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| **For Describing Genetic Research** |
| **All forms must be typewritten and submitted via email to irb@illinois.edu.** |

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| **When to use this form:** Research studies involving genetic testing fall into two basic categories to assist in the determination of further review. |
| **Genetic testing** means a test of a person’s genes, gene products, or chromosomes for abnormalities or deficiencies, including carrier status, that (i) are linked to physical or mental disorders or Impairments, (ii) indicate a susceptibility to illness, disease, impairment, or other disorders, whether physical or mental, or (iii) demonstrate genetic or chromosomal damage due to environmental factors. Genetic testing does not include routine physical measurements; chemical, blood and urine analyses that are widely accepted and in use in clinical practice; tests for use of drugs; and tests for the presence of the human immunodeficiency virus. *[Illinois Compiled Statutes Annotated Chapter 410 513/10]* |
| **Category A:** The study is looking for an association between a genetic marker and a specific disease or condition, but at this point it is not clear if the genetic marker has predictive value. The uncertainty regarding the predictive value of the genetic marker is such that studies in this category will not involve participant counseling. |
| **Category B:** The study is based on the premise that a link between a genetic marker and a specific disease or condition is such that the marker is clinically useful in predicting the development of that specific disease or condition. |

**Section 1. PROTOCOL INFORMATION**

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| **1A. Principal Investigator:** |
| **1B. Protocol Number:** |
| **1C. Project Title:** |

**Section 2. RESEARCH TYPE**

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| Category A  Category B |
| **If Category A, briefly describe the research here:** |
| **If Category B, complete the rest of the form.** |

**Section 3. CONSENT FORM**

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| **A description of any potential genetic results should be provided to participants in the consent form.** |
| **3A.** Will participants be told what information is being obtained through the genetic testing?  Yes  No |
| **3B.** Will participants be informed about the possibility of important incidental findings, such as paternity, disease, or conditions other than the one(s) investigated by this study?  Yes  No |
| **3C.** Will participants be given the option not to receive information?  Yes  No |
| **3D.** Will the data be protected from disclosure to third parties, such as employers and insurance companies?  Yes  No |
| **3E.** Will participants be told about the potential consequences of a third party, such as an employer or insurance company, becoming aware of any study findings?  Yes  No |
| **The following information should be included in the consent form:**   * What genetic information they will be given and when * That they may discover things about themselves or their family they did not want to know or will be uncomfortable knowing * If information generated about them during the study could compromise their insurability * Any risks study participation will expose them to * The confidentiality of the data * The rights they retain over data and biological samples * Consequences of withdrawal from the study * Costs associated with participation if those costs are not covered by the investigator or the institution |

**Section 4. SHARING GENETIC INFORMATION**

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| **4A. Describe the plan for sharing information with participants, including interim or inconclusive results:** |
| **4B. What genetic information will they receive?** |
| **4C. What will the implications of the genetic information be for participants?** |
| **4D. Are there plans to disclose research findings to participants or their physicians for clinical use?**  Yes  No |
| **4E. Are participants given a choice of whether this information is shared with their physicians?**  Yes  No |
| **4F. Will participants be protected against disclosure of medical or other personal information about themselves to family members?**  Yes  No  **If no, describe the information that will be disclosed and to who it will be disclosed:** |
| **4G. What will the implications of the genetic information be for participants’ relatives?** |
| **4H. Will relatives be invited to participate in the study based on genetic research results?**  Yes  No  **If yes, describe how they will be recruited:** |

**Section 5. DATA PRIVACY**

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| **5A. Will data be coded?**  Yes  No  **If no, explain why not:** |
| **5B. How will data be stored?** |
| **5C. What will happen to participant data in the event of participant withdrawal from the study?** |
| **5D. Do publication plans threaten the privacy or confidentiality of participants?**  Yes  No  **If yes, explain:** |