# Investigator's Assurance & Confidentiality Agreement

NORTH PARK UNIVERSITY

**Institutional Review Board**

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| Title of Study | | | |
| Name of Investigator | | | |
| Signature of Investigator | | Date | |

Your signature above,and initials by each of the numbered paragraphs below, indicate that you have read, understand and agree to be bound by all of the terms and conditions of the Investigator's Assurance & Confidentiality Agreement (Assurance).

**Attestations**

_____ 1. I have completed either the on-line course in *Protecting Human Research Participants* from the NIH Office of Extramural Research (http://phrp.nihtraining.com/) and have a certificate of completion on file, or I have completed a CITI (Collaborative Institutional Training Initiative) course and have a certificate of completion on file.

_____ 2. I have submitted a Package (IRB Application and supporting documents) to NPU's Institutional Review Board (IRB), which describes the proposed research study, including its purpose, methodology and the information to be collected. It also describes the provisions for confidentiality and the security of individually identifiable records and information. I affirm that all of the information and documentation provided to the IRB as part of this Package is correct.

_____ 3. I agree to comply with all Federal regulations and IRB policies and procedures designed to protect human subjects research, including key research investigator responsibilities as noted below and in the IRB Guidelines.

- Protect the rights and welfare of human research subjects.
- Provide a copy of the IRB approved informed consent document to each subject at the time of consent, unless the IRB has specifically waived this requirement.
- Promptly (within 5 days of discovery) report to the IRB any injuries or other unanticipated problems.
- Report progress of approved research and seek continuing renewal approval not less than once per year.
- Advise the IRB (and officials of other institutions) of the intent to admit human subjects to research protocols which are covered by NPU's Federal-wide Assurance, any related Inter-institutional Amendment, or Non-institutional Investigator Agreement. Institutions which plan to, or regularly, conduct human subject research, must possess an applicable OHRP-approved Assurance prior to the involvement of human research subjects.
- Report or publish research findings in a manner that does not identify subjects.
- Destroy the individual identifiers associated with the data as soon as the research study has been completed.
- Not disclose the records or information in individually identifiable form except to (1) the research professionals indicated the IRB Application or Application for Review of Evidence-based System Change Form or dissertation committee members; or (2) members of the IRB(s) who monitor, audit, and review the activities and methods of the research professionals engaged in this study.
- Notify the IRB of all requests for disclosure of information.
- Abide by any local laws that also govern this research.

_____ 4. I acknowledge that this study design shall not be altered in any form (including, but not limited to, location, subject number, or methodology) without the prior approval of the IRB.

_____ 5. I understand that in the event that I fail to comply with any terms of this Assurance, the IRB has the right under Federal Regulations to action, including termination of the project, and will report any action to the Provost at NPU, to any other Institutional Review Board that may be involved, and to the appropriate Federal and/or State authorities.