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The Patient Perspective on Tissue and Tissue Banking

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Advocate or patient...is there a difference?

Patient

- Usually knows little about their disease
- Focus is on self, family
- Main concern is treatment
- Emotions play significant role in decision making

Advocate

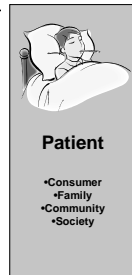
- Has more in depth knowledge about disease
- Focus is on the healthcare system/research
- Main concern is influencing research and healthcare delivery
- Emotions are channeled into working for larger community

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Advocacy



- **Translators of information**
- **Education and Awareness**
- **Representation**
- **Access Issues**
- **Policy**
- **Support**



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Chain of Trust

Patient assumption of integrity of process

- All donated tissues are usable for purpose stated
- Collected, stored and used with good controls
- Any abuses degrade the public trust of the entire system
- Regulations developed to safeguard against future abuses may deter research

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Patient Education

Challenges

- Lack of
 - information about uses of tissue
 - importance of tissue to research
 - understanding of the process of tissue collection, storage and quality controls
- Concern about
 - Confidentiality/use of identifiers
 - Who owns the tissue

Solutions

- Develop materials for patients, advocates and healthcare professionals
 - RAN is developing patient/advocate educational tools on the use of tissue in research

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Informed Consent

Challenges

- Inconsistency of form
 - Consent for tissue incorporated in consent for participation in clinical trial
 - Consent choices in the middle of the form, often not in context
 - Patient can be unclear about what s/he is consenting to

Solutions

- Involved constituencies needed to revisit templates
 - Consent for use of tissue should be separate unless a requirement for participating in a study
 - All consent choices should be at the end of the form
 - General statements about the future use of tissue rather than try to predict uses

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IRBs

Challenges

- Low number of community members
- Members are unaware of issues in the use of tissue for research

Solutions

- Increase the number of patient advocates serving as community members
- Education program to train community/patient advocates
- Mentoring/coaching service for advocates

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Rare Diseases

Challenges

- Smaller pool of patients to pull from
- More demand for tissue
- Longer time to research findings

Solutions

- Work with advocate organizations
 - Identify patients
 - Educate patients about research
 - Work with the research community

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Issues Requiring Attention

- **Informed consent**
 - Consistency
 - Language
 - Literacy
 - Sensitivity to cultural differences in decision making

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Issues Requiring Attention

- **IRBs**
 - Informed consents received are inconsistent
 - IRBs try to have consistency within their institutions
 - Result is inconsistency in what they require for tissue use

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Issues Requiring Attention

- **Withdrawal of consent or re-call of tissue**
 - Perception that this can easily be done. Can it?
 - What if all tissue is gone?
 - What if tissue has been used in research?
 - Can recall tissue but not data

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Issues Requiring Attention

- **Perceptions of Benefit to Others**
 - Will the tissue be sold?
 - Will the repository or clinician make money from the sale?
 - Will someone make money from the development of a new treatment?
 - Belief that one persons tissue is critical to the research. No understanding that the value of tissue is in the use of many samples
 - In rare cases one individuals tissue may results in a commercial product. How is that case handled?

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Issues Requiring Attention

- **Names**

- Multiple definitions of tissue.
 - Patients believe that it is a piece of the body
 - Fluids and other forms of "tissue" are not understood
- Tissue Repository or Bank
 - Repository may not be understood by a large majority of the public
 - Bank does not have one shared definition. It creates different images for different people.

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Issues Requiring Attention

- **Media Understanding**

- Public gets their information from the media
- The media has little understanding of medical research in general and even less about research using tissue
- The research community must take responsibility to get out accurate information.

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Thank You To

- My two partners
 - Mary Lou Smith
 - Elda Railey
- Advocates that have shared their concerns and suggested solutions about tissue
- Patients willing to donate tissue - without them we would not need this workshop

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