

PHARMACOGENETICS RESEARCH NETWORK - RECOMMENDATIONS FOR MODEL INFORMED CONSENT LANGUAGE, TERMS, AND PROCEDURES

The charge of the Human Subjects Subcommittee for the Pharmacogenetics Research Network is to develop recommendations and policies and potentially useful model language for use in Pharmacogenetics studies, both by the Network and by other research groups. The model language presented below should be considered a working draft that is potentially modifiable by local investigators to suit their particular study and IRB needs.

CHARGE #1: DEVELOP RECOMMENDATIONS FOR THE USE OF EXTANT SAMPLES (AND DEFINE TERMS).

DEFINE TERMS

Extant samples are samples that already exist in investigators' freezers, having been collected with an existing informed consent form or with an implied consent form at some past date and now the question is the use of these specimens for ongoing pharmacogenetics research. In this document, we will utilize the definitions put forth by the Trans-Industry Pharmacogenetics Working Group (<http://www3.diahome.org/committees/pharmacogenetics/background.asp>).

Categories for Genetic Research Samples/Data

- **Identified Samples/Data** are those labeled with personal identifiers such as Name or Social Security Number. Use of a clinical trial subject number does not make the sample/data identified.
- **Coded Samples/Data** are those labeled with a clinical trial subject number that can be traced or linked back to the subject only by the investigator. Samples do not carry any personal identifiers.
- **De-Identified Samples/Data** are double coded and labeled with a unique second number. The link between the clinical study subject number and the unique second number is maintained, but unknown to investigators and patients. Samples do not carry any personal identifiers.
- **Anonymized Samples/Data** are double coded and labeled with a unique second number. The link between the clinical study subject number and the unique second number is deleted. Samples do not carry any personal identifiers.
- **Anonymous Samples/Data** are those that do not have any personal identifiers, and the identity of the subject is unknown. Anonymous samples may have population information (e.g., the samples may come from patients with diabetes) but no additional individual clinical data.

POLICY

At the present time, in order to access stored specimens for retrospective or prospective studies, investigators need to choose between accepting anonymized specimens and obtaining a second

informed consent. In some special cases, investigators may be able to utilize a waiver of informed consent if initially there was implied consent on the part of the study subjects to the use of their specimens for genetic research. In cases where identifying data are critical to the scientific goal of the research, investigators may obtain institutional review board approval for the protection of the subjects. In judging the adequacy of previous informed consent when an application is received in pharmacogenetics research, several issues should be considered by the IRB. One, the nature of the disease proposed for study; two, the likelihood that knowing results of the research will harm or benefit an individual, relatives, or community; three, the availability to affect a treatment for prevention of the disorder; and four, the burden of such treatment.

CHARGE #2: DEVELOP MODEL PROCEDURES FOR PROTECTION OF CONFIDENTIALITY FOR SUBJECTS WHO DONATE SAMPLES FOR PHARMACOGENETICS RESEARCH.

POLICY

The basic posture of the Human Subjects Subcommittee is that as much data as possible should be placed on the Pharm GKB Network Website and made available to all researchers as possible consistent with protection of confidentiality of research subjects.

The second premise of the Human Subjects Subcommittee is that premature or inadvertent release of data that would identify any potential individual or participant would seriously jeopardize the research effort and undermine the goals of the network. Protection of individual research subjects' confidentiality, thus must be primary and takes precedence over the dissemination of information. At the present time, totally non-identifiable data, such as SNP polymorphisms, their position and allele frequency, and aggregate pharmacokinetic or pharmacodynamic data such as would appear in a manuscript can appear without review in the Pharm GKB Network. Phenotype data on individual subjects is, however, not releasable on the network website at the present time though it may be accepted for archiving on Pharm GKB and released later with appropriate safeguards. All prospectively collected data will be anonymized and submitted to the Pharm GKB data repository. A local Stanford subcommittee, consisting of representatives of both the knowledge base subcommittee and the human subjects subcommittee, will review data submission templates for receiving and publishing data, followed by approval of the human subjects committee. With regard to process prior to posting any data, individual investigators will clarify whether the data are to be public or withheld or otherwise processed to ensure patient confidentiality with the knowledge base P.I. with regard to posting of website information. This should be the minimally obtrusive and provide for the fastest data flow with regard to posting of information.

MODEL LANGUAGE

Confidentiality: Participation in research may cause a loss of privacy. All information gathered in this study will be used collectively with information from other participants. Your name will not be used in published results and data from the study will be reported in consolidated form. All your personal and medical data will be considered confidential. Once you have completed the study, all of the data collected on you will be coded by number. Only research staff will have access to the samples and records and the keys to the code, so as to minimize the risk of loss of confidentiality of genetic testing results.

Furthermore, the data obtained for your 'drug response genes' in this study will be deposited into the Pharmacogenetics Research Network Database (PharmGKB) on the World Wide Web. Information on this knowledge base may be used by researchers for further studies in other patients. However, the knowledge base will not include any information directly pertaining to the identity of the samples. Information identifying you will not be available on the knowledge base.

CHARGE #3: DEVELOP MODEL CONSENT LANGUAGE REGARDING SUBJECTS' RIGHTS TO INTELLECTUAL PROPERTY RESULTING FROM PHARMACOGENETICS RESEARCH.

POLICY

In general, the committee felt that individual research subjects should not retain intellectual property rights in genetics investigations. Sample language is proposed below.

COMPENSATION

All tissue and/or fluid samples are important to this research study. Your sample will be owned by (Hospital/University) or by a third party designated by (Hospital/University) (such as another university or a private company). If a commercial product is developed from this research project, the commercial product will be owned by (Hospital/University) or its designee. You will not profit financially from such a product.

Cells obtained from your body may be used to establish a cell line which may be shared in the future with other researchers and which may be of commercial value. A cell line will grow indefinitely in the laboratory. Cell lines may be useful because of the characteristics of the cells and/or the products they may produce.

CHARGE #4: DEVELOP MODEL CONSENT FORM LANGUAGE REGARDING ACCESS TO GENOTYPE AND PHENOTYPE DATA BY OTHER RESEARCHERS.

MODEL LANGUAGE

Your (your child's) samples will be used for scientific research. As part of this research, they may be shared with collaborators of the Pharm GKB Network. They may also be sold or licensed to third parties who may try to create products from them. You will not benefit directly from profits from these products, although you and others may benefit from the products if they improve health.