UVA HUMAN INVESTIGATION COMMITTEE

EXEMPT APPLICATION FORM

Box 800483 (434) 924-2620 Barringer, Room 4362 www.hsc.virginia.edu/hic

Please attach a New Protocol Information Form to the top of this form and submit to the HIC Office.

Will you be (Check all that apply)
o collecting samples/data at UVA
o receiving samples/date from outside UVA
o sending these samples/data outside of UVA

If you are receiving or sending samples from an institution outside of UVA do you have a contract or a Material Transfer agreement? □ Yes □ No

Title of Study:

A. Does this study involve?
□ Yes □ No Nonhereditary genetic research in which samples are linked/coded or identifiable
□ Yes □ No Hereditary genetic research
□ Yes □ No Surveys or interviews given to minors?
□ Yes □ No Any procedures that may cause a subject either physical or psychological discomfort or is perceived as harassment above and beyond what the person would experience in daily life?
□ Yes □ No Deception?
□ Yes □ No Observation of minors if the investigator participates in the activities being observed unless there is a federal statute covering the activity?
□ Yes □ No The study of a rare trait/disorder such that there is some risk of exposing the identity of sample donors or the research poses risk of community or cultural harm.

B. Does the study meet the following criteria?
□ Yes □ No Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens Existing Data: means that all the data, documents, records, or specimens are in existence prior to IRB Review, therefore specimens obtained prospectively from future discarded clinical samples do not qualify for exempt review.(1)
□ Yes □ No These sources are publicly available or the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects (i.e. history #'s, pathology accession #'s, initials and date of birth). (2) If both 1&2 checked: 45CFR46.101(b)(4)
□ Yes □ No Research involving the use of educational tests, survey procedures, interview procedures or observation of public behavior unless information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects and that any disclosure of the human subject's responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects financial standing, employability or reputation. 45CFR46.101(b)(2)

C. Please answer the following questions to the best of your ability:
□ Yes □ No Is the probability of the harm or discomfort anticipated in the proposed research greater than that encountered ordinarily in daily life or during the performance of routine physical or psychological examinations or tests?
□ Yes □ No Is the magnitude of the harm or discomfort greater than that encountered ordinarily in daily life, or during the performance of routine physical or psychological examinations or tests?

D. If you will be banking tissue, answer the following two questions:
□ Yes □ No Are the samples being collected for the sole purposes of this study?
□ Yes □ No Are the specimens coded by a third party and stored in a facility that will not break the code, even upon the request of a family member/ or medical emergency or considered minimal risk?

E. Will any of the following items be recorded? [18 identifiers per HIPAA under 164.514(b)(2)(i) and (ii)]
All items refer to those items affiliated with the subjects of this protocol.
□ Yes □ No 1. Name
□ Yes □ No 2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of the zip code if, according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same 3 initial digits contains more than 20,000 people and (2) The initial 3 digits of a zip code for all such geographic units containing 20,000 is changed to 000.

□ Yes □ No 3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages older than 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
□ Yes □ No 4. Telephone numbers
□ Yes □ No 5. Fax numbers
□ Yes □ No 6. Electronic mail addresses
□ Yes □ No 7. Social Security number
□ Yes □ No 8. Medical Record number
□ Yes □ No 9. Health plan beneficiary numbers
□ Yes □ No 10. Account numbers
□ Yes □ No 11. Certificate/license numbers
□ Yes □ No 12. Vehicle identifiers and serial numbers, including license plate numbers
□ Yes □ No 13. Device identifiers and serial numbers
□ Yes □ No 14. Web Universal Resource Locators (URLs)
□ Yes □ No 15. Internet Protocol (IP) address numbers
□ Yes □ No 16. Biometric identifiers, including finger and voice prints
□ Yes □ No 17. Full-face photographic images and any comparable images
□ Yes □ No 18. Any other unique identifying number, characteristic, code

F. Please answer the following question to the best of your ability:
□ Yes □ No Do you have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information?

G. Will any of the following items be recorded? [16 identifiers per HIPAA under 164.514(e)]
All items refer to those items affiliated with the subjects of this protocol.
□ Yes □ No 1. Name
□ Yes □ No 2. Postal address information, other than town or city, state, and zip code
□ Yes □ No 3. Telephone numbers
□ Yes □ No 4. Fax numbers
□ Yes □ No 5. Electronic mail addresses
□ Yes □ No 6. Social Security number
□ Yes □ No 7. Medical Record number
□ Yes □ No 8. Health plan beneficiary numbers
□ Yes □ No 9. Account numbers
□ Yes □ No 10. Certificate/license numbers
□ Yes □ No 11. Vehicle identifiers and serial numbers, including license plate numbers
□ Yes □ No 12. Device identifiers and serial numbers
□ Yes □ No 13. Web Universal Resource Locators (URLs)
□ Yes □ No 14. Internet Protocol (IP) address numbers
□ Yes □ No 15. Biometric identifiers, including finger and voice prints
□ Yes □ No 16. Full-face photographic images and any comparable images

H. Please answer the following question to the best of your ability.
□ Yes □ No Will this information be disclosed for purposes other than research, public health, or health care operations?

What kind of human samples (e.g., tissue, blood) or data will be obtained?

Informed Consent
Exempt research is not subject to federal regulations contained in 45 CFR 46, which include requirements for informed consent. Therefore, if the research is eligible for exemption, then "technically" informed consent is not required. It is up to the investigator to decide whether or not consent should be obtained and documented. Often the investigator will provide a letter of explanation or even a consent form. Again, this is not required, but may be the appropriate thing to do to ensure the rights and welfare of the subjects. If you plan to provide a consent form or letter, please submit it along with this form. If a questionnaire or interview will be done, please attach a copy of the questions.

Regulatory Requirements:
1. The Principal Investigator (PI) will notify the HIC prior to any change made to this protocol or consent form (if applicable).
2. The Principal Investigator will notify the HIC office within 30 days of a change in the PI or the closure of the study.

Principal Investigator (printed) Principal Investigator (Signature) Date

Source: University of Virginia, Charlottesville.