Changing the Law in California

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- The Law
- The process of changing the law
- The aftermath

The Law

AB 2328

- Consistent with the Common Rule (45 CFR §46) and other federal and state laws and regulations pertaining to human subject protection

- The law separates Emergency Room environment from Non-emergency Room environment (AD research)
- Criteria for use of a surrogate:
  - Research studies relating to cognitive impairment, lack of capacity, or serious or life-threatening diseases
  - Protocol specific.
  - Must be requested through the IRB.
  - IRB application must include a protocol specific plan for decision – making capacity assessment (DMC).
  - If subject expresses dissent or resistance, excluded from study.

Determining the Decision Making Capacity of the Subject

- Attempt to obtain informed consent from the subject.
- No gold standard
- Protocol specific plan for assessment should include understanding, expression of a reasoned choice, nature of research, consequences of participation, alternatives to participation (MacArthur Competency Tool, Dan Marson interpretation)

- Usually involves reiterating a simplified version of the consent and protocol specific questions.
- Assessment of the DMC of the surrogate is only used when there is reason to believe surrogate has impaired DMC.

When the subject lacks DMC

- Inform the subject of the investigator's intent to use a surrogate
- Document discussion in research file

Hierarchy of potential surrogates

- Person's agent named in an advance healthcare directive
- Conservator or guardian with authority to make health care decisions
- Spouse
- Domestic partner
- Adult son or daughter
- Custodial parent
- Adult brother or sister
- Adult grandchild
- Available adult relative with the closest degree of kinship

Disagreement

- No surrogate consent may be utilized if there is a disagreement whether to consent among members of the highest available priority class.

Responsibilities of the Investigator

- The surrogate must:
  - Have reasonable knowledge of the subject
  - Be familiar with the subject's level of impairment
  - Be willing to serve as substitute decision maker
  - Understand the risks, potential benefits, procedures and alternatives to the research participation.
  - Make decisions based on the subject's known preferences or surrogate's judgment of what subject's preference would be

Self Certification Form

- Surrogate must be advised that if a higher-ranking surrogate is identified at anytime, defer to his/her decision regarding participation in research
- If potential surrogate identifies a person at a higher rank, the investigator is responsible to contact such individual to determine if they want to serve as surrogate

Reconsenting Subjects

- Criteria which would normally trigger re-consenting a subject apply (SAEs, change in protocol)
- Change of surrogate
- Subject regains cognitive function

The Process

Did we have any idea of what we were getting ourselves into?

- Not a clue!
- First step: Educate ourselves

Our education

- Talk to a local legislator to assess legislative interest.
- We needed a sponsor.
- Contact UCSD IRB to learn their interpretation of the current law.

In search of a sponsor

- Alzheimer's Association – California Council – Public Policy arm
  - Not interested at this time
- UC Office of the President (UCOP)– moving a mountain
- UCOP agrees to sponsor legislation – 5 months after initial contact (Late summer 2001)
- Alzheimer's Association with a nudge from national – gives us their support

Finding support in the research community

- California AD researchers contacted through 10 state ARCC's.
- Ethics committee formed
- Informational meeting with experts: Jason Karlawish and Dan Marson
- Outcome: *Guarded support, fear of bringing attention to a major problem!*

Time to spread the net

- Researchers in other areas of cognitive impairment contacted
  - Stroke, Parkinson's disease, MS, Huntington's disease, head trauma, and HIV.
- Sample letters of support sent out
- ARCC's formed the backbone of the process

Support from family service groups and affected individuals

- Alzheimer's Association
- Family Caregiver Alliance
- Support groups contacted
- Sample letters sent out

Identification of potential opposition

- Mental health groups
- Civil rights groups
- *After the bill was introduced, they came forward.*

Legislative Timeline-The Assembly

- UCOP drafts language of the bill
- AB 2328 introduced to the CA Assembly – February 21, 2002 by San Diego Assemblyman Howard Wayne
- Assigned to two committees: Health and Judiciary-Hearings in April and May
- Amendments taken
- The floor of the Assembly-May

The Senate

- Assigned to two committees: Health and Human Services & Judiciary
- Health and Human Services – June
- Amendments taken
- Judiciary chair decided not to hear bill
- Floor of the Senate
- Floor of the Assembly

The final weeks

- The Bill is chaptered
- Sent to the Governor
- Signed September 11, 2002
- Bill would become law January 1, 2003

In the interim

- UCLA halts research involving human subjects who cannot consent for themselves
- UCSF is reprimanded for inappropriate consenting processes
- UC Davis VA halts human subject research
- March 2002 – Newsweek has on its cover – 'a human crouching in a cage'

The Aftermath

Implementation of the Law

- Committee formed to draft the Guidelines
- Finalized and sent to all UC IRBs
- Local policy formulated specific to each campus

Issues which have arisen

- Site issues
  - UCSF: IRB wants outside MDs to determine capacity to consent
  - Stanford VA: wants 2 VA MDs, not involved in the protocol, to determine capacity

Issues (continued)

- Opposition
  - Major opponent: new bill introduced AB 1371 Feb 2003
  - Attempts to change many features of our bill, including requiring primary care MD to determine capacity
  - UCOP legislative analysts meet with sponsor of AB 1371 to draft amendments

What we learned

- We were lucky
- The most unlikely issues will be raised as points of discussion
- It is possible to change the law! The process really does work!

The future

- Impact of the legislation is still being felt
- Presentation at GSA in November
- Manuscript describing the process, pitfalls, etc.

Acknowledgements

- Ruth Mulnard, UC Irvine
- Leon Thal, MD – UCSD
- Bill Jagust, MD – UC Davis
- Dan Marson, PhD, JD - U Alabama
- Jason Karlawish, MD - Penn
- Mary Beth Stamps, UC Davis
- Jean Coleman, UC Davis
- Karen Metz, UCLA