Access to Specimens and Associated Data: the Changing Landscape

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Availability of Specimens +/- Data

Critical to all IVD studies, trials, and FDA marketing submissions

Major Questions and Issues:

A. Changes to Common Rule ?

B. Residual, de-identified specimens no longer permissible ?

C. Pharma trials monopolize subjects/specimens, even institutions

D. "Market" conditions dictate costs – going up/not down

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Background

A. Back in the REALLY OLD Days…..

- No one asked if specimens were obtained from a patient who consented
- Laboratories/Pathologists/Hospitals took custody of the specimens and whatever data was requested or required
- There was no oversight by an independent party (IRB or Ethics Board) of the use of any specimens or data

B. IP happened and Lawyers got involved!

- HeLa, *etc*.

C. And the Government got involved!

- Rules, regulations, laws, and ….

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WWWtPS? (What would Winnie the Pooh say?)

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Currently….

So now, we have IRB and Ethics Boards, and Compliance Officers, and Sunshine Reporting Requirements….

What does Tom always say never to say?

“How much worse can things get?”

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WWDHD? (What would Dennis Hopper do?)

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"Bad Things, Man"

Lots of parties want to be sure that they protect against every possible contingency and risk.

1. **Institutions – Multiple departments with oversight concerns**
   - **Legal**
   - **Contracting/Sponsored Research**
   - **IRBs**
   - **Academic Department(s) that will conduct study(ies)**
   - **President's Office, Boards, *etc.***

2. **Non-Institutional Practices – Independent Practices, *etc*.**
   - some of the above but mostly Sunshine Reporting

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"Bad Things, Man II"

So, what caused the most recent increases in concerns at providers about providing access to specimens and data?

1. **Inspections by Outside Authorities/Regulators**
   - **JCAHO**
   - **IRB – *cf.*, MA investigator site approval requirements**
   - **FDA – 483, *etc.***

2. **New regulations, requirements, and/or guidelines**

   - Common Rule proposal – "What genius thought this would be a good idea?"

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Current Status

Some Institutions have withdrawn from providing deidentified residual specimens with or without supporting data:

<u>Three Examples – blood and tissue</u>

1. Serial sets of specimens from subjects diagnose with a particular primary cancer

2. Residual blood specimens with only a test result (x3)

3. H&E slides and Access to FFPE blocks

Other sites have raised their prices – extra legal, departmental, and IRB review

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Critical Issue & Suggestions

THE Critical Issue:

Can the US Government align practices with goals ?

- Personalized Medicine
- Cancer Moonshot
- *Et al*.
- What does Tom ALWAYS say?
  - "FOLLOW THE MONEY!"

Suggestions:

1. Do NOT change current policy on use of deidentified residual specimens
2. Do NOT suggest drastic changes as preliminarily proposed in revision to Common Rule
3. Do consider that "Words have meaning"
   - – Alarming providers of specimens +/- supporting data does NOT help!

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Utopia? 400 +/- Years (Past is Prologue)

Shakespeare's *Henry VI*, Part 2, Act IV, Scene 2

Original

JACK CADE. Be brave, then; for your captain is brave, and vows reformation. There shall be in England seven half-penny loaves sold for a penny: the three-hoop'd pot shall have ten hoops; and I will make it felony to drink small beer: all the realm shall be in common; and in Cheapside shall my palfrey go to grass: and when I am king,- as king I will be,-

ALL. God save your majesty!

JACK CADE. I thank you, good people:- there shall be no money; all shall eat and drink on my score; and I will apparel them all in one livery, that they may agree like brothers, and worship me their lord.

DICK. The first thing we do, let's kill all the lawyers.

Still True in the Future?

Captain Jean-Luc Picard: We humans know our past, even when we're ashamed of it. I recognize this court system as the one that agreed with that line from Shakespeare: "Kill all the lawyers."

Q: Which was done.

Captain Jean-Luc Picard: Leading to the rule "Guilty until proven innocent."

Q: Of course. Bringing the innocent to trial would be unfair.

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