Giving Tissue and Blood
Patient perspectives

Karl Schwartz
Patient advocate, Lymphoma

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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!