Establishment of NUAA's Research Ethics Committee: Discussion Paper

Introduction

Recognising the significant benefit that research provides in the delivery of effective health promotion and services, NUAA seeks to encourage researchers to participate in a process of peer review regarding ethical issues and to promote ethical conduct in human research in communities of people who use and inject drugs.

NUAA intends to establish a Research Ethics Review Committee (RERC) that will provide advice to NUAA on ethical issues relating to research and also to provide ethical guidance to health and social researchers and research participants on issues affecting people who use and inject drugs.

This paper will explore the requirements for establishing NUAA's RERC, discuss considerations and implications in maintaining and monitoring the RERC, and analyse successful models of delivery for existing ethics committees.

General Principles for Ethical Conduct in Human Research

The general principles for ethical conduct in research are outlined in the National Health and Medical Research Council (NHMRC) statement: National Statement on Ethical Conduct in Research Involving Humans[1]. Whilst the NHMRC policy does not make direct reference to research with diverse populations it identifies common standards that form a useful guide for the ethical evaluation of research.

NUAA intends to use the NH &MRC policy to inform case-by-case consideration of proposed research proposals with people who use and inject drugs that seek NUAA's support.

The main principles to consider are:

- Respect for human dignity
- Respect for free and informed consent
- Respect for vulnerable persons
- Respect for privacy and confidentiality
- Respect for justice and inclusiveness
- Balancing harms and benefits
- Minimising harm
- Maximising benefit

Additionally, UNAIDS identifies HIV and AIDS related "ethical principles that should guide the international, national, community and individual response to HIV/AIDS."[2] The application of these principles should also be considered for the purposes of ethical conduct in human research with people who use and inject drugs:

- Compassion
- Solidarity

[1] The NHMRC statement is available at http://www.nhmrc.gov.au/publications/synopses/_files/e72.pdf
[2] UNAIDS. (1996) HIV and AIDS related ethical principles. http://data.unaids.org/Publications/IRC-pub03/humanr_en.htm

- Responsibility
- Tolerance
- Information
- Empowerment
- Well-being/Beneficence
- Equity/Distributive justice
- Respect for persons
- Confidentiality
- Obligation to treat
- Informed consent

Why should NUAA establish a Research Ethics Review Committee?

The purpose of NUAA establishing a Research Ethics Review Committee (RERC) is to encourage researchers to participate in a process of peer review regarding ethical conduct in human research into issues affecting people ho use and inject drugs.

As the NSW drug user organisation, NUAA has a responsibility to ensure the protection and respect for its constituency in human research projects.

NUAA would also prefer to only work with research projects that have included the organisation as equal partners and allowed NUAA to contribute to the research agenda. NUAA also seeks to ensure that all research that it supports has good feedback mechanisms in place to report back to participants.

NUAA's RERC would operate as a principal committee for the NSW health sector for issues affecting people who use and inject drugs. Issues faced by people who inject drugs can be complex and varied. For example, societal and cultural issues, such as stigma and discrimination, can have a dynamic with health concerns such as HIV and hepatitis C transmission, and vice versa.

NUAA's RERC will have two principal roles:

- To provide internal organisational advice within NUAA. Approval from the RERC would be a prerequisite to NUAA staff determining support for or participation within particular research projects.

- To provide ethical guidance to researchers and research participants. The RERC would be a forum for ongoing consultation with and guidance for researchers in matters of ethics regarding human research within drug using communities.

What is important to acknowledge is that NUAAs RERC aims to not hinder existing research processes, for either NUAA staff or external researchers. The NUAA RERC aims to encourage, guide and facilitate research that explores issues affecting people who use and inject drugs, whilst protecting research participants in the drug using community from disrespect or harm.

Establishing NUAAs RERC

In order to establish and operate a successful and respected human research ethics committee, NUAA must ensure there are sufficient resources and support for the committee to run efficiently.

This section details requirements NUAA will need in establishing the RERC, the researchers in submitting research proposals to the RERC, and ethics committee membership for considering, reviewing and monitoring research proposals and projects.

Establishing the Committee

The role of the RERC is to review and approve research proposals involving people who use and inject drugs; particularly where NUAA support is sought.

The primary role of the RERC is to protect the rights and welfare of research participants. The primary responsibility of each member is to decide, independently, whether in his or her opinion the conduct of proposed research will so protect and respect its participants

Terms of reference must be set out by the institution or organisation when establishing an ethics committee. Terms of reference must include the scope of its responsibilities, relationship to non-affiliated researchers, accountability, mechanisms for reporting and remuneration, if any, for members.

Membership

The research ethics committee should consist of members who, collectively, have the qualifications and experience to review and evaluate the health, social and cultural aspects and ethics of the proposed research project as it would apply to people who use and inject illicit drugs. It is important, for the sake of NUAAs RERC, that the knowledge base is broad and collective. NUAAs RERC will be looking at research projects that affect people who use and inject drugs, and the issues covered by research in this area will be vast and various. Given the diverse and complex nature of issues affecting people who inject drugs, NUAAs RERC must have a membership that works collaboratively to ensure the best possible review of the research projects brought to it.

There would be peer representation on this committee, as well as social policy researchers, health professionals, medical practitioners or service providers. However the make up, the group must use its collective knowledge to broadly consider the implications for people who use and inject drugs within any given research project

NUAA must develop and determine the procedures for recruitment and of appointment to the research ethics committee, including the quorum needed for the committee to meet.

Procedures

Research ethics committees should establish and record working procedures concerning:

- Frequency of meetings;
- Preparation of agenda and minutes;
- Distribution of papers prior to meetings;
- Presentation of research protocols;
- Presentation of all documents and other materials used to inform potential research participants;
- Quorum and methods of decision-making;
- Requirements for submission of research projects for ethical approval;
- Registration of applications;
- Timely review and notification of decisions;
- Written notification of decisions to researchers;
- The recording in writing of decisions made by the Committee and reasons for decisions;
- Confidentiality of the content of the protocols and of a committee's proceedings;
- Reporting of adverse events;
- Reporting of amendments to protocols;
- Access to documents;
- Regular monitoring;

- Complaints procedures;

The RERC may approve, require amendment to, or reject a research proposal on ethical grounds. The ethics committee must record decisions in writing and should include reasons for rejection. RERC feedback should be structured so as to be instructive to the researchers concerned. Researchers should be made aware that their statement of ethical considerations should not be a rote checklist but a real engagement with ethical issues.

In considering a research protocol, the RERC may seek assistance from experts, but the committee must be satisfied that such experts have no conflicts of interest in relation to the research project under consideration.

The RERC must ensure that no member of the committee adjudicates on research in which that member has any conflict of interest in relation to the research project under consideration.

A researcher must disclose to the RERC the amount and sources, or potential sources, of funding for the research and must declare any affiliation or financial interest when proposing and when reporting the research.

A research proposal must include a statement of the ethical considerations involved in the proposed research. An ethics committee must be satisfied that the research protocol gives adequate consideration to participants' welfare, rights, beliefs, perceptions, customs and cultural heritage.

Researchers' proposals for health research to be conducted in community settings must include a clear plan on how the communities will be consulted or involved in the research process, and how, in general, they are to be kept informed.

The RERC must ensure that their members receive initial and continued education in research ethics and science, and are kept aware of current issues and developments in the broad area of ethics and science

Recording of Decisions

The RERC shall maintain a record of all research protocols received and reviewed including the:

- Name of responsible institution or organisation;

- Project identification number;

- Principal investigator;
- Title of the project;
- Date of ethical approval or non-approval;
- Approval or non-approval of changes to the protocol;
- Approval or non-approval of changes to the information sheets and informed-consent forms;
- Approval or non-approval of changes to advertising materials, letters and notices;
- Complaints from researchers whose protocols were not approved;
- The terms and conditions of approval of any protocol;
- Whether approval was by expedited review;
- Whether the opinion of another ethics committee was considered;
- Action taken by the ethics committee to monitor the conduct of the research.

For multi-centred research proposals, the RERC shall also record, from information provided by the investigator:

- Details of other centres involved
- The approval status of the study at each centre;
- Details of any amendments required at other centres.

The RERC shall retain on file a copy of each research protocol and application submitted to it for approval. The file shall include information sheets, consent forms and relevant correspondence, all in the form in which they were approved. A list shall be kept of committee members who were present during discussion of the application and when the final decision of the committee was reached.

Monitoring

The RERC has the responsibility to ensure that the conduct of all research approved by the committee is monitored. The frequency and type of monitoring should reflect the degree of risk to participants in the research project.

The RERC must request at regular periods, at least annually, reports from the principal investigator on matters including:

- Progress to date, or outcome in the case of completed research;
- Information concerning maintenance and security of records;
- Evidence of compliance with the approved protocol;
- Evidence of compliance with any conditions of approval.

The RERC should inform the principal investigator, in writing, of decisions made after the review of progress reports.

As a condition of approval of each protocol, the RERC shall require that researchers immediately report anything that might warrant review of ethical approval of the protocol, including:

- Serious or unexpected adverse effects on participants;
- Proposed changes in the protocol;
- Unforeseen events that might affect continued ethical acceptability of the project;
- A research ethics committee, as a condition of approval of the research proposal, may require researchers to inform the committee, giving reasons, if the research project is discontinued before the expected date of completion.

Suspension or Discontinuation of Research

Where the RERC is satisfied that such circumstances have arisen that a research project is not being conducted in accordance with the approved protocol and that, as a result, the welfare and rights of participants are not or will not be protected, the RERC may withdraw approval. The RERC shall also inform the researcher and the institution or organisation of its action, and shall recommend

that the research project be discontinued or suspended, or that other appropriate steps be taken.

Where ethical approval has been withdrawn, a researcher must discontinue the research and comply with any special conditions required by the committee if they wish to continue to be accredited through the NUAA RERC.

Considerations for successful operation of the RERC

Membership

The health sector NUAA currently works within can be quite demanding. With overlap of many stakeholders and partners across other non government organisations, as well as area health services and service providers, means that many key individuals are often already obligated to many other committees and working groups. Accessing and maintaining a high knowledge base of individuals to be members on NUAAs RERC may be a difficult task.

Attrition of these members will also be a key consideration as collective meetings, events and other general obligations arise.

Methods of obtaining research

Upon the establishment of the committee the NUAA RERC will have to develop a method of promotion or outreach to researchers and research centres to inform that the committee exists. New areas could be looked at reaching out to that NUAA has not previously worked with, such as universities.

Advocacy in research

NUAA should consider whether the RERC will have an advocacy role in research. Can the committee be used to promote messages or research? Should there be a review board for the RERC to consult with and seek advice on issues with to help guide the RERC processes?

Capacity Building for researchers

The NUAA RERC aims to aid researchers and students, and encourage their research to ethically acknowledge and treat its participants. Therefore NUAA should offer opportunities for researchers to consult with the committee before lodging a submission, and offer people with limited research experience advice and assistance in putting forward their submissions.

Parameters of ethical questioning

The fundamental component of assessing research projects will be whether it is harmful to the research participants. Therefore, it could be wise to establish some parameters of some key ethical considerations for people who use and inject drugs - what are the 'deal breaker' questions for research proposals?

Conclusions

As the NSW drug user organisation, NUAA has a responsibility to ensure the protection and respect for its constituency in human research projects.

Development of a NUAA RERC, that will encourage ethical research for people who use and inject drugs, that will help skill up researchers in our community to participate in ethical research, and that will provide advice and consultation with the organisations research activities will be a crucial and significant step in having people who use and inject drugs fairly and ethically represented health and social research projects in NSW.

Appendix

Ethics Committee Models: ACON

There are numerous examples of Human Research Ethics Committees across the world. NUAA has selected the AIDS Council of NSW as a model for establishing its ethics committee as it is the most comparable in terms of organisational location, objectives, and goals. Please review ACON Ethics Committee documentation attached.