

Research with Adults Who Cannot Consent: When is it Ethical?

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GS

- GS is a 34 year old woman originally from Warsaw who speaks only Polish.
- She has been married for 9 years. Her husband also speaks only Polish.
- GS has no advance directive and has not designated a surrogate.



Incapacity

- GS experiences a seizure. Work up reveals advanced HIV infection (CD4-20 cells/ml; HIV RNA-120,000 copies/ml) and multiple brain lesions.
- She is unable to make decisions for herself and unable to communicate.



Initial Treatment

- GS is admitted to a hospital, where she is started on treatment for presumed cerebral toxoplasmosis.
- After two weeks of antibiotics, GS shows no signs of improvement.



NIH Contact

- The NIH is contacted to discuss possible enrollment in a protocol designed to test faster methods to distinguish cerebral toxoplasmosis from lymphoma.
- The protocol involves brain biopsy, lumbar puncture, nuclear imaging and blood draws, procedures that may not be done if the patient were cared for at an outside facility.



Surrogate Permission

- The federal regulations allow incapacitated adults to be enrolled in non-emergency research by a legally authorized representative.
- The IRB allows adults who cannot consent to be enrolled by an appropriate surrogate, per CC policy.



CC Policy (MAS 87-4)

- The IRB categorized the study as greater than minimal risk, but offering a prospect of benefit.
- For this category, CC policy requires court appointment of a surrogate, and a bioethics consult to ensure the family understands the risks and potential benefits.



Discussion with Husband

- The team speaks with GS's husband, via a translator, to explain the risks and potential benefits, and make him aware of the policy requiring a court appointed surrogate.
- The team learns that the husband has not been informed his wife is HIV+.



Questions

- Is it ethical to enroll adults who cannot consent and have no surrogate?
- Is a clinically assigned surrogate acceptable for research? Is the next of kin an acceptable surrogate?
- Do the courts offer a useful protection, or unnecessary barrier?

