## 1 PURPOSE

1.1 Genetic information is uniquely personal information and has the potential to impact employment, insurance, finance, education, family relationships and possibly self-perception. Therefore, genetic information collected for research purposes must be carefully managed to protect individuals or groups from stigmatization, discrimination, or psychological harm.

1.2 The guidance begins when the Sharp HealthCare (SHC) Institutional Review Board (IRB) determines that a research proposal will involve genetic testing and/or collection/disclosure of subjects' genetic information.

1.3 The guidance ends when the research study is closed and/or the SHC IRB determines that the genetic research guidance should no longer be observed.

## 2 REVISIONS FROM PREVIOUS VERSION

2.1 Previous versions are available via the Human Research Protection Program (HRPP) Change Log.

## 3 POLICY STATEMENT

3.1 The following are to be considered when determining whether research involving genetic testing and/or collection/disclosure of subjects' genetic information is beyond the scope of routine clinical care.

3.1.1 Genetic assessments directly or indirectly include information about the relatives of the study subject. It is important to distinguish between the clinical and research contexts for including such information in analysis.

3.1.2 In many cases, family information is needed to diagnose an individual, as part of a diagnostic and therapeutic medical assessment, which is not as part of a research study. Thus, it is important to recognize the difference between collecting this information to confirm a diagnosis in an individual seeking clinical care and collecting this information for the purposes of research.

3.1.3 In context of research, it is possible that participation in some genetics studies may alter (positively or negatively) family relationships (e.g., genetic breast cancer studies in families). Even the solicitation of research participation within extended families may expose differences among relatives in attitudes or beliefs, which may cause problems in the family.

3.1.4 When individual research findings are returned to subjects, there is a potential to differentiate, or sort, relatives based on their "at risk" status, disease status, or reproductive risks and this can potentially create undesirable changes in family dynamics genetics research may raise issues stemming from the discovery of misidentified relationships, such as misattributed paternity or unknown adoption. These types of risks may also affect family members who are not subjects in the research. Therefore, IRBs should consider how to handle situations in which close family members (e.g., parents of adult children or identical twins) choose not to participate in the research. IRBs should ensure that any reasonably foreseeable psychological or social harm to which the research subject or extended family members may be exposed is explained during the consent process.

3.2 Depending on the nature of the information collected, third-party individuals may be affected by the research. An important issue for investigators and IRBs is determining when the information that is collected requires that a "third party" be classified as a human research subject per 45 CFR 46.102(e)(1). This is a controversial and unsettled area of human subjects' protection for genetics research at this time. Until clear guidance is available, investigators and IRBs must use their best judgment in determining when information on such "third parties" is both identifiable and private, when third parties must be consented, and when a waiver of consent for a third-party would be appropriate. When third party issues are discussed and solved by the IRB, it is essential that minutes reflect this discussion.

3.3 Investigators and the SHC IRB will comply with all applicable federal and state laws and statues.

## 4 RESPONSIBILITIES

4.1 Investigators submitting research that includes genetic testing and/or collection/disclosure of subjects' genetic information carry out these procedures.

4.2 The IRB Specialists and designated reviewers research which includes genetic assessments should confirm that the procedures below have been addressed satisfactorily.

## 5 PROCEDURE

5.1 When research involves genetic testing and/or collection of genetic information, the investigator will include the following information in the study protocol (e.g., via *TEMPLATE: Research Protocol (HRP-500)*) and will discuss the following with potential research subjects:

5.1.1 Information that can be obtained from DNA samples in general, and the specific questions to be addressed in this study

5.1.2 Identifying information available to other researchers if their sample and/or associated data are part of a registry or database.

5.1.3 The extent of subject and sample confidentiality if the sample and subsequent information are to be used in a registry or database.

5.1.4 The rights and limitations of subjects who chose to request destruction of their sample and/or associated data at a future date.

5.1.5 The rights of subjects to require that their sample and or associated data be stripped of any identifying information, and limitations on such rights of subjects.

5.1.6 Mechanisms for maintaining confidentiality in long-term studies, registries, or databases.

5.1.7 Potential for commercial profit by the institution, investigator or sponsor from information gathered in this study.

5.1.8 The any options for genetic counseling in cases if a study may reveal genetically important information (i.e., possessing genetic defects which could be passed on).

5.1.9 State that the sample/data, any cell lines, profits from data, etc., are the property of the Sponsor.

5.1.10 If genetic information will be disclosed to the subject or another party, the investigator disclosing the information must be named and the specific genetic information being disclosed must be stated.

5.1.11 How information to be disclosed to subject is consistent with the recipient's level of knowledge (e.g., information would be phrased differently when disclosed to a lay person versus a physician).

5.2 For research involving genetic testing or the collection of genetic information, the informed consent document(s) must include the Genetic Information Nondiscrimination Act (GINA) and California Genetic Information Nondiscrimination Act (CalGINA) verbiage from *TEMPLATE: Informed Consent Document with CA Bill of Rights and PHI Authorization (HRP-502)*. When the PHI authorization is a standalone document (e.g., *TEMPLATE: PHI Authorization (HRP-509)*), the genetic information to be collected and/or disclosed for the research must be stated.

5.3 Before involving minors in DNA research, the parent(s) or legal guardian(s) must review and sign the parent permission. See *TEMPLATE: Parent Permission with California Bill of Rights (HRP-505)*.

5.3.1 The parent permission must give parents/guardians the option of whether they want the results (if available) of the genetic analysis disclosed to them. Whenever appropriate, the minor's assent should also be solicited using *TEMPLATE: Child Assent (age 7-12) (HRP-503)* or *TEMPLATE: Adolescent Assent (age 13-17) (HRP-504)*.

5.4 If the subject requests that their information be disclosed when they reach the age of majority, that fact should be included in the child or adolescent assent (as appropriate). Investigators

must follow the appropriate measures regarding releasing such information (e.g., counseling, etc.).

## 6 MATERIALS

6.1 FORM: Initial IRB Review Application (HRP-211)

6.2 TEMPLATE: Informed Consent Document with CA Bill Of Rights and PHI Authorization (HRP-502)

6.3 TEMPLATE: Child Assent (age 7-12) (HRP-503)

6.4 TEMPLATE: Adolescent Assent (age 13-17) (HRP-504)

6.5 TEMPLATE: Parent Permission with California Bill of Rights (HRP-505)

6.6 TEMPLATE: PHI Authorization (HRP-509)

## 7 REFERENCES

7.1 DHHS: 45 CFR 46.102(e)(1); Guidance on the Genetic Information Nondiscrimination Act: Implications for Investigators and Institutional Review Boards; The Genetic Information Nondiscrimination Act of 2008 (GINA)

7.2 FDA / ICH: E18 Genomic Sampling and Management of Genomic Data Guidance for Industry

7.3 NIH: National Human Genome Research Institute – Regulation of Genetic Tests

7.4 California: California Genetic Information Nondiscrimination Act (CalGINA)

This document is available on www.sharp.com/research, IRBANA or by contacting research@sharp.com.