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| **Authorization to submit to WCG IRB (WCG)** |  |

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| NAME OF INSTITUTION | Thomas Jefferson University |
| PRINCIPAL INVESTIGATOR |  |
| STUDY TITLE |  |
| IRB# |  |
| SPONSOR NAME: |  |
| **Disclosure of Financial Interests** -Thomas Jefferson University will review the study team for potential **conflicts of interest**, and, if any are discovered they will be reported to WCG.* If a conflict of interest has been reported to TJU, the investigator is **required to provide to WCG** the specific disclosure language/management plan that has been submitted to the Jefferson Conflicts of Interest Committee.
* Please also note that the investigator is **required to notify WCG** if the Jefferson Conflict of Interest Committee requires changes to language in the consent form.
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| **Acknowledgement by Thomas Jefferson University**The Investigator(s) named at the beginning of this form are authorized to conduct the above referenced investigational research study at this institution and its affiliated entities under the jurisdiction of WCG.Signature: Date: The following are authorized to sign this form:Name: Walter KraftEmail address: Walter.Kraft@jefferson.edu Name: Kyle ConnerEmail address: Kyle.Conner@jefferson.edu Name: Crystal LijaduEmail address: Crystal.Lijadu@jefferson.edu |

P. 2 must be completed by PI prior to submission in the IRB Portal.

CERTIFICATION OF CONFIDENTIALITY & SECURITY OF PROTECTED HEALTH INFORMATION (PHI)

The following steps must be taken to ensure identifiable data remains confidential and secure. Please check each box to confirm your understanding. There are fields below to provide explanations and to describe deviations as well as additional measures. **This certification must be completed prior to submission in the IRB Portal.**

1. If an individual is a Jefferson patient and research subject, a separate medical record must be maintained apart from any records required for the research.
2. There are 18 identifiers described in 45 CFR 164.514 that make data identifiable. To be considered de-identified, data must not contain any of the identifiers (also see OHR-5 for list of identifiers).
3. When not in use, identifiable data should be stored in a locked cabinet or desk in a locked room.
4. Access to the data should be limited. Only the individuals who need the data should have access.
5. If hardcopies of identifiable data must be taken to another building, a locked container such as a banker bag should be used. The container should be marked with instructions for returning the container if misplaced.
6. If hardcopies of identifiable data must be mailed, there must be a contract in place which specifies the method of doing this. The data should be placed in one envelope inside of another envelope. Both envelopes should have tamper- evident seals and should be addressed to the specific recipient. Signatures should be required for receipt, or lockable mailboxes should be used.
7. If research data is stored on your Jefferson computer, encryption software must be installed on the computer. Contact IT if you are not sure if the encryption software is installed.
8. PHI may be emailed between Jefferson email addresses. Jefferson email must not be sent from or forwarded to a non-Jefferson email address such as your personal email.
9. Research data should not be stored on portable devices including laptops. If research data must be stored on a portable device, contact IT. Please see Jefferson University Policy 122.35 for complete information.
10. External monitors will only be given access to subjects’ medical records as specified in the signed consent form.

If you have any explanations for, or deviations to the items listed above, **please describe them:**

If applicable, **please describe any additional measures that will be taken:**

**The Principal Investigator certifies that all of the above conditions will be applied for the duration of the research study:**

Signature of Principal Investigator Date