**Aurora University has defined and provided guidelines for you to follow to decide whether your project will need IRB approval. Please read and follow the instructions to submit your determination form.**

**Definitions**

**Research**: Federal regulations define research as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge". This definition excludes instructional activities which are not designed to contribute in any way (e.g., through presentation or publication) to generalizable knowledge. Also excluded are activities related to routine course or program development/evaluation.

**Human Subject**: Federal regulations define a human subject as "a living individual about whom an investigator (whether a professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information".

**Examples of Research That DO Need IRB Approval:**

IRB review **is** required if the publicly available data set contains identifiers, or if the merging of multiple data sets might result in identification of the subjects.

IRB approval **is** required if a student is involved in an activity designed to teach research methodologies and the instructor or student wishes to conduct further investigation and analyses in order to contribute to scholarly knowledge.

IRB approval **is** required if it involves a test article and one or more human subjects, and the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit.

IRB approval **is** required if it is a clinical investigation or research involving one or more human subjects to determine the safety or effectiveness of a device.

\*\*\*Even when projects do not qualify as "research", as defined by federal regulations, they must be conducted with the utmost regard for University policies, ethical standards, and the welfare of human participants.

**SECTION I: Is my project Human Subjects Research?**

**1) Will the data collected be publicly presented or published? YES** [ ]  **NO** [ ]

**2) Do my research methods involve a) direct and/or indirect interaction with participants via interviews, assessments, surveys, or observations, or b) access to identifiable private information about individuals, e.g. information that is not in the public domain? YES** [ ]  **NO** [ ]

If you checked both boxes **YES**,your project is considered research with human subjects and is subject to federal regulations.You may need IRB approval. Proceed to Section II.

If you checked any box **NO**, do **not** complete Section II. Instead complete Section III: Exemption Verification and submit the entire document to the IRB chair, whose contact information can be found on the IRB website at <https://aurora.edu/academics/resources/irb/index.html>

**SECTION II: Does My Research Need IRB Approval?**

Fill out this section **ONLY** if you answered yes to both questions in Section I. The following are exemption categories for IRB review of Human Subject Research. Check any box that applies to your study.

[ ]  **Is your research conducted in established or commonly accepted educational settings, involving normal educational practices?** [see 45 CFR 46.101(b)(1)]

[ ]  **Does your research involve the use of educational tests, survey procedures, or observation of public behavior?** [see 45 CFR 46.101(b)(2)]

[ ]  **Does your research involve collection or study of existing data, documents, records or pathological or diagnostic specimens?** [see 45 CFR 46.101(b)(4)]

[ ]  **Does your research study, evaluate, or examine a public benefit or service program?**

 [see 45 CFR 46.101(b)(5)]

[ ]  **Does your research involve taste and food quality evaluation or consumer acceptance studies?** [see 45 CFR 46.101(b)(6)]

If you did not check any boxes in this section**,** you need IRB approval. Please submit a full application.

If you checked **any** box, your research **may** be exempt from IRB review. Complete Section III: Exemption Verification and submit the entire document to the IRB chair, whose contact information can be found on the IRB website at <https://aurora.edu/academics/resources/irb/index.html>

|  |
| --- |
| **SECTION III: Exemption Verification - If you have determined that your activities do not constitute human subjects research or may be exempt, complete this section and e-mail the signed form and any relevant supporting documents (i.e., grant, protocol, consent forms) to the IRB chair,** **whose contact information can be found on the IRB website at** [**https://aurora.edu/academics/resources/irb/index.html**](https://aurora.edu/academics/resources/irb/index.html) **.** |
| **Investigator Information** |
| Name (Last, First)  | Degree(s)  | University Status/Title |
| Department  | College  |
| Phone Number  | E-mail Address  |
| **Project Information** |
| Project Title |
| Name of Funding Source (i.e., Department, NIH, Foundation)      |
| Grant Number (if applicable)      |
| Project Description (describe the aims of the study and any activities involving interaction, intervention with human subjects, and/or their information or specimens)      |
| Justification for Exemption (Explain why your study is not Human Subjects research, or if it is why it is exempt, you may find the [federal regulations](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html) or [decision charts](https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html) helpful.      |
|  |

**Signature of Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**SECTION IV: IRB Determination (to be completed by IRB Office)\***

**The activities as described in the** [ ]  **submitted protocol and/or** [ ] **materials and description of activities provided by the investigator,**

[ ]  **Do not constitute research with human subjects in accordance with 45 CFR 46 and 21 CFR 50 & 56. IRB approval is not required.**

[ ]  **Are exempt from IRB review in accordance with 45 CFR 46. IRB approval is not required.**

**Authorized IRB Personnel Printed Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Authorized IRB Personnel Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

\*If any activities completed were or possibly were not in compliance with federal regulations regarding prior IRB review, please forward the form to the IRB Chair for review. For example, the chair reports activities which are already completed but initially required IRB approval.