



**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.



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**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)**



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  
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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