

STANDARD OPERATING PROCEDURE		
	Document Description	Version No.
	HANDLING RESEARCHER COMPLAINTS	2.0

1. Purpose

This document describes the procedures for the Nutromics Diagnostics HREC (ND HREC), handling of complaints from researchers.

2. Complaints about the conduct of Research

If a Researcher receives or has a complaint regarding any aspect of the Research, or the way in which Research is being conducted, the Principal Investigator should be notified. The Principal Investigator must act appropriately, impartially and in proportion to the complaint. In most cases, this person will be able to resolve the complaint by addressing the concerns of the complainant.

The Principal Investigator must also consider that they have a responsibility to determine whether to suspend/modify the Research should there be reasonable suggestion of harm to a Participant(s) and must report these concerns to the ND HREC via HREC@nutromics.com and may seek the ND HREC's assistance.

The ND HREC may impose a penalty on Researchers for not reporting relevant concerns and complaints received from Participants.

The Researchers, and participants can make complaints to the HREC directly, via email (HREC@nutromics.com), which will be addressed with the Principal Investigator, for them to resolve the complaint by addressing the concerns of the complainant. Additionally, the Principal Investigator must also report their own concerns regarding any aspect of a research, or the way a research is being conducted to the ND HREC.

Should the complaint not be resolved (or require further investigation) the Nutromics' Research Governance Office (RGO) will conduct a preliminary investigation into the complaint and determine the appropriate course of action. If urgent action is deemed to be required, the Chair may take appropriate steps to ensure that the rights and welfare of Participants are protected. Such action may include suspending the approval for a Research whilst an investigation is conducted.

Following the initial review of a complaint, possible outcomes are that:

- no further action is required; or
- There are sufficient grounds to investigate the complaint further.

If a further investigation is warranted, a meeting may be required between the ND HREC Chair or full ND HREC, the RGO and the Researcher(s). The following procedures which are recommended in the National Statement, may occur:

- Invite the Principal Investigator to explain the situation to the committee and to demonstrate why the Research should not be discontinued and ethical approval withdrawn;
- Advise the Principal Investigator that they may be accompanied by one or more colleagues including their line manager;



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- Reconsider the original research proposal and seek additional information from the Principal Investigator in relation to the conduct of the Research, or any other relevant factors, before making a final decision whether to revise or reconfirm the original decision to approve the Research.

Having considered the matter, the ND HREC may:

- Withdraw approval and stop the Research;
- Require amendments to the original Research proposal or to the conduct of the Research;
- Allow the Research to continue without amendment; and/or

The ND HREC should provide the Principal Investigator and the complainant with an explanation of the outcome. In some cases (e.g., if approval is withdrawn) it may be necessary to notify the other Research Participants.

In some circumstances, it is recommended that the complainant address the ND HREC or meet with Members of the ND HREC, depending on whether the complainant would be comfortable in this situation and nature of the complaint, to discuss the concerns.

3. Complaints regarding the ND HREC review process or outcome

Any concern or complaint about the ND HREC review process is to be submitted to the ND HREC Chair. This is done in writing via email and must detail the grounds of the concern or complaint, and all the material relating to the Research and the complaint will be considered by the ND HREC Chair.

If the complaint is regarding a Research submission which has not already been approved by ND HREC, then there are further opportunities to negotiate the details involved in the Research to ensure compliance with ethical issues. If a Research submission has had conditions placed upon it, in which the Researcher feels adversely affects the quality of the Research, the Researcher may request that the ND HREC reconsider its decision. This may involve the Researcher s being asked to attend a meeting to discuss the Research. The Committee may wish to also obtain expert advice at this stage.

The National Statement advises that if the matter is not thereby resolved to the satisfaction of the complainant, that the complainant may take further steps, including an appeal against the decision and seek a meeting with the ND HREC Chair, for further clarification.

The complainant(s) may be accompanied by one or more support persons, or, in the case of Researchers, one or more colleagues. A record of any such meeting should be kept. The Chair will investigate the appeal and recommend to the ND HREC the appropriate course of action within 4 weeks from the date of the appeal being lodged. The ND HREC will notify the appellant of the course of action and determination in a timely manner.

Following an appeal being lodged to the ND HREC Chair, if the appellant considers that the ND HREC has not followed due process or remains unsatisfied with the outcome, they may choose to lodge an appeal with the Nutromics' RGO.



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The Chair will provide the Nutromics' RGO with all relevant material, including:

- Details of the appeal;
- Material reviewed by the ND HREC; and
- The outcome/decision of the ethical review process by the ND HREC.

The RGO will determine if further investigation of the appeal is necessary. If so, a panel will be established to consider the appeal. The panel will include the following members:

- The Chief Executive Officer / delegate of the Institution;
- At least one nominee with relevant expertise in human research ethics; and
- Expert(s) in a discipline of research related to the project under consideration

The panel will allow the ND HREC and the appellant the opportunity to make submissions. The Nutromics RGO will notify the ND HREC and the appellant of the outcome of the investigation.

The possible outcomes include:

- The appeal is dismissed;
- The appeal is upheld, and the panel makes recommendation to resolve the issues based on the findings of the panel; or
- Referral of the Research submission to an independent ethics committee for re-review.

The panel or the Nutromics' RGO / delegate cannot reverse the final determination of the ND HREC.

