January 14, 2016

P. Pearl O'Rourke, M.D.
Director, Human Research Affairs

Dina N. Paltoo, Ph.D., MPH
Director, Genetics, Health, and Society Program
Office of Clinical Research and Bioethics Policy
National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892

Dear Dr. Paltoo:

We have reviewed the NIH GDS Online forms (80 Fed. Reg. 75,120) and would like to share a few questions and requests for clarification. While we appreciate the efficiency that can be gained with electronic submissions, we have some questions related to specific details in the forms themselves.

The Provisional Institutional Certification is an excellent addition and we have no comments on this form.

There are now separate Extramural Institutional Certification forms for studies using data generated from cell lines created or clinical specimens collected before and after January 25, 2015.

> The details for the certification both before and after January 25, 2015 are essentially the same with the only difference relating to the IRB/Privacy Board's assurance regarding the adequacy of the informed consent form in terms of "data submission and subsequent sharing for research purposes." For cell lines created or clinical specimens obtained prior to January 25, 2015, the data submission and sharing must not be inconsistent with the informed consent form. After January 25, 2015, date submission and sharing must be consistent with the informed consent form.
>
> We agree with the different requirements, but ask if NIH would consider a single form for data submissions from materials created or collected both before and after January 25, 2015. We have successfully used a single form by adding a footnote that states that for studies using data from specimens collected before the effective date of this policy, the IRB will review informed consent materials to ensure that data submission is not inconsistent with the informed consent provided to the research participants. A single form could be drafted that could distinguish between data from materials obtained prior to or after January 25, 2015.

Our final questions/request for clarification relate to specific language in the certification itself.

The first bulleted 'expectation" states:

> *"The data submission is consistent, as appropriate, with applicable national, tribal, and state laws and regulations as well as relevant institutional policies."*

We prefer restricting any institutional certification to compliance with local policies, Massachusetts state law and federal policies. We cannot certify for tribal or other state laws. We ask if the insertion of phrase *"as appropriate"* allows for our limited certification?

The IRB/Privacy Board is asked to assure, among other items that:

- "Consideration was given to risks to individual participants and their families associated with the data submitted to NIH-designated data repositories and subsequent sharing:
- To the extent relevant and possible, consideration was given to risks to groups or population associated with submitted data to NIH-designated data repositories and subsequent sharing;"

Given that decisions about subsequent data sharing are under the control of the DACs at NIH, it is not possible for local IRBs/Privacy Boards to be able to identify all potential risks of subsequent sharing either to individuals or groups. We note that in the bullet regarding risk to groups, the phrase "to the extent relevant and possible" is responsive to the limited review capacity of the local IRB/Privacy Board. We suggest that this same phrase should be added to the bullet re: consideration of risks to individuals.

We thank you for considering our comments and please contact us for clarification or additional information/thoughts.

Sincerely,

P. Pearl O'Rourke, M.D.
Director, Human Research Affairs
Partners Healthcare

PPO:lat

cc: Rosalyn Gray
Elizabeth Hohmann, M.D.
Mary Mitchell
Megan Morash
Susan Roudebush
Paula Sciabarrasi
Sarah White