THE NATIONAL HUMAN GENOME RESEARCH INSTITUTE
MEDICAL SEQUENCING PROGRAM

Cover Letter for Model Consent

Investigators:

Attached please find the final model consent language to be used by institutions in the development of consent forms and processes at the sites where samples have been collected for cancer research and are to now be "reconsented" for the Medical Sequencing Project (MSP). MSP is a unique and highly visible project and because we will be placing genetic and other health information in widely accessible databases, we believe it would be optimal for participants to be specifically consented for this project. We have reviewed many existing consent forms and have concluded that consent forms of the past do not discuss many of the elements that will be part of this project.

NHGRI staff drafted the original language for this consent and have had input from numerous outside experts and advocates. The reading level of the attached document is above high school. We realize that it may be too high for many populations. We also realize that there will be required language from some institutions that will have an impact the final form that each site's consent document will take. However, it is critical that the following elements are specifically included in any consent form that is developed.

(Taken directly from the final page of the consent document)

To participate in this research, you must agree to <u>ALL</u> of the following statements:

- I voluntarily agree to donate a blood (or other tissue) sample or a cheek tissue sample to be used for this <u>and</u> for other research projects.
- I agree to release information from my medical records for this <u>and</u> for other research projects.
- I agree to have my coded genetic information and coded medical information placed in databases accessible by the Internet, as described in the *Storage and Release of Samples and Medical Information* section on page 2 of this document.
- I understand that my coded genetic information and coded medical information in the Internet databases will be used in this <u>and</u> in other research projects.
- I understand that there is a risk that someone in the future might be able to use information in these databases to identify me or possibly my blood relative(s).
- I agree to be recontacted in the future to see if I am willing to provide additional samples or follow-up information about my health or medical care. (Only required if the study design involves re-contact.)

For the purposes of this project, it will not be possible for participants to pick and choose the parts of the project that they want to participate in. They must agree to all parts of the

project, or they should not participate. In addition, it is important for participants to understand that once they have contributed samples and health information and they have been transferred to multiple labs and put into the databases, it will not be possible for them to withdraw.

We believe it is likely that investigators will need to work with their own IRBs to develop their own consent form so that it is acceptable to them. We would be happy to work with investigators, IRBs, and recruiters to help them in the development or implementation of their reconsenting process. We would like to have an opportunity to review each investigator's consent form before final IRB approval. In addition, we would very much like an opportunity to evaluate this reconsenting process so that we learn from it and it can help to inform future MSP processes.

Finally, we would like to suggest that each investigator consider applying for a Certificate of Confidentiality from NHGRI to attempt to further protect the identity of the research participants. See http://grants1.nih.gov/grants/policy/coc/ for more information on Certificates of Confidentiality.

Please don't hesitate to contact us if we can be of help to you.

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