Development of the caHUB Informed Consent Template

As part of the planning process for the cancer Human Biobank (caHUB), the NCI Office of Biorepositories and Biospecimen Research (OBBR) convened several expert working groups, including a subgroup devoted to ethical, legal and social issues (ELSI). The ELSI Subgroup consisted of members from government and academia with expertise in ethics, law, and patient advocacy. The ELSI Subgroup generated a document entitled "Preliminary Ethical, Legal, and Social Considerations for caHUB" containing their preliminary recommendations in the areas of governance, privacy, access to data and biospecimens, data sharing, custodianship and intellectual property, return of research results, informed consent, and conflicts of interest. In developing its recommendations for informed consent, the ELSI Subgroup reviewed several national regulatory and guidance documents, Federal regulations governing research with human subjects, policies and recommendations of national ethics advisory committees and biobanking initiatives in the United States and elsewhere, and the research ethics literature.

The ELSI Subgroup's recommendations focus on how the ethical and regulatory elements of informed consent laid out in the above-cited sources apply specifically to the caHUB. Notably, the ELSI Subgroup gave particular consideration to some of the central issues associated with informed consent—among them the scope of consent, content of informed consent documents, protection of privacy and confidentiality, return of research results, termination of participation, custodianship and intellectual property, and access to and sharing of biospecimens and associated information. Once consensus had been reached as to how to approach these issues, the ELSI Subgroup began developing specific language for inclusion in a template informed consent document. As part of the process for developing the informed consent document, the ELSI Subgroup analyzed informed consent documents for biobanking from various sources. Several teleconferences were held to discuss the content of the informed consent document and ensure that the language accurately represented the mission and approach of caHUB.

The consensus informed consent template developed by the ELSI Subgroup was then reviewed by the Group Health Research Institute Program for Readability in Science and Medicine (PRISM). The PRISM reviewed and revised the consent template to improve readability and lower the reading level (currently Flesch-Kincaid Grade level of 8.7). The PRISM also re-organized and re-formatted the consent template to make it more reader-friendly and removed redundancy to shorten the document.

The NCI OBBR partnered with the NCI Office of Advocacy Relations to identify cancer patient advocates to participate in focus groups about the caHUB informed consent template. The purpose of the focus groups was to hear patient advocate opinions about the language and content of the informed consent template. Participants were instructed to read the consent template once casually and then a second time noting language that was unclear or seemed inconsistent for any reason. Two focus groups were held with a total of 14 patient advocates. Participants highlighted language that was unclear or misleading, provided suggestions for improvement, and noted redundancies. Comments from all the participants were summarized and changes to the template were made as appropriate. The NCI OBBR also provided a copy of the informed consent template to the Office for Human Research Protections (OHRP) and discussed the structure and organization of caHUB with OHRP.

The OBBR has devoted significant effort and involved a variety of stakeholders in the development of the caHUB informed consent template in order to create a document that will meet the scientific needs of caHUB while ensuring the adequate consent of research participants.
The OBBR believes it is important to maintain consistency in the approaches to certain central issues across all caHUB participating biospecimen sites, while also incorporating relevant local considerations for each community and ensuring that the informed consent document is easily understood by a diverse audience.