Developing Issues in Human Subjects Research Compliance

Right to Try and Social Media

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Right to Try
Abigail Alliance for Better Access to Developmental Drugs and Washington Legal Foundation v. Andrew C. von Eschenbach, MD and Michael O. Leavitt

Abigail Burroughs 1980-2001

Arguments for Access

- Fifth Amendment
- *Cruzan* decision
Arguments Against Access

- No evidence in our history and traditions of a right to access experimental drugs.
- Potential risks to patients are very high
- Challenges our system for evaluating drug safety and efficacy

What is the state of current legislation?
- Bills are consistently proposed in Congress, but none passed so far
- 28 states have passed Right To Try
- 23 additional states are considering the law this year (but not Washington state)

http://righttotry.org/in-your-state/
Are State Right to Try Laws Enforceable?

- Jurisdiction Issues
- Legal challenges
- Social/ Ethical Implications

FDA & Expanded Access
Social Media

Company denies drug to dying child

By Elizabeth Cohen, Senior Medical Correspondent
9 September 2013

Josh Hardy

Ethical Challenges

- Creation of false hope
- Therapeutic misconception
- Informed consent possible?
- Equity-Justice and exposure to risks
- Making available patient options
- Risks and harms, lack of benefit
- Effect on product development
- Participatory model?
Developing Issues in Social Media and Research

- Using social media to recruit subjects
- Gathering information from Facebook, Twitter
- Using social media to interact with subjects
- Research subjects using social media

Questions/ Comments?