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| **FORM 2.11 APPLICATION FOR WAIVER OF CONSENT**  |

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| WVSU-URERC Protocol Number |  |
| Sponsor Protocol Number |  |
| Study Protocol Title |  |
| Principal Investigator/ Researcher |  |

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| 1. **REQUEST FOR WAIVER OF INFORMED CONSENT**

**(Please check the reason(s) for requesting waiver)** |
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|  |  | Research involves not more than minimal risk |
|  |  |  |
|  |  | There is no direct contact between the Investigator/Researcher and Participant(s) |
|  |  |  |
|  |  | The waiver will not adversely affect the rights and welfare of the participant(s) |
|  |  |  |
|  |  | Secondary data collection only (e.g., records, laboratory, histopath results, etc.) |
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|  |  | Any other (please specify) |
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| 1. **LIST OF PROTECTED HEALTH INFORMATION INVESTIGATOR / RESEACHER PLANS TO KEEP**

*For example: names, dates, or identification numbers such as social security numbers.* |
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| 1. **EXPLAIN HOW INVESTIGATOR / RESEARCHER WILL ANONYMIZE THE PROTECTED HEALTH INFORMATION AND MAINTAIN CONFIDENTIALITY OF THE DATA COLLECTED**
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| 1. **EXPLAIN WHY THE RESEARCH COULD NOT BE PRACTICABLY CONDUCTED WITHOUT USING THE PROTECTED HEALTH INFORMATION**

*For example: protected health information is needed to identify eligible participant records; or identifiable information is needed to link records to additional information about the participants of the study* |
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| 1. **EXPLAIN WHY THE RESEARCH COULD NOT BE PRACTICABLY CONDUCTED WITHOUT THE WAIVER**

*For example, complete the following sentence, “If I had to obtain consent, the research could not be conducted because…”* |
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| 1. **EXPLAIN WHY THE RESEARCH AND PRIVACY RISK OF THE RESEARCH ARE NO MORE THAN MINIMAL.**

*For example: because the main risk is a breach of confidentiality and procedures are in place to make such breaches very unlikely* |
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| 1. **DESCRIBE THE MEASURES THAT WILL BE TAKEN TO ENSURE THE WAIVER OF CONSENT WILL NOT ADVERSELY AFFECT THE RIGHTS AND WELFARE OF THE PARTICIPANTS OF THE STUDY.**

*For example: because the information to be collected is for clinical care and the research will not change the care that will be received (or being received) by the participant(s) of the study* |
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| 1. **PROVIDING ADDITIONAL PERTINENT INFORMATION FOR PARTICIPANTS OF THE STUDY**
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|  | **If applicable or appropriate, will the Investigator / Researcher provide additional pertinent information to participant(s) of the study?** Yes □ No □ Not Applicable □ |
|  | **If yes, please explain how additional pertinent information will be provided:** |
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|  | **URERC Recommendation (for URERC use only)** |
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|  |  | Approved (Waiver Granted) |
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|  |  | Additional information required (indicate information) |
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|  |  | Recommend further action (indicate action) |
|  |  |  |
|  |  | Disapproved  |
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| --- | --- | --- | --- | --- |
| Name of Reviewer |  | Signature  |  | Date |
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