special responsibility for ensuring that a fair agreement and a written contract was established. In any cross-boundary research collaboration parties should treat each other with respect. This entails firstly that the parties communicate with each other openly and frequently, and secondly that the benefits and costs of the research are distributed fairly among the partners (draft to *The Montreal Statement*, http://www.wcri2013.org/Montreal_Statement_e.shtml, retrieved 8 October 2013). None of these standards of collaboration seem to have been fulfilled in this case.

The committee recognizes that GenØK does not offer any satisfactory explanation as to why the data were withheld until recently. The raw data have now been shared with Anthra, but only after explicit recommendation from NENT. However, as the data are presented as conclusions, rather than interpretations, they exclude contributions and suggestions from a cooperating partner.

Standards of authorship

That the data are being presented in the manner described is particularly problematic considering that GenØk has offered Anthra authorship. According to the ICMJE Recommendations (commonly referred to as “the Vancouver rules”), authorship should be based on the following four criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved

(http://www.icmje.org/new_recommendations.html , retrieved 10 October 2013).

According to the guidelines, “All those designated as authors should meet all four criteria for authorship, and all who meet the four criteria should be identified as authors.” The criteria are not intended for use as a means to disqualify colleagues from authorship who otherwise meet authorship criteria by denying them the opportunity to meet criterion 2 or 3. Therefore, all individuals who meet the first criterion should have the opportunity to participate in the review, drafting, and final approval of the manuscript.

The *Guidelines for Research Ethics in Science and Technology* worked out by NENT offer similar criteria. In sum, international and national guidelines on authorship require *a substantial and direct academic contribution*.

The committee cannot see that any representative from Anthra has been provided the opportunity to fulfill the criteria sketched above. Anthra has been denied access to the data, and has thereby been prevented from contributing to the drafting of the work or revising it critically for important intellectual content. In addition, Anthra has so far not been invited into a final approval of any version to be published. Anthra has thereby been denied the opportunity to represent a part that qualifies for rightful authorship.

NENT does not know whether the research project actually will result in any scientific publications. In that case, questions related to authorship need to be reconsidered, and the parties should strive to reach a consensus on authorship, in what order the authors will be listed, etc. NENT is pleased to offer further assistance and support in these discussions.

Reporting research results

The committee finds that the researchers have a responsibility to convey the results to the community in which the initial field experiments were carried out. The key findings should be communicated in a form that is comprehensible to the recipients, in this case, the farmers. This is important in order to pay respect to research participants and others who have contributed with their resources or knowledge. NENT here refers to *The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization*, article 5:

In accordance with Article 15, paragraphs 3 and 7 of the Convention, benefits arising from the utilization of genetic resources as well as the subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention.

“Benefits” here include non-monetary benefits, such as the sharing of research results. The farmers participated in the study with the understanding that they would receive something in return. Accordingly, Anthra sent the blood samples to GenØk with a reasonable expectation that they would take part in the project and that the main findings and insights of the project would be discussed and shared with them. So far, this has not happened.

The lack of communication of the research results seems closely related to the lack of any scientific publications from the project. Through publication, results are communicated to the rest of the scientific community, the public and research participants and others who have contributed with their resources or knowledge in the research process. Publication and communication thus ensures that others with knowledge in the area are able to confirm the results or point out possible mistakes and inaccuracies. Moreover, such openness means that key findings and insights from the research are shared with concerned parties who have participated and who may benefit directly from the research. NENT finds it important to emphasize that no findings also is a finding that can and should be conveyed. Even in the lack of a scientific publication, there are other ways of communicating key findings.

Conclusions

In summary, NENT finds that the case raises several research ethical challenges. In particular, GenØk has failed to meet central standards of collaboration, related to the establishment and management of the collaboration and the outcomes of the collaborative research. The committee recommends the following in the closing stage of the research:

- If the research project will result in any scientific publications, questions related to authorship need to be reconsidered and the parties should strive to reach a consensus. In this regard NENT emphasizes that all individuals who have contributed substantially, to the conception or design of the work or the acquisition, analysis, or interpretation of data should have the opportunity to participate in the review, drafting, and final approval of the manuscript.
- The results of the research should be conveyed to the community in which the initial field experiments were carried out. Considering the status of the research project, NENT finds it important to emphasize that a lack of result is also a result that can and should be communicated.

On behalf of The National Committee on Research Ethics in Science and Technology,



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