



**AIR FORCE RESEARCH LABORATORY  
INSTITUTIONAL REVIEW BOARD**

**EXEMPT REQUEST WORKSHEET**

**PURPOSE**

Use this worksheet to determine whether an activity is "exempt" research\* involving human subjects\*\*. The six categories of exempt research involving human subjects are identified on page five of this worksheet.

\* Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

\*\* Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains:

- (1) Data through intervention or interaction with the individual, or
- (2) Identifiable private information.

**GENERAL INSTRUCTIONS**

1. If you know your activity is not exempt, OR if the activity involves any of the following products (1a-1c below), STOP. Contact the AFRL IRB administrative office (IR) before completing this worksheet. You may need a different form.
  - a. An experimental product\* that has not been approved by the Food and Drug Administration (FDA)
  - b. An FDA approved product\* used in accordance with its FDA approved purpose
  - c. An FDA approved product\* NOT used in accordance with its FDA approved purpose
- \* Any medical device, vaccine, drug, nutritional supplement or laboratory assay (In Vitro Diagnostic (IVD))
2. Complete all items (no blanks). If not applicable, add "N/A".
3. Type all entries.
4. Use official contact information only (no personal e-mail addresses).
5. Do not alter the layout of the form.
6. Complete the attached AFRL Exempt Worksheet.
7. Attach any data collection tools (e.g., surveys, questionnaires, focus group questions).
8. If using surveys, polls, or focus groups, ensure the activity is compliant with AFI 38-501, Air Force Survey Program.
9. Submit the worksheet to IR by e-mail. Contact IR with questions: [AFRL.IR.ProtocolManagement@us.af.mil](mailto:AFRL.IR.ProtocolManagement@us.af.mil).

**NEXT STEPS**

1. IR will review the worksheet to ensure it is complete. IR will contact you if more information is needed.
2. IR will provide complete worksheets to the IRB for review.
3. The IRB will document its determination. This will include a justification for the determination, supported by facts.
4. IR will provide the IRB's determination to you. If the IRB determines the activity is not exempt, IR will provide to you the form needed for standard submission to the IRB.



**AIR FORCE RESEARCH LABORATORY  
INSTITUTIONAL REVIEW BOARD**

**EXEMPT REQUEST WORKSHEET**

**PART I: GENERAL INFORMATION**

**Date Submitted to AFRL IRB:**

**Name of Principal Investigator:**

**Rank/Title:**

**Official e-mail:**

**Commercial Phone:**

**DSN:**

**Supporting Organization/Office Symbol:**

**Name of Alternate Contact:**

**Rank/Title:**

**Official e-mail:**

**Commercial Phone:**

**DSN:**

**Project Title:**

**Funding Source (Agency/Dept./External Sponsor):**

**Funding Amount:**

**PART II: SUMMARY**

**Briefly (3-5 sentences) describe the purpose of the activity and intended use of results. Please use lay terms. Include sufficient detail to allow the IRB to make its determination.**

### PART III: DESCRIPTION

**B. Provide a brief, one page description of the activity. Include: (1) methods & procedures, (2) equipment & facilities, (3) subject population (describe (describe inclusion/exclusion criteria, number to be included, & source), (4) subject recruitment plan, (5) activity duration, (6) location, (7) data to be used (type, source, related processess (e.g., proposed use and mainenance)), and (8) description of reasonably foreseeable risks.**

**PART II: ACTIVITY DESCRIPTION (additional space, if needed)**



# AIR FORCE RESEARCH LABORATORY INSTITUTIONAL REVIEW BOARD

## EXEMPT REQUEST WORKSHEET

**EXEMPT CRITERIA:** "Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy." See 32 CFR 219.101 (b). **Check all that apply.**

	<p><b>32 CFR 219.101 (b)(1)</b> Research conducted in established or commonly accepted <u>educational settings</u>, involving <u>normal educational practices</u>, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.</p>
	<p><b>32 CFR 219.101 (b)(2)</b> Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), <u>survey procedures</u>, interview procedures or observation of public behavior, unless: (i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; <u>and</u> (ii) Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.</p>
	<p><b>32 CFR 219.101 (b)(3)</b> Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) The <u>human subjects are elected or appointed public officials or candidates for public office</u>; or 32 CFR 219 (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.</p>
	<p><b>32 CFR 219.101 (b)(4)</b> Research, involving the collection or study of <u>existing data*</u>, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. *Data includes but is not limited to: records, datasets, recordings, biometric data (e.g. fingerprints, photos and voice recordings), or specimens.</p> <p style="text-align: right;">Have you obtained a Data Use Agreement (DUA) for research purposes? <b>If so, attach it.</b></p>
	<p><b>32 CFR 219.101 (b)(5)</b> Research and demonstration projects which are conducted by or <u>subject to the approval of department or agency heads</u> [e.g., SECDEF], and which are designed to study, evaluate, or otherwise examine: (i) <u>Public benefit or service programs</u>; (ii) Procedures for obtaining benefits or services under those programs; (iii) Possible changes in or alternatives to those programs or procedures; or (iv) Possible changes in methods or levels of payment for benefits or services under those programs.</p>
	<p><b>32 CFR 219.101 (b)(6)</b> Taste and <u>food quality</u> evaluation and consumer acceptance studies, (i) If wholesome foods without additives are consumed or (ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.</p>
	<p>Will this activity will involve the use of biological samples/tissue? If yes, chose one of the following:</p> <div style="display: flex; justify-content: space-around;"> <span>Specimens will be identifiable</span> <span>Specimens will be de-identified</span> </div> <p>Provide additional detail on the Exempt Request Worksheet (project description) regarding how samples will be provided to the investigator, labeled, stored, maintained or destroyed, etc. Please read sections 3 and 4 of the attached supplement for more information (click on paperclip at top left of PDF).</p>

This activity has received safety review. Attach a copy to this submission.

This activity has not received a safety review. Contact the AFRL Safety Officer with question about AFRL safety review requirements: keith.vossler@us.af.mil.

I assure that the information provided in this worksheet is complete and accurate.

**PI or Designee Signature**

**Date**

**Signatures:** This form can only be electronically signed by a submitter with a Common Access Card (CAC). If you do not have a CAC, please print the completed worksheet, sign and date in ink, and scan the signed document for submission to IR by e-mail.

**REMAINDER OF THIS PAGE  
INTENTIONALLY LEFT BLANK**

AFRL IR Protocol Number:

IRB Member Basis for Determination/Comments:

## THIS PAGE TO BE COMPLETED BY AFRL IRB MEMBER

This purpose of this worksheet is limited to consideration of whether an activity falls under the purview of the AFRL IRB in accordance with 32 CFR 219, DoDD 3216.2, AFI 40-402, and related human research subject regulations. The AFRL IRB is not responsible for the oversight of activities that are determined not to be research involving human subjects (e.g., test and evaluation activities). Any modifications to this activity must first be reviewed by the AFRL IRB.

If this activity is a survey, attitude or opinion poll, questionnaire, or interview, it might require approval by the Air Force Survey Office (HQ AFPC/DSYS). See AFI 38-501, Air Force Survey Program. Contact HQ AFPC/DSYS with questions: [af.surveys@us.af.mil](mailto:af.surveys@us.af.mil).

Other reviews and determinations may be required before this activity can begin. If other reviews are required, they should be pursued separately (note, AFRLI 61-103 v.2). Contact the AFRL Safety Officer, Mr. Keith Vossler, AFRL/SE, regarding requirements applicable to test and evaluation: [keith.vossler@us.af.mil](mailto:keith.vossler@us.af.mil).

### IRB MEMBER DETERMINATION:

Based on the information provided, the IRB reviewer has determined:

The human subjects research does not meet any exempt criteria. Referred to IRB Chair for IRB review.

The research uses an *In Vitro* diagnostic device with specimens that are NOT individually identifiable. Referred to IRB Chair to determine compliance with applicable FDA regulations.

The human subjects research meets the following exempt criteria (check all that apply):

32 CFR 219.101(b)(1): conducted in common educational settings with normal educational practices...

32 CFR 219.101(b)(2): involves educational tests, survey, interview procedures or observation of public behavior...

32 CFR 219.101(b)(4) involving the collection or study of (check all that apply):

Existing data/documents

Restrospective medical records

Specimens

Other:

IRB Reviewer Signature

Date