MADONNA UNIVERSITY
Graduate School

Center for Research
Room 2107 Administration Building
36600 Schoolcraft Rd, Livonia, MI 48150
Phone: (734) 432-5666 Fax: (734) 432-5862 CenterForResearch@madonna.edu

ELECTRONIC SUBMISSION REQUIRED

APPENDIX B
Waiver of HIPAA Research Authorization

PROJECT TITLE	INVESTIGATOR NAME

Complete this form to request a waiver/alteration of HIPAA authorization to access, use, or disclose Protected Health Information (PHI) for the proposed research. The Privacy Rule permits waivers (or alterations) of authorization if the research meets certain conditions.

PHI is health information containing one or more 18 identifiers, see HIPAA Definitions and Identifiers.

For more information, see 45 CFR Parts 160 and 164 or "Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule."

1. Indicate the type of waiver/alteration requested:		
		Partial Waiver (recruitment purposes only)
		Full Waiver (entire research study)
		Alteration (written documentation)
2. List the source(s) of the PHI (e.g., health care agency, physician's office records, clinical database, etc.). Be as specific as possible.		
3. Provide information below about the PHI involved in the research (e.g., medical record number, health history, diagnosis, test results, etc.).Be as specific as possible.		
a. Describe the PHI ***accessed*** for the research.		
b. Describe information that will be ***recorded*** and ***provide a copy of the data collection form(s) to be used.***		
4. Explain why access to and/or use of the PHI is essential to conduct the research.		
5. Explain how the PHI described above represents the minimum necessary information to accomplish the objectives of the research.		
6. Explain how the access, use, or disclosure of PHI presents no more than a minimal risk to the privacy of the individual.		

7. Describe your plan to protect the identifiers (or links to identifiable data) associated with the PHI from improper use and disclosure, including where PHI will be stored, what security measures will be applied, and who will have access to the information. Describe the safeguards for electronic and/or hard copy records.
8. Will identifiers (or links to identifiable data) be destroyed?
Yes – Describe the plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research. Include **when** and **how** identifiers will be destroyed.
No – Provide the legal, health, or research justification for retaining the identifiers. Legal justification should include a brief description/citation of the legal requirement.
N/A – Will not record identifiers or create links or codes to connect the data.
9. Explain why a waiver or alteration (instead of written authorization) is needed to conduct the research.

Investigator Assurance

I assure that the Protected Health Information obtained as part of this research will not be reused or disclosed to any other person or entity other than those listed (except as required by law for authorized oversight of the research project) without additional approval and that I will seek HSRC approval for other research involving the use or disclosure of this PHI. As necessary, I must document and account for all disclosures or releases of identifiable information granted under this waiver. My signature below indicates my agreement to collect only the minimum necessary Protected Health Information to meet the research objectives and to limit access to this information as described above. I acknowledge that it is my responsibility as the Principal Investigator that all Co-Investigators, research staff, employees, and students assisting in the research are trained on privacy and confidentiality and will be informed of their obligations in complying with the above.

Signature of Principal Investigator (or Advisor) Date

Printed name of Principal Investigator (or Advisor)

All persons who will access medical information must sign and date below:

I assure that the Protected Health Information obtained as part of this research will not be reused or disclosed to any other person or entity other than those listed (except as required by law for authorized oversight of the research project) without additional approval and that I will seek HSRC approval for other research involving the use or disclosure of this PHI. My signature below indicates my agreement to collect only the minimum necessary Protected Health Information to meet the research objectives and to limit access to this information as described above.

Signature Date

Signature Date

Signature Date

Signature Date

Signature Date

Signature Date

HSRC Approval

Signature of HSRC Chair Date