Ethics

Kate Parker, Discipline of Oncology, Auckland University

Ethics Committees

- Ethical approval for any clinical research involving humans is required
- A national system of Health & Disability Ethics Committees (HDEC) was established under the NZ Public Health and Disability Act 2000
- The government held an inquiry into clinical research in 2011
- As a result of the inquiry, the current national HDEC system introduced 1st July 2012

Health and Disability Ethics Committees

Ethics Committees Role

- Protect rights and well being of participants
  - Prevent studies that pose an unacceptable risk of harm to participants
  - Ensure participants are aware of what their participation involves and have given informed consent
  - Review trial documents such as protocol and informed consent documents
  - Provide ethical opinion and give approval for trial to commence (or not!)

Ethics Committees

- Four national committees:
  - Northern A, Northern B, Central and Southern
- 8 members per committee
  - mix of health care professionals and lay members
- Each member is appointed by the Minister of Health
- Committees are public
- Remit to review ethical issues (not scientific or governance issues)

Health research that presents more than 'minimal risk' must receive HDEC review.

- Minimal risk is defined as cases where "potential participants could reasonably be expected to regard the probability and magnitude of possible harms resulting from their participation in the study to be greater than those encountered in those aspects of their everyday life that relate to the study".
  - Use of anonymous heath information
  - Qualitative research with nurses or clinicians as the participants
  - Filling out a questionnaire

HDECs and Māori Consultation

- HDECs strongly encourage researchers to:
  - Proactively consult with Māori
  - Consider how Māori can be involved throughout the whole research pathway
  - Demonstrate how the research provides benefit to Māori
  - Proactively include Māori participants,
  - Consider dissemination and presentation of findings.

Principles to consider

- **PARTNERSHIP**: working together with iwi, hapū, whānau and Māori communities to ensure Māori individual and collective rights are respected and protected in order to achieve health gain
- **PARTICIPATION**: involving Māori in the design, governance, management, implementation and analysis of research, particularly research involving Māori
- **PROTECTION**: actively protecting Māori individual and collective rights, and Māori data, cultural concepts, norms, practices and language in the research process.

Consultation

- Comprehensive Māori consultation required
- Where possible, include access to Māori support as part of consent process
- Consider importance of research to Māori health
- Where possible / relevant, researchers should include information on how they will ensure that Māori benefit at least equally (and actually how they can disproportionately benefit if they are disproportionately burdened) from the research

Issues raised by genomic research

- Science moves quickly – often more quickly than the guidelines governing it!
- As an HDEC member, we often deal with issues raised by genomic research, e.g.:
  - Future unspecified use
  - Sending tissue overseas
  - Use of tissue without patient consent
- These all have specific importance to Māori

Collection of tissue for FUR

- Consent to do additional (often genomic) testing later in the research
  - Done to enable future advances to inform the research they are conducting
  - Need to be clear around the parameters
    - What this data will be used for
    - How long will the tissue be kept
    - Will it be returned / disposed of with a karakia
    - How (or whether) the information will be reported
  - How or if the information is fed back to participants – (use of incidental findings committee etc.)
  - Use of tissue for FUR always requires a second consent

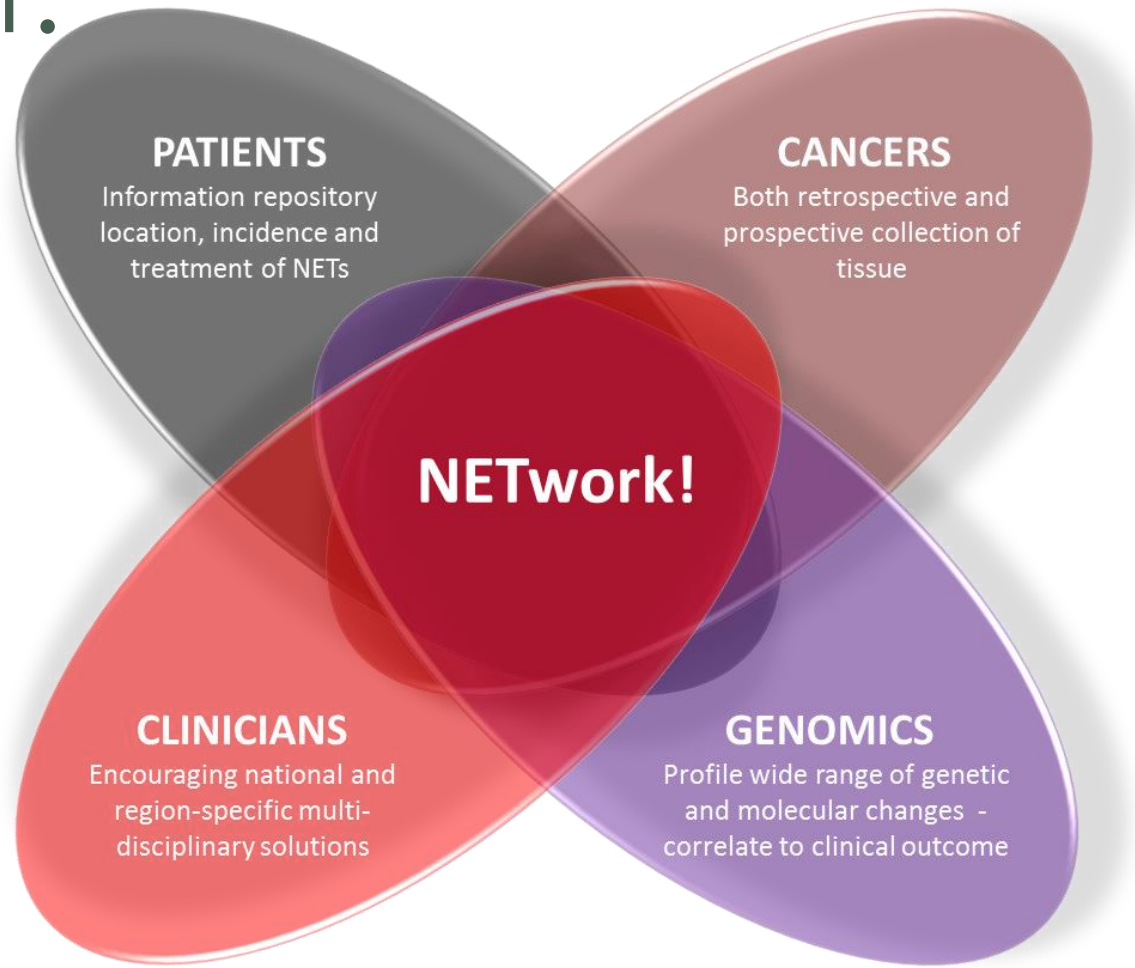
Sending tissue overseas

- Often desirable, especially in international collaborative projects
  - Be clear about whether this will happen, and why
  - Be clear if there is an option to “opt out” of this requirement for the research
  - Provide opportunity for cultural advice and input of the whanau to participants

Use of tissue without consent

- When conducting research on human tissue, obtaining informed consent is most desirable
  - Instances when this is either not practical or would bias the research
  - Consultation is key to this type of research being approved
    - Māori, patient, ethics
  - Be very clear around practices for handling data and results obtained on tissue used without consent

PUKUmahi! or NETwork! is a multifaceted project.



PUKUmahi:

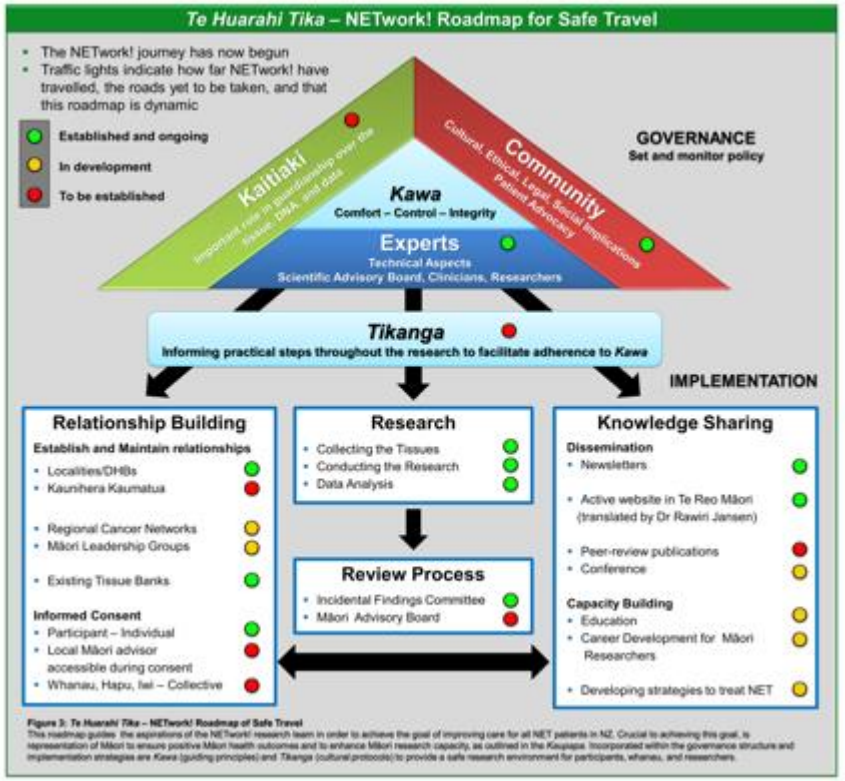
- *puku* (tumour)
- *mahi* (work)
- *pukumahi* (industrious, hardworking, diligent)

PUKUmahi! or NETwork!

- Nationwide research that involves Māori and relates directly to Māori health.
- Translational genomic research – need to establish culturally safe practices to implement this and to ensure positive outcomes for Māori health
- Recognise the importance of the gifts we are using
  - Tissue is precious
  - DNA is precious – connects with the individual and their wider family (whakapapa)
  - Data is precious

Striving to work in a culturally safe research environment

- "NETwork Roadmap for Safe Travel"
- Establishing a set of core guiding principles that are culturally safe
- Implementing polices that ensure these principles are adhered to
- Covers all aspects of research programme
- Dynamic roadmap



Conculsion

- Not always one clear answer to ethical issues
- Consultation and communication can help to find a safe and acceptable way forward
- If possible, consultation should continue throughout the research process