CONSENT WAIVER ADDENDUM

A waiver of **consent entirely** may be requested for research involving **only** secondary analysis of existing research data or existing or to-be-collected non-research records. A waiver of consent is needed for secondary analysis of identifiable private information. In addition to answering the five (6) questions below, make clear in the *body of your application proposal* what data you will use, where it is, from whom you will receive it, whether the keeper of the data requires a "data use agreement", and how you will maintain confidentiality.

A waiver of **selected elements of consent** may be requested when the research design requires withholding some significant study details at the beginning of the study, as in a study involving a significant (but not harmful) deception about the study's true purpose so as not to bias the participants' responses. Include a complete description of what you plan to say and why in the *body of your application proposal* and respond to the five (6) questions below.

If you wish to apply for a waiver of consent entirely, or for selected elements, you must be able to answer "YES" to the following five (5) questions and provide reasonable justification. Justification need not be lengthy, but it should be sufficient. If you need to access patient records for research, you must also be able to answer the 7th question.

1. **I am requesting:**
   - ☐ A waiver of consent entirely
   - ☐ A waiver of selected elements of consent
2. **Will the research involve no greater than minimal risk to participants or their privacy?**
   - ☐ No
   - ☐ Yes

   Justification:

3. **Is it true that the waiver will not adversely affect the rights and welfare of participants?**
   - ☐ No
   - ☐ Yes

   Justification:

4. **When applicable to your study, do you have plans to provide participants with pertinent information after their participation is over? That is, will you provide details withheld during the consent process, as in a "debriefing" afterwards?**
   - ☐ No
   - ☐ Yes

   Justification:

5. **Would the research be impracticable without the waiver? That is, how would the regulatory requirement to obtain consent make it impracticable or impossible to conduct the study?**

   ☐ No

   ☐ Yes

   Justification:

6. **Is the risk to privacy reasonable in relation to benefits to be gained (rarely) or the importance of the knowledge to be gained?**

   ☐ No

   ☐ Yes

   Justification:

7. **Would the research be impracticable if you could not record or use Protected Health Information (PHI)?**

   ☐ No

   ☐ Yes

   Justification: