Author's response to reviews

Title: National Mesothelioma Virtual Bank: A Standards Based Biospecimen and Clinical Data Resource to Enhance Translational Research

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Version: 2 Date: 23 July 2008

Author's response to reviews: see over
Revised Manuscript: 4677143731958176

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Reviewer #1:

Comment #1:

Reference number 10, 13 and 27 need, at least, a link. On contrary they should be deleted.

Response to Comments #1:

The web links are provided to reference number 10, 11 and 23.

Comment #2:

Quality Assurance Policies: Are external audits programmed?

Response to Comments #2:

There is no external audit program.

Comment #3:

Fig 1 is barely informative. If published, please improve its quality.

Response to Comments #3:

The figure visual quality has been improved

Comment #4:

Fig 2 could be transcribed to a table better than a figure. If published, please improve its quality.

Response to Comments #4:

The figure visual quality has been improved.

Reviewer # 2
Comment #1:

The data given on page 13 must be updated to the current time: “At the end of first quarter of 2008 we project the resource to have over 700 annotated cases of pleural, peritoneal and pericardial mesothelioma specimens along with blood and DNA samples available” This must be replaced by the data gathered now.

Response to Comments #1:

We added the most current numbers of clinically annotated cases in the result part of manuscript which is as follow;
“The NMVB resources hold over 650 archived mesothelioma cases and prospective cases. The resource provides more than 775 biospecimenes that are accrued from surgical resections and biopsies and also includes whole blood and DNA samples. This collection is made possible by the collaborative efforts of University of Pennsylvania, University of Pittsburgh and New York University. At the end of second quarter of 2008 we project the resource to have over 700 annotated cases of pleural, peritoneal and pericardial mesothelioma specimens along with blood and DNA samples available to the mesothelioma research community”.

Comment #2:

The honest broker is mentioned several times to act as a guardian of privacy. However, it is not mentioned what role the honest broker has in the whole process. Is it the local biobank manager, a lawyer, a database application or a notary? The honest broker role must be described who is or are they.

Response to Comments #2:

Honest broker is the person, system or organization that de-identifies the protected health information (PHI) and provide only de-identified information to investigators. It would not be reasonably possible for the investigators or others to identify the corresponding patients directly or indirectly. The honest broker can be a biobank manager, database application manger and cancer registrar but cannot be one of the investigators or researcher.

We have made addition and elaborated the role of honest broker more clearly in our manuscript under the header of **Patient Health Information Protection and De-Identification Process** in paragraph 4 as follows “An honest broker is an individual, organization or system acting for or on behalf of the covered entity to collect and provide health information to the investigators in such a manner whereby it would not be reasonably possible for the investigators or others to identify the corresponding patients-subjects directly or indirectly. The honest broker cannot be one of the investigators / researcher. A researcher may use the services of an honest broker system/service to obtain the Protected Health Informations in a de-identified manner. De-identification
means that the patient-subjects cannot be identified by researchers or others directly or indirectly through identifiers link to the patient-subject. This honest broker system/service will de-identify medical record information by automated and/or manual methods. All honest broker systems/services are approved in advance by both the IRB of record and UPMC. If an honest broker system/service is not part of the UPMC covered entity, a valid business associate agreement with UPMC is executed with UPMC in order to access UPMC-held Protected Health Informations for de-identification. If an honest broker system/service is to be used to obtain de-identified Protected Health Informations, this fact must be identified in the study's IRB submission. The honest brokers are individuals who have clinical responsibilities as tissue bankers in the Health Sciences Tissue Bank (HSTB), postdoctoral fellows to manage the pathology data or as cancer registry specialists in the UPMC Network Cancer Registry. Based on their clinical job duties, their educational backgrounds and experiences vary. Depending on the nature of the projects, these bankers can work autonomously or collaboratively to meet biospecimen and/or data needs. ”