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NEBRASKA’S HEALTH SCIENCE CENTER OFFICE OF REGULATORY AFFAIRS (ORA)

 Institutional Review Board (IRB)

# CONTINUING REVIEW OF HUMAN BIOLOGICAL MATERIAL (HBM) RESEARCH

# OR HBM TISSUE BANK

SECTION I

1. IRB: #:

2. TITLE OF PROTOCOL:

3. PRINCIPAL INVESTIGATOR (PI):

**A. DEPARTMENT:**

**B. PHONE:**

**C. EMAIL:**

**D. ADDRESS/CAMPUS ZIP:**

4. LEAD COORDINATOR:

**A. PHONE:**

**B.** **EMAIL:**

5. STATUS: **Mark the status of the protocol.**

|  |  |  |
| --- | --- | --- |
| **[ ]**  | **A.** | No HBM has been collected to date. Re-approval requested. |
| **[ ]**  | **B.** | HBM collected and/or subjects accrued. Re-approval requested. |
| **[ ]**  | **C.** | No further HBM will be collected or subjects accrued. Research-related tests ongoing. Re-approval requested. |
| **[ ]**  | **D.** | On-going data analysis or maintenance of the tissue bank only |

6. DESIGN: **Mark what kind of sample collection is being done and complete sections as indicated:**

|  |  |
| --- | --- |
| **Design Category** | **Complete Section II** |
| **[ ]**  | **A.** | Retrospective and/or prospective collection of HBM  | All (except 3) |
| **[ ]**  | **B.** | Prospective collection of HBM by a routine clinical procedure or by an intervention performed specifically for research purposes only (i.e., blood draws, biopsy etc.,) | All (except 3) |
| **[ ]**  | **c.** | Tissue bank ONLY | All (except 2, 4A, 4B, 5) |

6. CERTIFICATION OF PRINCIPAL INVESTIGATOR

 **This application contains complete and accurate information.**

Printed Name of Principal Investigator

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Signature of Principal Investigator Date

7. PRINCIPAL INVESTIGATOR'S ASSURANCE

***The PI understands and accepts the following obligations to protect the rights and welfare of research subjects/donors in accordance with the protocol:***

* I certify that I have carefully reviewed this application and all supporting documents. I have determined that the application is accurate, complete and ready for submission to the IRB.
* I certify that I, and all listed personnel, have the necessary qualifications, expertise, and hospital credentials, and will continue to conduct this research/tissue bank in a manner which fully protects the rights and welfare of research subjects/donors.
* As the PI, I will continue to fulfill my responsibility to ensure that this research/tissue bank and the actions of all personnel involved in conducting the research or maintaining the tissue bank conform to the: 1) IRB approved application, 2) detailed protocol, 3) HRPP policies, 4) HHS regulations for the protection of human subjects (45 CFR 46), 5) applicable FDA regulations, 6) other applicable federal regulations, 7) HIPAA Rule and 8) state law.
* As the PI, I will continue to fulfill my responsibility to ensure that valid informed consent/assent (if required) has been obtained from all research subjects/HBM donors or their legally authorized representatives (LARs). I will ensure that all personnel involved in the process of consent/assent are trained properly and are fully aware of their responsibilities relative to the obtainment of informed consent/assent according to federal regulations, state laws, and HRPP policies.
* I certify that the minimum amount of protected health information (PHI) or other identifiers necessary will be used, maintained and disclosed to conduct this research/tissue bank. I have implemented reasonable safeguards to protect the PHI/identifiers at all times.
* I will promptly inform the IRB of any unanticipated problems involving risk to subjects, donors or others, in the time frame defined by HRPP policies.
* I will promptly inform the IRB if I become aware of: 1) any complaints from research subjects, donors, LARs, or others about the research; 2) violations of HHS regulations at 45 CFR 46 and applicable FDA regulations; 3) violations of the HIPAA Rule; or 4) violations of HRPP policies.
* I will promptly inform the IRB of the results of external audits performed by sponsors, Contract Review Organizations (CROs), cooperative groups or FDA.
* I will not initiate any change in protocol without IRB approval except when it is necessary to reduce or eliminate a risk to the subject/donor, in which case the IRB will be notified as soon as possible.
* I will maintain all required records on file and I recognize that representatives from the IRB, OHRP, HHS, and FDA (as applicable) are authorized to inspect these records.
* I certify that there continues to be adequate resources and facilities to safely carry out and complete this research/maintain this tissue bank. This includes sufficient staff, funding, space, record keeping capability, and resources necessary to address any unanticipated problems involving risk to the subject, donors or others. If the necessary resources become unavailable I will notify the IRB.
* I will promptly inform the IRB of any significant negative change in the risk/benefit relationship of the research as originally presented in the protocol and approved by the IRB.
* I understand that continuing review by the IRB is required at least annually in order to maintain approval status. I will maintain IRB approval as long as this study is active.
* I understand that I am responsible for appropriate research billing in accordance with ***UNMC Clinical Trial Professional and Technical Fee Billing Policy #8008***or applicable Children’s Hospital & Medical Center policy.
* I certify that I and all other personnel listed in Section I of the IRB Application have disclosed all potential financial conflicts of interest as required and are in full compliance with the ***UNMC Conflict of Interest Policy #8010*** and ***HRPP Policy.*** I further certify that all potential financial conflicts of interest are appropriately managed in order to ensure protection of the rights and welfare of subjects.
* I understand that if there are any changes in the financial interests of responsible personnel during the course of the research or maintenance of the tissue bank, the IRB must be notified as soon as possible.
* I understand that failure to comply with HHS regulations, applicable FDA regulations, HRPP policies and the provisions of the protocol as approved by the IRB may result in suspension or termination of my project, and/or other administrative or legal actions.

 Printed Name of Principal Investigator

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Signature of Principal Investigator Date

**SECTION II**

***Instructions:*** *Research is approved by the IRB for a maximum period of one year. In order to review your Application for Continuing Review, the IRB must have the following information pursuant to its charge by HHS Regulations at 45 CFR 46.109(e) and FDA Regulations at 21 CFR 56.109(e).*

*The Study Design category in Section I determines which subparts must be completed. Please include sufficient information to facilitate an effective review by all members of the IRB including non-specialists. All abbreviations and terms not part of common usage should be defined and simplified language should be used as much as possible. Applications that do not allow for an effective review may be returned to the investigator, without IRB review, for revision and resubmission.*

HUMAN BIOLOGICAL MATERIAL SAMPLE INFORMATION (1-3)

**1. HUMAN BIOLOGICAL MATERIAL**

**A.** **What type of human biological material (HBM) has been or will be collected for the purpose of this research/tissue bank?** *See Application Guide*

**B. What is the source(s) of the HBM?** *See Application Guide*

**C.** **Are there any new objectives or tests being added at this time?** *See Application Guide*

**[ ]  No**

**[ ]  Yes. Attach a** ***Request for Change*** **form.**

**2. NUMBER OF SAMPLES FOR RESEARCH PURPOSES**

**A.** **How many samples of HBM has the IRB approved to be utilized in the research?**

*See Application Guide*

**B.** **What is the total number of HBM samples that have been collected:**

**1) Since initial activation of the research?**

**2)** **Since the last IRB continuing review?**

**C.** **If no HBM samples have been collected since initial activation or since the last IRB continuing review, or if the number of samples is significantly lower than anticipated, please explain and describe measures to improve collection rates.** *See Application Guide*

**D. Does this research also involve the creation of a tissue bank?**

**[ ]  No**

**[ ]  Yes. Please answer the following:**

**1) What is the total number of HBM samples that have been banked:**

**a) Since the initial activation of the tissue bank?**

**b) Since the last IRB continuing review?**

**2) Have any investigators requested samples from the tissue bank for use in IRB approved research protocols?**

**[ ]  No. Please explain why the samples have not been used thus far.**

**[ ]  Yes. Please provide the number of investigators who have requested samples.**

**3. NUMBER OF SAMPLES FOR TISSUE BANKING PROTOCOLS ONLY**

**A.** **What is the total number of HBM samples that have been collected:**

**1. Since the initial activation of the tissue bank?**

**2.** **Since the last IRB continuing review?**

**B.** **If no HBM samples have been collected since initial activation or since the last IRB continuing review, or if the number of samples is significantly lower than anticipated, please explain and describe measures to improve collection rates.** *See Application Guide*

**C. Have any investigators requested samples from the tissue bank for use in IRB approved research protocols?**

**[ ]  No. Please explain why the samples have not been used thus far.**

**[ ]  Yes. Please provide the number of investigators who have requested samples.**

ACCRUAL & DEMOGRAPHIC INFORMATION (4)

**4.** **Does this research/tissue bank involve the obtainment of informed consent?**

**[ ]  No.**

**[ ]  Yes. Please answer the following:**

**A. How many subjects has the IRB approved to be consented for participation?** *See Application Guide*

**B. What is the total number of subjects/donors who have signed the consent form:** *See Application Guide*

**1) Since initial activation of the research/tissue bank?**

**2)** **Since the last IRB continuing review?**

**C. If no subjects/donors have been consented since initial activation of the research/tissue bank or the last IRB continuing review, or if accrual is significantly lower than anticipated, please explain and describe measures to improve accrual.** *See Application Guide*

**D. Please provide the demographic characteristics. If the demographics are not known, please explain.** *See Application Guide*

**1) *By gender and age:***

|  |  |
| --- | --- |
| ***Gender/Age*** | ***Number of Subjects/Donors*** |
|  |
| Male >= 19 years of age |  |
| Female >=19 years of age |  |
| Male <19 years of age |  |
| Female <19 years of age |  |

 **2) *By ethnic origin:***

|  |  |
| --- | --- |
| ***Ethnic Origin*** | ***Number of Subjects/Donors*** |
|  |
| Caucasian |  |
| Black, not of Hispanic origin |  |
| Hispanic |  |
| Asian/Pacific Islander |  |
| American Indian/Alaska Native |  |
| Other |  |

**E.** **Since initial approval of the protocol, was any subject/donor involuntarily (e.g. NOT at the subject/donor’s request) withdrawn from the research or had their samples removed from the tissue bank by the investigator or by the sponsor?** *See Application Guide*

**[ ]  No**

**[ ]  Yes. *Describe the cause of the withdrawal for each subject/donor. Mark withdrawals occurring since the last IRB continuing review with an asterisk (\*).***

**F.** **Since initial approval of the protocol, did any subject/donor voluntarily choose to withdraw from the research or have their sample(s) removed from the tissue bank for any reason?** *See Application Guide*

**[ ]  No**

**[ ]  Yes. *Describe the reason for the withdrawal for each subject/donor. Mark withdrawals occurring since last IRB continuing review with an asterisk (\*).***

STUDY RESULTS & LITERATURE REVIEW (5-6)

**5. STUDY RESULTS**

**Provide a brief summary of data collected to date and preliminary analysis.** *See Application Guide*

**6. CURRENT LITERATURE**

**A.** **Have any data been published or presented since the last IRB review that has made the aims of this research or justification of the tissue bank more or less important?** *See Application Guide*

**[ ]  No**

**[ ]  Yes. *Describe the data and provide the literature citations****.*

**B.** **Can the aims of the research or the goals of the tissue bank still be accomplished by using the source(s) of the HBM and other resources available to the investigators?** *See Application Guide*

**[ ]  Yes**

**[ ]  No**

INTERNAL ADVERSE EVENTS (7)

**7.** **Since initial approval of the research or tissue bank have there been any internal adverse events (AEs) (unexpected, related or possibly related) reported to the IRB?** *See Application Guide*

**[ ]  No**

**[ ]  Yes. Provide a brief summary of the number and nature of the internal adverse events. *Mark events reported since the last IRB review with an asterisk (\*).***

PROTOCOL DEVIATIONS AND NON-COMPLIANCE (8-9)

**8. PROTOCOL DEVIATIONS**

**Since initial approval of the research or tissue bank have there been any single subject/donor protocol deviations approved by the IRB?** *See Application Guide*

**[ ]  No**

**[ ]  Yes. Provide a brief description of each deviation.  *Mark deviations reported since the last IRB review with an asterisk (\*).***

**9. NON-COMPLIANCE**

**Since initial approval of the research or tissue bank have there been any reported incidents of non-compliance reported to the IRB?** *See Application Guide*

**[ ]  No**

**[ ]  Yes. Provide a brief description of each incident of non-compliance (e.g. violations). *Mark reported incidents of non-compliance occurring since the last IRB review with an asterisk (\*).***

COMPLAINTS AND PROBLEMS (10-11)

**10. COMPLAINTS**

**Since initial approval of the research or tissue bank have there been any reported complaints?** *See Application Guide*

**[ ]  No**

**[ ]  Yes. Provide a brief description of each complaint. *Mark complaints occurring since the last IRB review with an asterisk (\*) and indicate the date the complaint was submitted to the IRB.***

**11. PROBLEMS INVOLVING RISKS TO SUBJECTS, DONORS OR OTHERS**

**Since initial approval of the research or tissue bank have there been any problems involving risk to subjects, donors or others that were not considered an adverse event, non-compliance or a complaint?** *See Application Guide*

**[ ]  No**

**[ ]  Yes. Provide a brief description of each problem. *Mark problems occurring since the last IRB review with an asterisk (\*).***

CURRENT RISK/BENEFIT ASSESSMENT (12-13)

**12. MINIMIZATION OF RISK**

**Since the last IRB review (initial or continuing) are there any possible changes in procedure that should be made at this time which would further reduce risk to subjects/donors?** *See Application Guide*

**[ ]  No**

**[ ]  Yes. *Attach a* *Request for Change Form*.**

**13. RISK/BENEFIT RELATIONSHIP**

**Since the last IRB review (initial or continuing) are there any events or data which would significantly alter the risk/benefit relationship of the research in either a negative or positive direction?** *See Application Guide*

**[ ]  No**

**[ ]  Yes. *Explain.***

INFORMED CONSENT EVALUATION (14-16)

**14. OBTAINMENT OF INFORMED CONSENT**

**Since initial approval of the research or tissue bank, have there been any problems in the obtainment of informed consent?** *See Application Guide*

**[ ]  Not applicable. A waiver of consent was approved by the IRB.**

**[ ]  No**

**[ ]  Yes. *Provide a brief summary of the problems. Mark problems occurring since last IRB continuing review with an asterisk (\*).***

**15. CURRENT INFORMATION ACCURACY ASSESSMENT**

**Are the consent forms and/or study information sheets still acceptable?** *See Application Guide*

**[ ]  Not applicable. A waiver of consent was approved by the IRB.**

**[ ]  Yes**

**[ ]  No. *Attach a Request for Change******describing the required modifications in the consent and/or assent forms.***

**16. TYPES OF CONSENT FORMS AND STUDY INFORMATION SHEETS**

**Check all types of consent forms and study information sheets which are being used in the protocol:** *See Application Guide*

[ ]  **Adult consent form** **[ ]  Parental/Guardian consent form**

**[ ]  Adult addendum consent form [ ]  Parental/Guardian addendum consent form**

**[ ]  LAR consent form** **[ ]  Child study information sheet**

**[ ]  LAR addendum form** **[ ]  Youth study information sheet**

**[ ]  Screening consent form** **[ ]  Adult study information sheet**

**[ ]  Other: Specify.**      **[ ]  Not applicable (waiver of consent)**

ADDITIONAL INFORMATION (17-19)

**17. PROJECT PERSONNEL**

**A. List all personnel involved in the research/tissue bank according to the classifications below.**

**1) *Principal Investigator:***

**2) *Secondary Investigator:***

**3) *Participating Personnel:***

**4) *Lead Coordinator:***

**5) *Coordinator:***

**6) *Administrative/data management:***

**B.** **List personnel *added, deleted* *or whose responsibility has been modified* at this time. Include the classification for each person (i.e., Secondary Investigator, Participating Personnel, Lead Coordinator, Coordinator, Administrative/data management). DO NOT list individuals who have been previously added or deleted.** *See Application Guide*

|  |  |  |  |
| --- | --- | --- | --- |
| **TYPED FULL****LEGAL NAME, DEGREE/LICENSURE*****PLEASE DO NOT USE NICKNAMES.*** | **CLASSIFICATION** | **ADDED, DELETED OR MODIFIED?** | **IF INDIVIDUAL IS ADDED** |
| **FINANCIAL INTEREST\*?** | **DOCUMENT INFORMED CONSENT?** |
|       | [ ]  Principal Investigator[ ]  Secondary Investigator[ ]  Participating Personnel[ ]  Lead Coordinator[ ]  Other Coordinator[ ]  Data/Administrative  | [ ]  Added[ ]  Deleted[ ]  Modified | [ ]  No[ ]  Yes**\****See Application Guide* | [ ]  No[ ]  Yes[ ]  N/A |
|       | [ ]  Principal Investigator[ ]  Secondary Investigator[ ]  Participating Personnel[ ]  Lead Coordinator[ ]  Other Coordinator[ ]  Data/Administrative  | [ ]  Added[ ]  Deleted[ ]  Modified | [ ]  No[ ]  Yes**\****See Application Guide* | [ ]  No[ ]  Yes[ ]  N/A |
|       | [ ]  Secondary Investigator[ ]  Participating Personnel[ ]  Lead Coordinator[ ]  Other Coordinator[ ]  Data/Administrative  | [ ]  Added[ ]  Deleted[ ]  Modified | [ ]  No[ ]  Yes**\****See Application Guide* | [ ]  No[ ]  Yes[ ]  N/A |
|       | [ ]  Secondary Investigator[ ]  Participating Personnel[ ]  Lead Coordinator[ ]  Other Coordinator[ ]  Data/Administrative  | [ ]  Added[ ]  Deleted[ ]  Modified | [ ]  No[ ]  Yes**\****See Application Guide* | [ ]  No[ ]  Yes[ ]  N/A |

**1)** **Is an** **Appendix - Personnel Change Form\*\* attached?** *See Application Guide*

 **[ ]  No**

 **[ ]  Yes. *Please specify # of forms attached***

*\*\* If additional space is needed for personnel changes, fill out the “Appendix - Personnel Change Form” located in the Miscellaneous section of the Forms sections on the IRB website and answer questions above.*

**C.** **List all personnel who are authorized to document the obtainment of consent (that is, sign the consent form).** *See Application Guide*

**18. FINANCIAL INTEREST**

**Are there any changes in the financial interests of investigators or other key personnel?**

**[ ]  Not applicable. This study is not funded by a commercial sponsor.**

**[ ]  No**

**[ ]  Yes. *Submit an updated******UNMC Disclosure of Potential Conflict of Interest******form to the ORA.***

**19. PERFORMANCE SITES**

**A.** **List all UNMC or Joint Pediatric IRB approved HBM collection sites at which this research is conducted.** *See Application Guide*

**B.** **If this is a multi-institutional protocol where UNMC, TNMC, CH&MC, or UNO serves as the lead site with responsibility for data analysis and/or security of the HBM, provide a list of all HBM collection sites where this protocol is conducted.**

SECTION III

**GENERAL INFORMATION**

* Federal regulations require the IRB to conduct continuing review of research not less than once per year. This means continuing review must occur within twelve (12) months from the date the protocol was last reviewed by the IRB (or within any shorter approval period specified by the IRB). HHS and FDA regulations prohibit the IRB from granting extensions or temporary approval.
* Information must be provided insufficient detail to allow the IRB to perform the required review. Failure to provide all necessary information may delay IRB re-approval of the protocol and could result in an expiration of IRB approval if there is not sufficient time for the IRB to complete its review prior to the current approval expiration date.
* Should expiration of IRB approval occur, all subject accrual must cease as of the date of expiration and research related procedures can no longer be performed on human subjects who are currently enrolled in the study.
* Per institutional policy, all new investigators and participating personnel must have successfully completed the CITI training before IRB approval for continuation of the study can be granted. Alternatively, any individual who has not completed the CITI training must be removed as listed study personnel.
* If the study is classified as completed or closed, submit the *Study Completion Report.*

**SUBMISSION DEADLINE**

The IRB strongly recommends your application be submitted at least 60 days prior to the date of expiration of IRB approval to provide sufficient time to resolve all issues prior to the approval expiration date.

**SUBMISSION CHECKLIST**

**A.** Attach each of the following items to the electronic IRB application:

[ ]  This completed Continuing Review application, signed by the Principal Investigator

[ ]  The consent form used to enroll the **last** subject or reconsent **any** subject in this study, whichever is most recent. *Note: The subject’s name and signature must be obliterated to protect confidentiality.*

[ ]  The current IRB-approved Human Biological Material Research application

*[ ]  If subject accrual remains open,* **attach the Word file** of each consent form and/or youth/child information sheet (saved on departmental letterhead) intended for use during the next IRB approval period.

**B.** Attach each of following, as applicable, to the IRB application:

*[ ]* All publications derived from this study since last IRB review.

[ ]  Request for Change form and all supporting documents relating to all modifications in the protocol and/or consent forms and youth/child information sheets. *Note: A Request for Change is not required for adding or deleting personnel.*

**ADDITIONAL REVIEW REQUIREMENTS**

[ ]  ***Fred & Pamela Buffett Cancer Center Scientific Review Committee (SRC):*** Continuing review by the SRC is required for all protocols involving cancer patients unless it has been determined that the protocol is SRC exempt.