

Conflict Resolution & Adjudication

By

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Introduction

- At times, in the process of submission, review & oversight of scientific researches, stake holders encounter differences of opinions, or a state of opposing ideas or interests.

This could occur between:

- Investigators & institutional/local ethics committees
- One institutional/local ethics committee or the other or
- Local investigators & international collaborators

Introduction

- Such conflicts could vary in intensity, number of parties involved as well as the possible consequence on ethical conduct of scientific research

Introduction

- To avoid, its possible negative effect on conduct of scientific inquiries, it often becomes necessary to resolve or adjudicate over conflicts occurring in the process of ethical review of research proposals and conduct of research.

Introduction

- This presentation therefore highlights common causes of conflicts, parties involved and more especially the guidelines contained in the Nigeria's National Code for Health Research for managing conflicts in protocol review and research conduct.

Meaning of Conflict Resolution & Adjudication

- Resolution means analysis into clear components for finding a solution to a problem
- Adjudication means the final judgment in a legal proceeding; the act of pronouncing judgment based on the evidence presented

The Background

- An inconsistency or impropriety regarding any stage in the research process (including protocol review to result presentation of result or publication) may be perceived or alleged in the process of ethical review

The Background

- It is the duty of the ethics committee to investigate such complaints
- Reports obtained therefore should be deliberated upon, leading to a variety of possible decisions including:
 - -suspension
 - -revision of suspension or
 - -termination of research

Process for Suspension of Research

- HREC shall have authority to suspend research that is not being conducted:
 - In accordance with HREC requirements or
 - In accordance with existing legislation or
 - In accordance with existing institutional guidelines; or
 - Where research is associated with unexpected serious harm to participants.

Process for Suspension of Research

- Any suspension of research shall include a statement of the reason(s) for the HREC action and shall be reported within 2 weeks to the researcher(s), institution(s), sponsor(s) and the NHREC.
- Researcher(s), institution(s) or sponsor(s) shall be entitled to ask for a reconsideration of the decision of HREC to suspend research within 2 weeks of receipt of notification.

Process for Revision of Suspension

- HREC may reverse its decision to suspend research if the precipitant(s) of the action is resolved to HREC satisfaction

Process for Revision of Suspension

- The HREC will determine the case at its next regular meeting and may require that the researcher sign an agreement with HREC on its finding(s) and agreed remedial measure(s).

Process for Revision of Suspension

- Where HREC allows resumption of research, an oversight review of the research shall be carried out within 6 months or at least once during the lifetime of the research if it is shorter than 6 months.

Process for Termination of Research

- Where the researcher(s), sponsor(s) or institution(s) is unable to offer or the HREC is unable to ascertain or enforce satisfactory remediation of the precipitant, HREC shall terminate the research.

Process for Termination of Research

- HREC shall indicate the reason(s) for the termination of research in writing within 2 weeks to the researcher(s), institution(s), sponsor(s) and the NHREC.

Process for Termination of Research

- Researcher(s), institution(s) or sponsor(s) shall be entitled to appeal the decision of HREC to terminate research to the NHREC within 2 weeks of receipt of notification.

Process for Appeal of HREC Decision to Terminate Research

- Upon receipt of an appeal of the decision of a HREC to terminate research, NHREC may, at its discretion, take up such an appeal.

Process for Appeal of HREC Decision to Terminate Research

- Where the appeal is sustained,
 - NHREC may with reasons and in consultation with the institutional HREC, direct the institutional HREC to approve the research.
 - NHREC may with reasons and in consultation with the institutional HREC mandate modifications, which if undertaken, can allow the research to proceed or resume as the case may be.

Process for Appeal of HREC Decision to Terminate Research

- Where the appeal is sustained,
 - Where NHREC mandates restoration of the research, the institutional HREC shall have powers of continuing oversight as outlined in relevant sections of this code
- NHREC may sustain the decision of the HREC and dismiss the appeal.

Summary

- Research ethics committee activities regarding review of research proposals, and oversight of research process may not run smoothly occasionally
- Improprieties, allegations, and complaints may come up at times

Summary

- Research ethics committee members are expected to be familiar with the guidelines and process of handling such challenges
- This lecture focused on the guidelines contained in the National Code for Health Research

Conclusion

- One unique feature of the National Code of Health Research Ethics is the observation that conflicts could arise in the conduct of review of research proposals and monitoring of research process

Conclusion

- Section E, subsections i to l of the document spells out the mechanism for handling such challenges

Conclusion

- Research ethics committee members and all stake holders are therefore encouraged to consider the guidelines in managing possible conflicts arising from ethical review process and research monitoring