Center for Clinical and Translational Science (CCTS) Enterprise Data Center Data Use Agreement (DUA) (For Internal Use)

I am requesting access to specimens from the Kentucky Research Registry and Specimen Bank for purposes of research or health care operations ("Purpose"). Such specimens may contain patient data and demographic information and collection date, including Protected Health Information ("PHI") as defined by the Health Insurance Portability and Accountability Act and its implementing regulations ("HIPAA"). Such specimens are housed in the CCTS Biospecimen Core and data is housed in the CCTS/IBI Enterprise Data Center for such Purpose. The PHI may be in the form of a Limited Data Set ("LDS") as defined by HIPAA and any reference to PHI in this DUA shall include a LDS. I agree to only use or disclose the PHI for such Purpose.

I understand that in order to be granted access to the biospecimens and data, including PHI, I must abide by certain requirements in regards to usage, storage, and destruction of any data copied and/or extracted from the CCTS/IBI Enterprise Data Center. I understand the DUA is in effect for the entire length of the project.

I understand that the use of the PHI that I may be granted is restricted to me and the PHI will not be disclosed, loaned, duplicated or shared with any other individual or institution without first securing written permission from the Kentucky Research Registry and Specimen Bank. If such permission is received, I will ensure that any individual, institution or agent provided such specimens or data will agree to the same restrictions and conditions that apply to me with respect to such specimens or data.

I will use and implement appropriate safeguards to prevent use or disclosure of the PHI other than as provided for by this DUA. Appropriate administrative, technical and physical safeguards include, but are not limited to, encryption, password protection, access control, periodic audits, data backup, and virus software, which I will implement.

I will report immediately to the UK HealthCare Privacy Officer and Biomedical Intelligence Reporting Officer any suspected or alleged unauthorized use or disclosure of PHI, including any Breach of PHI. (A Breach is defined as the acquisition, access, use or disclosure of PHI in a manner not permitted by the HIPAA Privacy Rule, which compromises the security and privacy of PHI.) This report will include an accounting of the disclosure of PHI in accordance with 45 CFR 164.528 and any information requested by the UK HealthCare Privacy Officer or Biomedical Intelligence Reporting Officer.

I have reviewed training on HIPAA Privacy and Security and understand my responsibility regarding protection of the specimens or data and reporting any Breach or unauthorized uses or disclosures that may occur. I will not use or further disclose the specimens or data other than as permitted by this DUA or as otherwise required by law. Furthermore, I attest I will neither attempt to re-identify any specimens or data I might receive or in which I am granted access nor contact the individuals associated with such specimens or data. In the event that I identify a significant health concern I will notify the Biobanking Executive Steering Committee with data which suggests that a humanitarian intervention may be warranted. The BioBank Executive Steering Committee then will present this information to the appropriate Institutional Review Board for adjudication and determination of whether the patient should be contacted with this incidentally discovered information.

I agree to dispose of any and all data stored locally (on my hard drive, temporary storage, or removable media) in accordance with approved policies and applicable law.

I agree to use the <u>appropriate citation</u> on any publication using data received by the CCTS/IBI Enterprise Data Center, and I agree to report any publications supported by the CCTS/IBI Enterprise Data Center upon the request of the Biomedical Intelligence Reporting Officer.

I acknowledge that all specimens that I receive are potentially infectious and I understand that I must implement universal precautions when performing experiments and/or manipulations. That is, I will treat all specimens as if they are known to be infectious for bloodborne pathogens.

I understand that my access to these specimens and data may be terminated if I fail to comply with or violate this DUA.

I have read and understand this DUA. By signing below, I agree to all terms and conditions stated above.

Requestor's Signature Email:	Print Name Phone:	Date	
Sponsoring Faculty Signature [Required for students & non-UK colla Email:	Print Name aborators] Phone:	Date	
	James Aaron		
Biomedical Intelligence Reporting Officer's Signature	Print Name	Date	
Email: jraaro1@uky.edu	Phone: 323-7139		