

APPENDIX E

SPECIAL CONSIDERATIONS FOR THE COLLECTION AND USE OF TISSUE SAMPLES AND BIOLOGICAL SPECIMENS FOR GENETIC STUDIES AND OTHER RESEARCH PROJECTS

I. Definitions

A. Genetic Research: Research (not diagnostic testing) which involves either:

1. The analysis of human chromosomes or DNA from an individual and/or family members for the purpose of deriving information concerning the individual or family about the presence, absence or mutation of genes, DNA markers, gene products or inherited characteristics; or
2. Biochemical measurements of proteins and metabolites with the intent of collecting and evaluating information about the heritability of diseases and/or characteristics within a family.

B. Subject Identifiers: The name, medical record number, or social security number of an individual study subject.

C. Anonymous Samples: Tissue samples are obtained by the research investigator(s) without any subject identifiers and without a link to an individual subject's identity.

II. General Requirements for IRB Approval and Written Informed Consent

Research using human tissues and biological specimens will typically fall into one of the following categories:

A. Tissue samples or biological specimens obtained specifically for research purposes, which would not be collected otherwise.

The performance of a procedure (i.e., intervention) on an individual for the specific purpose of obtaining tissue (e.g., blood, biopsy samples, the collection of extra biological material during a clinically indicated procedure) or biological specimens for use in a research project **requires** prior approval of the project by the IRB, and **requires (1)** that the involved subjects provide prospectively their written informed consent for the research collection and use of their tissue or biological specimens. For blood samples (i.e., with volume limitations) and certain biological

(1) Unless a waiver of the informed consent requirement is granted by the IRB (see IRB Reference Manual, section 8.3)

specimens (e.g., excreta and external secretions), this IRB approval can be handled in an expedited manner **(2)** (see the IRB Reference Manual for details).

B. Use of fresh tissue that is a residual sample (i.e., in whole or in part) of that which was removed surgically for clinical treatment and/or pathology purposes (i.e., “residual fresh tissue samples”).

Research involving the use of “residual fresh tissue samples” **requires** prior approval by the IRB.

1. Research involving the use of “residual fresh tissue samples” **requires (3)** the prior written informed consent of involved patients if subject identifiers are included with the samples or related subject information (e.g., demographic data, medical record information) obtained by the investigators, or if the investigators have direct access to information (i.e., “linkage code information”) linking subject identifiers with codes assigned to the tissue samples and related subject information.
2. “Residual fresh tissue samples” may be used for research **without a requirement** for prior written informed consent of involved patients provided that: (a) subject identifiers are NOT included with the samples or related subject information obtained by the investigators, and/or the investigators do NOT have direct access to linkage code information; and (b) the investigators make no attempt to link the “residual fresh tissue samples” and related subject information with respective subject identities. **Both of these requirements (i.e., (a) and (b), above) must be met for the research to be exempt from the requirement for prior written informed consent of the involved patients.** Contingent upon meeting these requirements, the research project may be submitted for IRB approval using an abbreviated exempt research determination form [see Appendix A].

Note: A suggested mechanism to achieve compliance with requirements (a) and (b), above, and still permit additional or future collections of subject information (e.g., medical record information) respective to the “residual fresh tissue sample” is to incorporate the participation of an “honest broker” in the research study. An “honest broker” is an individual (e.g., pathologist) who, by virtue of his/her routine clinical responsibilities, would normally have access to the tissue sample

(2) Approved by the IRB chairperson or a vice-chairperson

(3) Unless a waiver of the informed consent requirement is granted by the IRB (see IRB Reference Manual, section 8.3)

and related patient/subject information. This “honest broker” assigns a code number to the “residual fresh tissue sample” and related subject information prior to providing the sample and information to the research investigator(s). The “honest broker” maintains the linkage code information (i.e., independent of the research investigators) and can provide additional or new subject information upon the request (i.e., by code number) of the research investigators.

The release of “residual fresh tissue samples” for research **requires** prior authorization by a pathologist, and cannot occur until the clinical pathology requirements are adequately addressed. The investigator, with the agreement and in the presence of a pathologist, can temporarily store part of the tissue; however final release of this stored “residual fresh tissue sample” for research use is contingent upon completion of the diagnostic evaluation. **To ensure compliance with this clinical necessity, a pathologist is required to be included as a co-investigator on all research protocols involving the use of “residual fresh tissue samples”.**

- C. Use of archived or banked tissue samples, such as paraffin blocks or fixed pathology specimens, or tissues that have been previously collected for a different research project (i.e., “existing tissue samples”).

The use of “existing tissue samples” in a research project **requires** prior approval of the project by the IRB.

1. Research involving the use of “existing tissue samples” **requires** the prior written informed consent of involved subjects **(4)** if subject identifiers are included with the samples or related subject information (e.g., demographic data, medical record information) obtained by the investigators, or if the investigators have direct access to information (i.e., “linkage code information”) linking subject identifiers with codes assigned to the tissue samples and related subject information.
2. “Existing tissue samples” may be used for research **without a requirement** for prior written informed consent of involved patients/subjects provided that: (a) patient/subject identifiers are NOT included with the samples or related patient/subject information obtained by the investigators, and/or the investigators do NOT have direct access to linkage code information; and (b) the investigators make no attempt to link the “existing tissue samples” and related subject information with respective patient/subject identities. **Both of these requirements (i.e., (a) and (b), above)**

(4) Unless a waiver of the informed consent requirement is granted by the IRB (see IRB Reference Manual, section 8.3)

must be met for the research to be exempt from the requirement for prior written informed consent of the involved patients/subjects. Contingent upon meeting these requirements, the research project may be submitted for IRB approval using an abbreviated exempt research determination form [see Appendix B].

Note: A suggested mechanism to achieve compliance with requirements (a) and (b), above, and still permit future or additional collections of subject information (e.g., medical record information) respective to the existing tissue sample is to incorporate the participation of an “honest broker” in the research study. An “honest broker” is an individual (e.g., pathologist or other research investigator) who, by virtue of his/her responsibilities, would have access to the reference banked tissue samples and related patient/subject information. This “honest broker” assigns a code number to the existing tissue sample and related patient/subject information prior to providing the sample and information to the current research investigator(s). The “honest broker” maintains the linkage code information (i.e., independent of the current research investigators) and can provide additional or new subject information upon the request (i.e., by code number) of the current research investigators.

If there are questions regarding these requirements, investigators should contact the IRB Office before taking any actions, which may place them, and the institution in noncompliance of federal regulations and guidelines addressing human subject research.

III. Informed Consent for Genetic Research Studies (5)

In developing an informed consent document for participation in a genetic research study, the following issues should be addressed:

A. Under the Description section:

1. Inform the potential research subject that his/her biological sample will be used for genetic research. Describe the purpose of the intended genetic research and the reason why the potential subject is being asked to participate.

Note: The potential subject should be given sufficient information regarding the specific research use of his/her biological sample

(5) It is recognized that some genetic research studies may not involve the collection of tissue samples. Respective investigators should consider the consent form issues outlined below and address those which are felt to be applicable to their research study. Additional assistance may be obtained by contacting the IRB Office.

and genetic material so as to permit an informed decision whether or not to consent to such use. I.e., to simply state that the biological sample will be used for “genetic research studies” provides inadequate information to the potential subject regarding the potential benefits of study participation. It is recommended, however, that the stated intended use be not so specific that it will prevent use of the biological sample (i.e., with subject identifiers) for related research studies. Appropriate statements would include, for example, “for genetic research studies involving cancer”, or “for genetic research studies involving diseases of the elderly, e.g., cancer, heart disease, Alzheimer’s disease.”

2. Address the specific procedures that will be performed for obtaining the biological sample.
3. Indicate the planned length of storage of the biological sample and genetic material.
4. If applicable, address plans for the inclusion of family members of the proband in the research study.

Note:

- a) *Within families, each person is an individual who deserves to have information about him- or herself kept confidential. Family members are not entitled to each others’ diagnoses. Before revealing medical or personal information about individuals to other family members, investigators must obtain the consent of the individual.*
- b) *In genetic (i.e., pedigree) studies, it is common for the proband or other family member to be asked to provide information about other members in the family. The ethical and regulatory question presented by this practice is whether that information can become part of the study without the written informed consent of the person about whom the data pertains. Note that the federal regulations define a “human subject” as “an individual about whom an investigator conducting research obtains --- identifiable private information.” Hence, investigator-solicited information about a family member, wherein the family member is specifically identified by name, renders that information regarding the family member subject to the regulations governing human subject research. Research involving questionnaires or surveys is exempt (see 45 CFR 46.101 (b) (2)) from the requirement to obtain informed consent “unless (1) information obtained is recorded in*

such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (2) any disclosure of the human subjects' 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." Hence, if the requested information about other members of the family is sensitive in nature (and the family member will be specifically identified in the research records), written informed consent of the family member should be sought prior to obtaining this information. If the research could not practicably be conducted without obtaining the specific identities and written informed consent of family members, the IRB recommends that the principal investigator request a waiver of the respective informed consent requirement. This waiver request should be accompanied by a justification as to why obtaining the specific identities of the family members is necessary to the conduct of the research (i.e., at this stage in the research project) and for what purposes this information will be used. The waiver request should also address 1) why the research study could not be practically carried out unless a waiver of the written informed consent requirement is granted; 2) why it is felt that a waiver of the requirement to obtain written informed consent of the family members will not adversely affect their rights and welfare; and 3) why it is felt that this aspect of the research study constitutes a minimum risk to the involved family members.

c) To avoid a "cold calling" scenario, plans for inclusion of family members in the research study should provide for proband introduction of the research study to his/her family members. With agreement of the family member, the family member's name and address/telephone number may be provided, by the proband, to the research investigators for subsequent contact. Alternately, the family member may be instructed, by the proband, to contact the research investigators if s/he is interested in study participation.

5. Indicate if the research subject will be informed of personal results of the genetic research study.

Note: In making this decision, the investigators should take into consideration the fact that the biological samples and genetic material are being analyzed in the context of a research study; that the research findings, if provided, may be clinically irrelevant with

regard to available strategies for prevention or treatment of the respective disease; that most research laboratories are not CLIA authorized to provide data upon which to base subsequent clinical decisions; and that informing the study participants of the research findings may represent a major source of the risk (i.e., psychological risks) of study participation.

a) If personal genetic information will NOT be provided to individual research subjects:

(i) Include an explanation as to why this information is not being provided.

E.g., this can be justified on the basis that the involved research laboratory is not CLIA certified and/or the genetic data cannot yet be interpreted or applied in a clinically relevant or meaningful manner.

(ii) Address any circumstances whereby the personal genetic information may be disclosed to the subject in the future.

E.g., indicate that should the genetic information become clinically relevant as a result of the availability of new strategies for the prevention or treatment of the respective disease, it will be provided to the subject.

b) If personal genetic information will be given to individual research subjects:

(i) Address if personal genetic information will be provided routinely to all subjects or only upon specific request of a subject. If it is the intent to provide personal genetic information to all subjects, indicate that individual subjects retain the right to refuse such information and that genetic or medical counseling should be sought in making this decision.

(ii) Describe the procedures for disclosure of the personal genetic information.

(iii) Indicate at what point in the research study the personal genetic information will be disclosed.

E.g., indicate that interim results may not allow definite answers, and that waiting until the entire study is complete will delay communication of the findings.

- (iv) Provide, if the involved research laboratory is CLIA certified, instructions re. obtaining medical or genetic counseling to address the clinical ramifications of the personal genetic information.
 - (v) Provide, if the involved research laboratory is NOT CLIA certified, instructions re. obtaining additional documentation of the personal genetic information and medical or genetic counseling, as appropriate. It must be clearly stated that, since the research laboratory is not CLIA-approved, the personal genetic information is valid for research purposes only and should not form the basis (i.e., without additional validation) for subsequent lifestyle or medical decisions.
6. Incorporate the following statement: “If you agree to participate in the research project, use of your biological sample and genetic material will be under the control of the principal investigator of this research project.”
7. Inform potential research subjects if their biological samples, genetic material, or related subject information will be given, with subject identifiers, to secondary investigators (i.e., other than those involved in the current research project) or external entities.

Note: Secondary use of the subjects’ biological samples, genetic material, and related subject information in an anonymous manner (i.e., without any subject identifiers and without a link to an individual subject’s identity) is exempt from the requirement for their informed consent. See I.C.2., above.

- a. Indicate, if applicable, that the secondary use of the subjects’ biological samples, genetic material, and related subject information, with identifiers, will be for the same specific research use(s) as identified for the current research project (see A.1., above).

Note: It is recommended that investigators provide (i.e., under the Voluntary Consent section of the consent form; see I., below) potential subjects with the option of

consenting to secondary use of their biological sample, genetic material, and related subject information, with identifiers. This approach will permit participation in the primary study should a potential subject not wish to consent to secondary use of their samples or related subject information.

- b. Indicate, if applicable, that subjects will be recontacted for consent if the secondary use of their biological samples, genetic material, and related subject information, with identifiers, is for a different specific research use than that which is identified for the current research project.

Note:

(i) *It is recommended that investigators provide (i.e., under the Voluntary Consent section of the consent form; see I., below) potential subjects with the option of indicating their willingness to be recontacted re. a different research use of their biological sample, genetic material, and related subject information, with identifiers. This approach will permit participation in the primary study should a potential subject not wish to be recontacted re. a different research use of their samples or related subject information.*

(ii) *Investigators are reminded that secondary use of the subjects' biological samples, genetic material, or related subject information in an anonymous manner (i.e., without any subject identifiers and without a link to an individual subject's identity) is exempt from the requirement for their informed consent. See I.C.2., above.*

B. Under the Risks and Benefits section:

1. Address the potential risks of study participation; for example:
 - a. The physical risks/discomforts associated with biological sample collection.
 - b. The potential for breach of confidentiality which could impact future insurability, employability, or reproduction plans, or have a negative impact on family relationships, and/or result in paternity suits or stigmatization.

- c. If the personal genetic information will be disclosed to the research subjects; the impact of learning the results (e.g., of finding out things about themselves or their family that they did not really want to know, or that they may be uncomfortable knowing), the impact of learning results which may not be accurate, the impact of learning the results if no effective strategies are available for prevention or treatment of the disease, that actions they may take as a result of their participation may expose them to risks (e.g., submitting false or incomplete medical histories in obtaining insurance coverage).
2. Address the potential benefit(s) that may reasonably be expected to result from the research study; for example:
 - a. If applicable, state explicitly that individual research subjects will receive no direct benefit from study participation.
 - b. As appropriate, address other potential benefits of study participation (e.g., advancement of knowledge; potential future benefit to society as a whole; clinical relevance to subject and/or family members if disclosure of research findings is planned.)

Note: Investigators should avoid promises of significant breakthroughs in diagnosis, treatment or outcome to entice participation.

- c. Inform potential subjects of uncertainties regarding any proposed benefits of study participation.

C. Under the Alternative Treatments section:

Note: Since genetic research studies do not involve treatment, this section may be deleted.

D. Under the New Information section:

Incorporate the following statements:

“You have been informed previously that the personal results of this research study (*will/will not*) be provided to you. You or your representative will be promptly notified if any other information about this research study develops during the course of the study

which may cause you to change your mind about continuing to participate.”

E. Under the Costs and Payments section:

1. Inform potential research subjects if there will be any costs (i.e., to the subject) associated with study participation; for example, the cost of genetic or medical counseling.
2. Inform potential research subjects of any payment they may receive associated with the time and inconvenience of their study participation.
3. Incorporate the following statements:

“Your biological sample or genetic material may lead, in the future, to new inventions or products. If the research investigators are able to develop new products from the use of your biological sample or genetic material, there are currently no plans to share with you any money or other rewards that may result from the development of the new product”.

F. Under the Compensation for Injury section:

Incorporate the standard IRB consent form statements for this section.

G. Under the Confidentiality section:

1. Address the specific procedures that will be used to protect the confidentiality and privacy of personal information associated with the biological sample, genetic material, and related subject information.
E.g., explain how linkage codes will be utilized to protect subject confidentiality, and describe plans for physical security of linkage code information and/or for biological samples, genetic material and related subject information which contain subject identifiers.
 - a. If applicable, address how confidentiality will be maintained for biological samples and genetic material, which may be sent to external laboratories for analysis.
 - b. If applicable, address provisions of a Certificate of Confidentiality granted for this research study.
2. State that the subject’s personal research results will not be put in his/her medical record.

3. State that the subject or subject's family will not be identified in any publication of the research study.
4. State that the subject's written authorization will be obtained prior to providing personal research results to relatives, personal physicians, insurance companies, or any other third party.
5. Address possible exceptions to ensuring confidentiality; for example:
 - a. The required reporting of observations of abuse or behavior suggesting potential harm to self or others (i.e., as per standard IRB consent form statements for this section).
 - b. In unusual circumstances, the subject's research records may be inspected by appropriate government agencies or released in response to a court order (i.e., as per standard IRB consent form statements for this section).
 - c. The possibility that demographic information contained in the publication of pedigree studies may permit identification of the subject/subject's family. Inform the potential research subject that his/her permission for publication will be obtained if such identification is readily possible.

H. Under the Right to Withdraw section:

Incorporate the standard IRB consent form statements for this section. In addition, inform potential research subjects what will happen to their biological samples, genetic material, and related subject information (e.g., destroyed, rendered anonymous) upon a decision to withdraw from study participation.

I. Under the Voluntary Consent section:

Incorporate the applicable, standard IRB consent form statements for this section. In addition, incorporate the following statements:

1. "I give my permission to use my biological sample or genetic material, with personal identifiers, in other research projects involving the study of (*indicate specific research use(s) as per that (those) identified in the Description section of this consent form*)".

YES _____ NO _____

2. “I give my permission to be recontacted to obtain my consent if there is a desire to use my biological sample or genetic material, with personal identifiers, in other research projects involving the study of different diseases or conditions (i.e., diseases or conditions other than those specified in the Description section of this consent form)”.

YES _____ NO _____

IV. Informed Consent for Non-Genetic Research Studies Involving the Collection and Use of Tissue Samples and Biological Specimens

In developing an informed consent document for participation in a non-genetic research study involving the collection and use of tissue samples and biological specimens, the following issues should be addressed:

A. Under the Description section:

1. Inform the potential research subject that his/her biological sample will be used for research. Describe the purpose of the intended research and the reason why the potential subject is being asked to participate.

Note: The potential subject should be given sufficient information regarding the specific research use of his/her biological sample so as to permit an informed decision whether or not to consent to such use. I.e., to simply state that the biological sample will be used for “future research studies” provides inadequate information to the potential subject regarding the potential benefits of study participation. It is recommended, however, that the stated intended use be not so specific that it will prevent use of the biological sample for related research studies. Appropriate statements would include, for example, “for research studies involving cancer”, or “for research studies involving diseases of the elderly, e.g., cancer, heart disease, Alzheimer’s disease.”

2. Address the specific procedures that will be performed for obtaining the biological sample.
3. Indicate the planned length of storage of the biological sample.
4. Indicate if the research subject will be informed of personal results of the research study.

In making this decision, the investigators should take into consideration the fact that the biological samples are being analyzed in the context of a research study; that the research findings, if provided, may be clinically irrelevant with regard to available strategies for treatment of the respective disease; that most research laboratories are not CLIA authorized to provide data upon which to base subsequent clinical decisions.

a) If personal results of the research study will NOT to be provided to individual research subjects:

(i) Include an explanation as to why this information is not being provided.

E.g., this can be justified on the basis that the involved research laboratory is not CLIA certified and/or the research findings cannot yet be interpreted in a clinically relevant or meaningful manner.

(ii) Address any circumstances whereby personal results of the research study may be disclosed to the subject in the future.

E.g., indicate that should the research results become clinically relevant as a result of the availability of new strategies for the prevention or treatment of the respective disease, it will be provided to the subject.

b) If personal results of the research study will be provided to individual research subjects:

(i) Address if the personal research results will be provided routinely to all subjects or only upon specific request of a subject. If it is the intent to provide personal research results to all subjects, indicate that individual subjects retain the right to refuse such information and that medical or psychological counseling should be sought in making this decision.

(ii) Describe the procedures for disclosure of the personal research results.

- (iii) Indicate at what point in the research study the personal research results will be disclosed.

E.g., indicate that interim results may not allow definite answers, and that waiting until the entire study is complete will delay communication of the findings.

- (iv) Provide, if the involved research laboratory is CLIA certified, instructions re. obtaining medical counseling to address the clinical ramifications of the personal research results.

- (v) Provide, if the involved research laboratory is NOT CLIA certified, instructions re. obtaining additional documentation of the personal research results and medical counseling, as appropriate. It must be clearly stated that, since the research laboratory is not CLIA-approved, the results are valid for research purposes only and should not form the basis (i.e., without additional validation) for subsequent lifestyle or medical decisions.

- 5. Incorporate the following statement: “If you agree to participate in the research project use of your biological sample will be under the control of the principal investigator of this research project.”
- 6. Inform potential research subjects if their biological samples and related subject information will be given, with subject identifiers, to secondary investigators (i.e., other than those involved in the current research project) or external entities.

Note: Secondary use of the subjects’ biological samples and related subject information in an anonymous manner (i.e., without any subject identifiers and without a link to an individual subject’s identity) is exempt from the requirement for their informed consent. See I.C.2., above.

- a. Indicate, if applicable, that the secondary use of the subjects’ biological samples and related subject information, with identifiers, will be for the same specific research use(s) as identified for the current research project (see A.1., above).

Note: It is recommended that investigators provide (i.e., under the Voluntary Consent section of the consent form;

see I., below) potential subjects with the option of consenting to secondary use of their biological samples and related subject information, with identifiers. This approach will permit participation in the primary study should a potential subject not wish to consent to secondary use of their samples or related subject information.

- b. Indicate, if applicable, that subjects will be recontacted for consent if the secondary use of their biological samples and related subject information, with identifiers, is for a different specific research use than that which is identified for the current research project.

Note:

(i) It is recommended that investigators provide (i.e., under the Voluntary Consent section of the consent form; see I., below) potential subjects with the option of indicating their willingness to be recontacted re. a different research use of their biological sample and related subject information, with identifiers. This approach will permit participation in the primary study should a potential subject not wish to be recontacted re. a different research use of their samples or related subject information.

(ii) Investigators are reminded that secondary use of the subjects' biological samples and related subject information in an anonymous manner (i.e., without any subject identifiers and without a link to an individual subject's identity) is exempt from the requirement for their informed consent. See I.C.2., above.

B. Under the Risks and Benefits section:

1. Address the potential risks of study participation; for example:
 - a. The physical risks/discomforts associated with biological sample collection;
 - b. The potential for breach of confidentiality which could impact future insurability or employability.
 - c. If the personal research results are to be disclosed to the research subjects, the impact of learning the results, the impact of learning results that are not accurate, the impact

of learning the results if no effective strategies are available for treatment of the disease.

2. Address the general benefit(s) that may reasonably be expected to result from the research study; for example:
 - a. If applicable, state explicitly that individual research subjects will receive no direct benefit from study participation.
 - b. As appropriate, address other potential benefits of study participation (e.g., advancement of knowledge; potential future benefit to society as a whole; clinical relevance to subject if disclosure of research findings is planned.)

Note: Avoid promises of significant breakthroughs in diagnosis, treatment or outcome to entice participation.

- c. Inform potential subjects of uncertainties regarding any proposed benefits of study participation.

- C. Under the Alternative Treatments section:

Note: If the research project involving the collection and use of biological samples does not involve treatment, this section may be deleted.

- D. Under the New Information section:

Incorporate the following statements:

“You have been informed previously that the personal results of this research study (*will/will not*) be provided to you. You or your representative will be promptly notified if any other information about this research study develops during the course of the study which may cause you to change your mind about continuing to participate.”

- E. Under the Costs and Payments section:

1. Inform potential research subjects if there will be any costs (i.e., to the subject) associated with study participation; for example, the cost of psychosocial or medical counseling.
2. Inform the potential research subjects of any payment they may receive associated with the time and inconvenience of their study participation.

3. Incorporate the following statements:

“Your biological sample may lead, in the future, to new inventions or products. If the research investigators are able to develop new products from the use of your biological sample, there are currently no plans to share with you any money or other rewards that may result from the development of these new products”.

F. Under the Compensation for Injury section:

Incorporate the standard IRB consent form statements for this section.

G. Under the Confidentiality section:

1. Address the specific procedures that will be used to protect the confidentiality and privacy of personal information associated with the biological sample and related subject information.

E.g., explain how linkage codes will be utilized to protect subject confidentiality, and describe plans for physical security of linkage code information and/or biological samples and related subject information which contain subject identifiers.

a. If applicable, address how confidentiality will be maintained for biological samples which may be sent to external laboratories for analysis.

b. If applicable, address provisions of a Certificate of Confidentiality granted for this research study.

2. State that the subject’s personal research results will not be put in his/her medical record.

3. State that the subject will not be identified in any publication of the research study.

4. State that the subject’s written authorization will be obtained prior to providing any personal research results to relatives, personal physicians, insurance companies, or any other third party.

5. Address possible exceptions to ensuring confidentiality; for example:

a. The required reporting of observations of abuse or behavior suggesting potential harm to self or others (i.e., as per standard IRB consent form statements for this section).

- b. In unusual circumstances, the subject's research records may be inspected by appropriate government agencies or released in response to a court order (i.e., as per standard IRB consent form statements for this section).

H. Under the Right to Withdraw section:

Incorporate the standard IRB consent form statements for this section. In addition, inform potential research subjects what will happen to their biological samples and related subject information (destroyed, rendered anonymous) upon a decision to withdraw from study participation.

I. Under the Voluntary Consent section:

Incorporate the applicable, standard IRB consent form statements for this section. In addition, incorporate the following statements:

- 1. "My biological sample may be used, with personal identifiers, in other research projects involving the study of (*indicate specific research use(s) as per that (those) identified in the Description section of this consent form*)".

YES _____ NO _____

- 2. "I give my permission to be recontacted to obtain my consent if there is a desire to use my biological sample, with personal identifiers, in other research projects involving the study of diseases or conditions other than those specified in the Description section of this consent form".

YES _____ NO _____

