**Bellarmine University**

**Limited IRB Review Form**

The revised federal regulations regarding human subjects research ([CFR Title 45 Part 46](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html)) require limited IRB review for protocols which meet exempt categories 2(iii) and 3(c), effective January 21, 2019. Limited review is intended to protect the privacy of subjects and maintain the confidentiality of information.

The new provision for limited IRB reviews allows certain research to be categorized as exempt, even when the identifiable information might be sensitive or potentially harmful if disclosed. To qualify for exemption, the study must meet the standards of the limited IRB review. The limited IRB review assures adequate protections for the privacy of subjects and adequate plans to maintain the confidentiality of the data.

Please complete this form and submit it with your IRB application package.

1. Include a list of the identifiable information to be collected and include the source(s) of the information: \_\_\_\_\_
2. Describe the proposed use of the information: \_\_\_\_\_
3. Describe the nature of the identifiers associated with the data: \_\_\_\_\_
4. Provide a justification for needing identifiers to conduct the research: \_\_\_\_\_
5. Describe the study population: \_\_\_\_\_
6. List those who will have access to the identifiable information and include the process used to share data as applicable: \_\_\_\_\_
7. Describe the likely retention period for identifiable data and how they will be destroyed: \_\_\_\_\_
8. Describe the security controls in place including,
   1. Physical safeguards for paper records: \_\_\_\_\_
   2. Technical safeguards for electronic records: \_\_\_\_\_
9. Describe overall sensitivity of the data being collected and the potential risk for harm to individuals that would occur if the security of the data was compromised: \_\_\_\_\_