

Ethics Approval and the Evaluation of Alcohol and Drug Programs

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Structure

- Should proposed evaluations be subject to formal ethics review?
- Are existing processes for ethics review appropriate for evaluations?
- Is there scope to develop alternative approaches to the ethics review of evaluations?



Structure (cont.)

- ▣ Principles and guidelines on ethics
- ▣ The Ethical Facilitation Process at Turning Point
- ▣ Recent developments and associated challenges
- ▣ Directions for ethics and evaluation



National Health and Medical Research Council (NHMRC)

- Key body guiding the ethical conduct of health-related research in Australia
- Has developed National Standards on the ethical conduct of research involving humans
- With conditions for Human Research Ethics Committees (HREC)



The AES

- Code of ethics ~ a statement of the values and principles which members uphold in their work in evaluation
- Guidelines for the ethical conduct of evaluations ~ 17 standards which are intended to promote better practice in evaluation as well as informing those commissioning and conducting evaluations



Turning Point

- Specialist alcohol and drug organisation
- Providing:
 - A range of clinical treatment programs
 - Education and training
 - Clinical, epidemiological, and evaluation research



Ethical Facilitation Process (EFP)

- Developed within Turning Point
 - Designed for service evaluations and research projects other than clinical interventions
- With three aims
 - To foster a culture where ethical and methodological issues are considered simultaneously
 - Supporting staff development around ethical issues
 - Providing accountability to agencies and services involved in research conducted by Turning Point

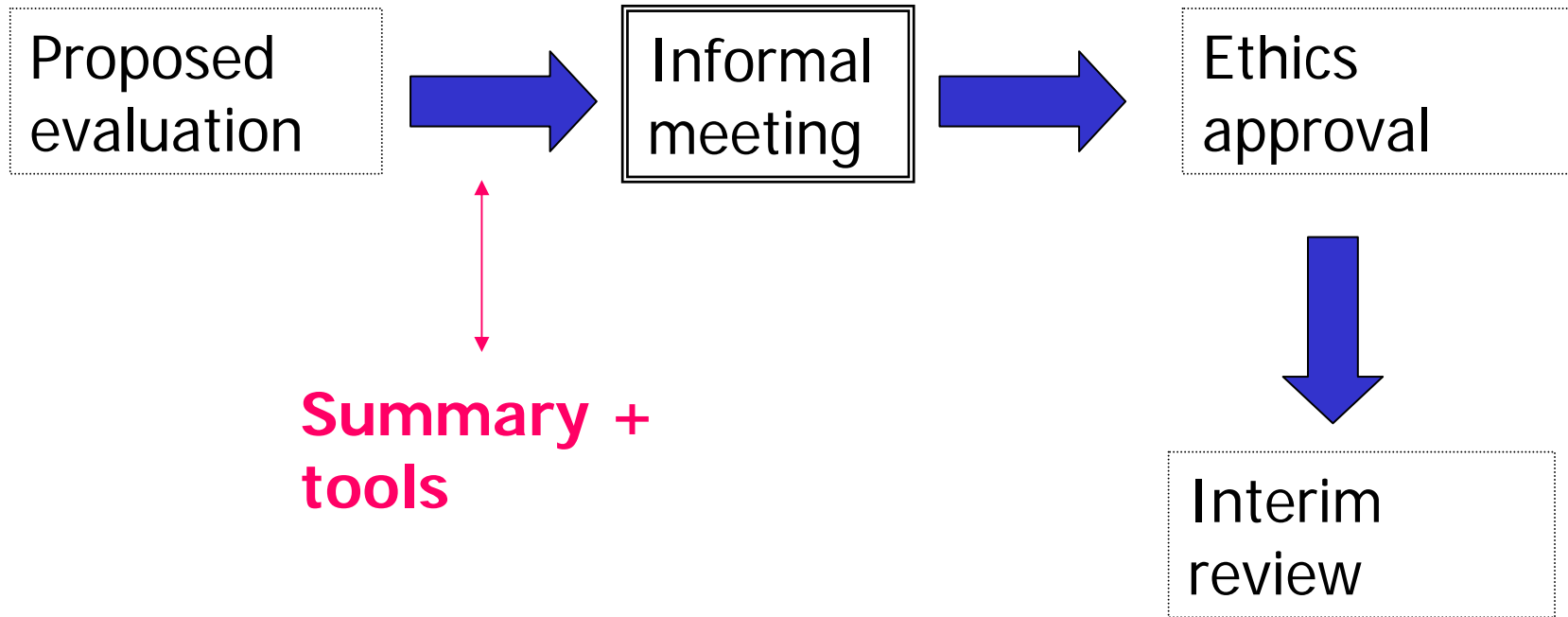


The ethical facilitation team

- Representatives from across the organisation
 - Clinicians
 - Trainers
 - Researchers
- Chair



The Ethical Facilitation Process



Guidelines for the EFP

1. Does the study meet the NHMRC Ethical Guidelines?
2. Does the study need to be submitted to an HREC?
3. Confidentiality
4. Informed consent
5. Potential harms to participants
6. Payment to participants
7. Benefits, if any, to participants and benefits to the wider community
8. Health and safety of researchers
9. Dissemination
10. Other issues for careful consideration in drug research



Shifting the focus....

- The evaluation has been planned to comply with the *Guidelines for the Ethical Conduct of Evaluations* prepared by the Australasian Evaluation Society. NHMRC guidelines are also applied where appropriate and consideration is given to specific policies developed by Turning Point (e.g., around age and informed consent). The AES guidelines are available at http://www.aes.asn.au/about/code_of_ethics.pdf.



Examples.....

- Examining steps to ensure evaluator competence to undertake a particular study
- Using appropriate language in information sheets regarding the need to report particular activities to authorities
- Deciding on young people's competence to give consent to take part in interviews
- Placing limits on confidentiality, such that key stakeholders are listed in the appendix of an evaluation report



Benefits of the EFP

- A streamlined process
- Minimal preparation
- Flexibility
- Application of AES guidelines and inclusion of other guidelines/standards as appropriate
- Ethical review involving those with expertise in clinical practice, education, and research into alcohol and drugs
- Awareness raising for the organisation



Challenges of the EFP

- The emphasis on the NHMRC standards
 - Focus is on individuals not programs or organisations
 - Methods orientation that is not typical of evaluation (e.g., randomisation)
- What is missing (w/o AES guidelines)
 - Issues for evaluation (e.g., identifying self and commissioners, reporting significant problems with a program under evaluation)



Developments and dilemmas

- Recent changes in the EFP, moving closer to the HREC process
 - 18 page application form
 - Categories and questions not dominant in evaluation methods (e.g. 'statistical or other analyses', 'inclusion / exclusion criteria')
 - The sense that the scope for flexibility and negotiation is diminished



The problem!

- Attempting to squeeze evaluation into a format that doesn't fit



Options

- Integrate AES guidelines into the newly developed EFP
- Develop a process exclusive to evaluation
- Draw from approaches used by other organisations
 - Checklists?
 - Peer review?
 - Other?



Some ideas....

- AES Code and Guidelines used as the basis for ethics review of evaluation proposals
- Additional standards should be applied as appropriate to specific projects
- Flexibility should be maintained, to allow for project context
- Expediency should be built into the process
- Strategies for communication and collaboration among the evaluators and reviewers will help to identify and resolve ethical issues



For discussion

- Comments, questions
- Your experience with ethics
- Directions for ethics and evaluation

