Proxies and “Legally Authorized Representatives”

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These slides represent no one’s views but my own.
I have a legal education but I’m not your lawyer. This isn’t legal advice, this is educated opinion from a stranger whom you have not employed, and who hasn’t investigated your particular situation, or your state’s laws, in any way.
I have no conflicts to declare.
The Plot of This Tale

- Where a human subject lacks capacity to consent to participate in research, the Common Rule requires consent of that subject’s Legally Authorized Representative (“LAR”).
- The Common Rule leaves LAR to be defined by state law (as interpreted by OHRP), and (in the absence of state law) by institutional policy.
- Most states have no law defining LAR for research purposes.
- OHRP has historically piggy-backed on state law of proxy decision-makers for clinical care; and now will have to interpret institutional policy.
- State law and OHRP interpretation of state law is confusing, and institutional policy is often ad-hoc and undocumented.
- So you should always be nice to your attorney.
1) LAR means an individual or . . . other body authorized . . . to consent on behalf of a . . . subject to the subject’s participation in the procedure(s) involved in the research.

2) If there is no . . . law addressing this issue, LAR means an individual recognized by institutional policy as acceptable for providing consent in the nonresearch context . . . to the subject’s participation in the procedure(s) involved in the research.
In Sum:

• LARs—whether persons or bodies, consent on behalf of subjects

• An LAR has to be authorized by law to consent to the procedures in the research, or

• Authorized by law—or, under the new version of the Common Rule, by institutional policy—to consent in the non-research context “to the procedures involved in the research.”
The Problem

• Only a very few states have laws that designate LARs for consent to research
• This means LARs have to be those who are permitted to consent in the non-research context, that is, in clinical care
• OHRP has opined that it will permit legal authority for consent to clinical care to be treated as authority to consent for research—most of the time
The Hierarchy of Consent to Clinical Care

• This is a matter of state law, but most states agree:
  – A patient with capacity makes her own choices
    • A patient who’s lost capacity may have expressed her preferences
      – Via a living will
      – By appointing a Durable Power of Attorney for Health Care, or a more general Durable Power of Atty, or a Healthcare Proxy Decisionmaker
      – By working with a physician to enter a MOLST or POLST order in the chart
Living Wills and All That

- In general, state laws don’t require physicians to obey living wills; instead, they relieve physicians of all liability if they obey the living will.
- But some states have found common-law damages flowing from harmful failure to obey living wills.
- MOLST/POLST are medical orders
- DPAHC, DPA, Healthcare Proxy, vary a bit by state but generally empower a decision-maker to decide, without limiting the choice to being one that the patient would have made.
Next down the hierarchy

• If the patient has lost capacity and has left no evidence, orders, or proxy-appointments in writing, then:
  – A proxy or surrogate decisionmaker should make a substituted judgment for the patient ("decide as the patient would have")
  – State law determines who can be a proxy or surrogate decisionmaker
  – State law determines how much and what kind of evidence is needed to make a substituted judgment
  – But usually neither of these issues ends up being contested
State laws on proxies

- Laws on who can be a proxy and what kind of evidence they need vary widely.
- Many states have ordered lists: parents of minors, spouse, adult child of senior, next-of-kin, even down to “close friend.”
- Some states make ethics committees proxies for unbefriended patients, and special ethics committees for wards of the state, prisoners.
- Some states have ethics boards serve as proxies for special circumstances: emergency medical situations, public health emergencies.
- OHRP is generally reluctant to give special-authority bodies authority to decide about research participation.
State evidence for proxies

- Cruzan v. Missouri: States can decide level of evidence necessary for proxy to show that their decision is a “substituted judgment.”
- The same words, e.g., “clear and convincing evidence,” can mean different things in different states
- In the absence of enough evidence, then instead of making a substituted judgment, proxy and medical team must decide in the patient’s best interest.
Applying State Proxy Law to Research Consent

• In general, OHRP has permitted research consent to be given by a person empowered by law to consent to clinical treatment.

• ...except not necessarily special-purpose committees.

• So, family, state-empowered ethics committees for unbefriended patients, count.

• Advance directives don’t work for research consent.

• And Advance Directives, MOLST, etc., still in effect during research.
Apply State Proxy Law to Research Consent, cont.

• Where proxy lacks evidence sufficient for substituted judgment, “best interest” is the standard. Participation in research may be in the patient’s best interest, if there is a prospect of direct benefit.

• But, there is some lack of clarity. If procedures in research are novel, it may be that the proxy does not have pre-existing state legal authority to consent to the procedure in the non-research context, and so may not be able to consent.
The updated Common Rule permits research consent by parties empowered to consent by institutional policy. Doubts about when this went, or will go, into effect. But institutional policies are apt both to be consonant with state law, and to be more clear than state law, because of demand by hospital physicians and researchers. So this will all become easier if and when new rule is effective.
Thank you and time for questions

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