

Giving Tissue and Blood

Patient perspectives

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Participant: 2005, NCI Workshop on Biospecimen Access and Ethical, Legal, and Policy

Biospecimen to Biomarkers

- We urgently need practice-guiding biomarkers!
 - the trial-and-error approach to choosing therapy, for example, often leading to unproductive toxicity – to a narrowing range of choices

*If danger can be seen in terms of a **narrowing range of choices**, Billy Tyne's choices have just ratcheted down a notch.” ~ The Perfect Storm.*

- **Patients want to contribute!**
 - The larger concern is the disease



But, is your study likely to add to the science - benefit future patients?

- Level of supporting evidence?
- Will you have enough biosample to do the analysis?
- Is the study size sufficient to have confidence in findings?
- Is the capture, storage , and analysis standardized?
 - Can the data be pooled to validate the findings?

Collaboration and standardized methods are needed to find answers that are likely to help patients.

Patients' Concerns

- Is it painful, dangerous, burdensome?
 - Travel expenses; time off from work?
 - Do other equally appropriate protocols require less of me?

** Curt, Chabner, 2008, The Oncologist
One in Five Cancer Clinical Trials are Ever Published,
most often from failure to accrue*

- Privacy and Consent— best practice*
 - Is my privacy protected?
 - Other uses ...

** NCI Best Practices for Biospecimen Resources*

... Uses of “my” biospecimen?

- Will you publish the status and uses of tissue, along with de-identified associated clinical data?
- “Ownership” versus stewardship
- Is my associated clinical information de-identified when shared?
- Are future uses limited to disease-specific study?
 - Based on merits of the science?
 - Cooperative group study – with standardized methods and informatics?
 - Sold to a company for commercial uses?

Perspective:

When we communicate with the public about the uses and the status of contributed biospecimen, we are encouraging also best practices and fostering public trust in clinical research.

*But doing this efficiently would require an informatics system, which is also a recommended part of best practices**

** NCI Best Practices for Biospecimen Resources*

Requiring Biospecimen Contribution

- To make sure the patient is appropriate for the study
 - Genuine uncertainty about the diagnosis?
 - Does the target of the drug exist in the tumor?
- To monitor for safety , especially for a new class of drug
 - Detect toxicity early
 - Monitor clearance, where it goes, etc.
- To see if new class of study drug is helping in sampled region
 - Effective in the marrow?
- When the finding is likely to help future patients –
 - To discover or validate biomarkers that can guide practice - reduce pain and suffering, and improve survival

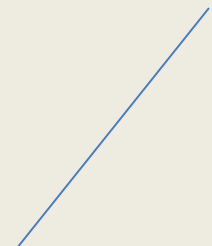
Coercion?

When might requiring a high-risk or painful procedure to acquire biospecimen be considered coercion by the patient?

- When eligibility is already determined?
- When the analysis isn't tied to the primary study questions?
 - Particularly when there are high expectations about the efficacy of the study protocol – that harm will result if not accepted in the study.

Defined:

“The threat of further harm may lead to the cooperation or obedience of the person being coerced.”



Optional Biospecimen Contribution?

- When the procedures are burdensome or worrisome –

... and would add significantly to the challenge of accrual -- putting other important clinical questions in your study at risk.
- Ask patient representatives for guidance!

Summary

- Urgent need for validated biomarkers
 - To guide clinical practice and research
 - To improve efficacy and reduce unproductive toxicity
- But it's not easy to do right: often requires large studies using standardized methods - collaboration
- Required tissue contribution
 - When is it Coercion?
 - Feasibility – consider burden, risks, and patient perceptions –the impact on accrual. Are there competing protocols that ask less of the patients?
- Communication about uses?
 - Would build public trust and foster best practice
 - Burdensome – if done without an informatics system to automate publication to website

? Do we inform the participants when findings are practice-changing?

Sincere thanks for the work you do on behalf of patients – all of us!