



# The Presidential Commission for the Study of Bioethical Issues

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**Session 5: International Research Panel  
Results and Discussion**

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# **International Research Panel Recommendations**

- 1. Researchers must demonstrate respect for human subjects and their communities in all phases of clinical trial design and implementation. Recognizing other cultural standards and practices through community engagement is one concrete means of showing respect.**
  - Ongoing international dialogue between U.S. and international bodies is critical to protecting human subjects in research.**
  - U.S. and foreign investigators would benefit from clarification of the U.S. regulatory exception for foreign “protections that are at least equivalent to those” in the United States (“equivalent protections”) found at 45 C.F.R. § 46.101(h) and how it can be applied.**



## **International Research Panel Recommendations**

- 2. Funders of human subjects research should support ethics training for investigators and others, including IRB members.**



## **International Research Panel Recommendations**

- 3. Greater efforts are needed to enhance transparency, monitor ongoing research, and hold researchers and institutions responsible and accountable for violations of applicable rules, standards, and practices. To enhance transparency and accountability, governments should consider requiring all greater than minimal risk research to be registered and results reported.**



## **International Research Panel Recommendations**

- 4. The United States should implement a system to compensate research subjects for research-related injuries.**



## **International Research Panel Recommendations**

- 5. Continued efforts to harmonize and guide interpretation of rules should be made a priority over creating new rules.**