

GUIDANCE: Genetic Research

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HRP-085	10/1/2014	Center For Research	Institutional Official	Investigators and IRB Specialists	Required: X Elective:	Page 1 of 3

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 a study, 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 genetic information will be used.
- 1.3 The guidance ends when the IRB determines that the genetic research guidance should no longer be observed.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None.

3 POLICY STATEMENT

- 3.1 The IRB specialists are to use this guidance when genetic information of research participants is disclosed.
- 3.2 The following are to be considered when determining whether genetic information collected or used for research is beyond that in found routine clinical care.
 - 3.2.1 Genetic assessments directly or indirectly include information about the relatives of the person being studied. It is important to distinguish between the clinical and research contexts for including such information in analysis.
 - 3.2.2 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 in order to confirm a diagnosis in an individual seeking clinical care and collecting this information for the purposes of research
 - 3.2.3 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.
 - 3.2.4 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.
- 3.3 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, in accordance with Title 45 Part 46 of the Federal Policy.
- 3.4 This is a controversial and unsettled area of human subjects’ protection for genetics research at the 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.

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4 RESPONSIBILITIES

- 4.1 Investigators submitting research which includes genetic assessments should ensure these procedures are carried out to protect the genetic information of its participants.
- 4.2 The IRB specialists and members reviewing research which includes genetic assessments should confirm that the procedures below have been addressed satisfactorily.

5 PROCEDURE

- 5.1 The investigator is to include the following as part of their initial study submission *using FORM: Initial IRB Review Application (HRP-211)* when genetic information is collected for a specific study:
 - 5.1.1 Discuss information that can be obtained from DNA samples in general, and the specific questions to be addressed in this study
 - 5.1.2 Discuss identifying information available to other researchers if their sample and/or associated data are part of a registry or database.
 - 5.1.3 Discuss 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 Discuss 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 Discuss 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 Discuss mechanisms for maintaining confidentiality in long-term studies, registries, or databases.
 - 5.1.7 Discuss potential for commercial profit by the institution, investigator or sponsor from information gathered in this study.
 - 5.1.8 Discuss 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 A clear statement that the sample/data, any cell lines, profits from data etc., are the property of the University.
 - 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 Discuss 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 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)*.
 - 5.2.1 The parent permission must give parents/guardians the option of whether or not 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)*.
- 5.3 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 with regard to releasing such information (e.g., counseling, etc.).

6 MATERIALS

- 6.1 FORM: Initial IRB Review Application (HRP-211)
- 6.2 TEMPLATE: Child Assent (age 7-12) (HRP-503)
- 6.3 TEMPLATE: Adolescent Assent (age 13-17) (HRP-504)
- 6.4 TEMPLATE: Parent Permission with California Bill of Rights (HRP-505)



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7 REFERENCES

7.1 http://www.dnapolicy.org/images/issuebriefpdfs/FDA_Regulation_of_Genetic_Test_Issue_Brief.pdf

This document is available on www.sharp.com/research , [IRBANA](#) or by contacting research@sharp.com.