Request for Exempt Determination Review

Office of the Assistant Secretary of Defense for Health Affairs (HA)/TRICARE Management Activity (TMA)
Human Research Protection Program Office
770 Arlington Boulevard, Suite 5101
Falls Church, VA 22042

Instructions for completing this template may be found on Page 8.

1. Project Title

2. Principal Investigator (PI)	
Name (include rank)	Title
Affiliation (vendor, command, installation, *etc*.)	
Work email	Work phone

3. Government Project Manager	
Name (include rank)	Title
Affiliation (vendor, command, installation, *etc*.)	
Work email	Work phone

4. Training Attestation	Yes	No
Have all investigators and key personnel completed the required Collaborative Institutional Training Initiative (CITI) training within the past three (3) years? (We do not accept the CITI refresher training.)	☐	☐

5. Financial Conflicts of Interest	Yes	No
Does any investigator (including PI and associate investigators), key personnel, or their immediate family members have a financial interest (including salary or other payments for services, equity interests, or intellectual property rights) that would reasonably appear to be affected by the research, or a financial interest in any entity whose financial interests would reasonably appear to be affected by the research?	☐	☐

6. Funding or Other Support	Yes	No
Is the research funded, or has funding been requested?	☐	☐
Is any support other than monetary (*e.g.,* materials, equipment) being provided for this study?	☐	☐

7. Location of the Research
Location name or description

8. Screening Questions	Yes	No	N/A
Will the research expose participants to discomfort or distress beyond that normally encountered in daily life?	☐	☐	☐
Could disclosure of participants' responses outside the research reasonably place participants at risk of criminal or civil liability or be damaging to participants' financial standing, employability or reputation?	☐	☐	☐
Does any part of the research require deception or incomplete disclosure of information to participants?	☐	☐	☐
Will prisoners (or their data and/or specimens) be participants in this research?	☐	☐	☐
For studies proposed under Category 1, will the research be conducted outside of commonly accepted educational settings or deviate from normal educational practices?	☐	☐	☐
For research proposed under Category 2, will the research involve surveys or interview procedures with children?	☐	☐	☐
For research proposed under Category 2, will the research involve observations of the public behavior of children, during which an investigator participates in the activities being observed?	☐	☐	☐
For research proposed under Category 4, will any of the data, documents, records or biological specimens be collected or created after the date of this application for exemption?	☐	☐	☐
For research proposed under Category 4, will any of the information obtained from private sources of data, documents, records or biological specimens be recorded by an investigator in such a manner that participants could be identified directly or through identifiers linked to the participants?	☐	☐	☐
For research proposed under Categories 1-5, is the research subject to Food and Drug Administration (FDA) Regulations?	☐	☐	☐
If you checked YES to ANY of the questions above, then your research is NOT EXEMPT from Institutional Review Board (IRB) review. Do not complete this template.			

9. Research Methods and Activities (Check all that apply. Attach a copy of all applicable materials/documents.)	
☐ Audio, video, digital or image recording	☐ Record review (which may include protected health information (PHI))
☐ Existing data, not publicly available	☐ Bio-specimens (must be existing at time of application)
☐ Existing data, publicly available	☐ Surveys, questionnaires or interviews (one-on-one)
☐ Focus groups	☐ Surveys, questionnaires or interviews (group)
☐ Internet or email data collection	☐ Taste testing
☐ Observation of participants (including field notes)	☐ Other (specify):
☐ Oral history (does not include medical history)	

10. Summary of the Research
Briefly summarize the purpose and procedures of the proposed activity, preferably in non-technical language: *If your response exceeds the space available, please attach additional pages and reference "Exempt Determination Review, Section 10, Summary of the Research, Brief Summary."*
Describe how the proposed research meets the criteria for exemption. Reference the exemption categories (see instruction sheet) and the categories' corresponding criteria: *If your response exceeds the space available, please attach additional pages and reference "Exempt Determination Review, Section 10, Summary of the Research, Criteria for Exemption."*
Provide the estimated start and end dates of the project: Start: End:

11. Participant Population Demographics	Specify age range of possible participants to years of age
☐ Adults	☐ Non-English speaking
☐ Children (<18 years)	☐ Unknown (*e.g.,* secondary analysis – de-identified)
☐ Active Duty	☐ Pregnant women, human fetuses, neonates
☐ Prisoners	☐ Other (specify):

12. Participant Identification, Recruitment and Selection
Describe how potential participants will be identified (*e.g.,* advertisements, record review, personal contact). Explain how investigators will gain access to this population: *If your response exceeds the space available, please attach additional pages and reference "Exempt Determination Review, Section 12, Participant Identification."*

13. Participant Population Demographics	Yes	No
Will participants receive compensation or other incentives to participate in this study?	☐	☐
If "yes", then describe the incentives, including the amount and timing of all payments: *If your response exceeds the space available, please attach additional pages and reference "Exempt Determination Review, Section 13, Incentives to Participants."*		

14. Informed Consent Process	
Indicate the consent process(es) and document(s) to be used in this study. Check all that apply. **Provide copies of the documents as applicable.**	
☐ Informed Consent – Form	☐ Parental Permission – Form
☐ Informed Consent – Verbal Script/Online/Unsigned	☐ Parental Permission – Verbal Script/Online/Unsigned
☐ Assent – Form	☐ Translated Consent/Assent –Form(s), Script(s) *etc.* (provide English version only)
☐ Assent – Verbal Script/Online/Unsigned	☐ Other (specify):
☐ Not Applicable (existing data or bio-specimens)	
Describe the consent process. Explain when and where consent will be obtained and how subjects and/or their legally authorized representatives will be provided with sufficient opportunity to consider participation. (or ☐ N/A) *If your response exceeds the space available, please attach additional pages and reference "Exempt Determination Review, Section 14, Informed Consent Process."*	

15. Privacy of Participants
Describe the provisions in your protocol to protect the privacy interests of participants. **Include the circumstances and nature of information to be obtained, taking into account factors (*e.g.,* age, gender ethnicity, rank) that may influence participants' expectations of privacy.** *If your response exceeds the space available, please attach additional pages and reference "Protection Provisions, Section 15, Privacy of Participants."*

15. Privacy of Participants (continued)	Yes	No
Does the study require access to personally identifiable information (PII)?	☐	☐

If "Yes", then describe the PII involved in the study: List the information source(s) (*e.g.,* educational records, medical records, surveys, databases).

If your response exceeds the space available, please attach additional pages and reference "Exemption Determination Review, Section 15, Privacy of Participants, PII."

16. Confidentiality of Data

Explain how electronic and hard copy information is handled, stored, secured, and transmitted/transported. Also identify who will have access to the information. Include both electronic and hard copy records.

If your response exceeds the space available, please attach additional pages and reference "Exempt Determination Review, Section 16, Confidentiality of Data."

Indicate what will happen to the identifiable data at the end of the study. **Study-related records should be retained for a period of at least three (3) years after the study has been discontinued. Other regulations may require longer retention periods.**

☐ Identifiers will be permanently removed from the data and destroyed (de-identified)

☐ Identifiable/coded (linked) data will be retained

☐ Identifiable data will not be collected

17. Health Insurance Portability and Accountability Act (HIPAA) Authorization
Will individually identifiable PHI subject to the HIPAA Privacy Rule requirements be accessed, used or disclosed in this study? ☐ No ☐ Yes

All information provided in this Application and the accompanying attachments are complet and accurate. I understand that Exempt Determination Request is binding upon and will inure to the benefit of the Principal Investigator of the above-referenced research project and his/her respective successors and/or assigns.

_____ _____

Signature of the Principal Investigator Date

_____ _____

Printed Name of the Principal Investigator Title/Rank

Instructions for Completing the Request for Exempt Determination Review

As with all other requests submitted to the OASD(HA) and TMA Human Research Protection Program Office, Requests for Exempt Determination Review must be submitted *via* IRBNet. You can access the submission page through Army Knowledge Online at the Defense Medical Research Network link.

1. Project Title: self-explanatory

2. Principal Investigator: self-explanatory

3. Government Project Manager: self-explanatory

4. Training Attestation: Proof of human subject research protection program (HRPP) training within the past three (3) years for all researchers and the government project manager. Training is obtained through CITI (http://www.citiprogram.org/) and when prompted for your Participating Institution, select the option for the "Office of the Under Secretary of Defense (Personnel and Readiness)." If you have completed training provided by your institution, then you need only complete the CITI Training Module titled: Non-DoD Researcher Training Requirements.
   Note: Office of the Under Secretary of Defense for Personnel and Readiness (OUSD(P&R)) is under "O" for "Office." Most will need to take the Social and Behavioral Health Investigators modules. Because of the particularly vulnerable nature of the DoD population, HRPP does NOT accept refresher training in lieu of completing the full course

5. Financial Conflicts of Interest: self-explanatory

6. Funding or Other Support: self-explanatory

7. Location of Research: Identify the physical location(s) at which the research will be conducted, including installation name, command, department, university campus, *etc*. Building name/number, city, state, zip code are also expected.

8. Screening Questions: Respond to each question as it relates to the study design. Refer to the exempt categories for information on the criteria for each.

9. Research Methods and Activities: self-explanatory

10. Summary of Research: Whenever possible, stay within the text field provided and use non-technical language.
    B sure not to miss the space for indicating estimated start and en dates for the study.

Instructions for Completing the Request for Exempt Determination Review (continued)

11. Participant Population Demographics: self-explanatory. **B sure to note age range where asked.**

12. Participant Identification, Recruitment and Selection: self-explanatory

13. Incentives to Participate: self-explanatory

14. Informed Consent Process: self-explanatory. **B certain to provide copies of consent documents**.

15. Privacy of Participants: Recognize the particularly vulnerable nature of the DoD/Active Duty population.

16. Confidentiality of Data: Breaches of data that include PII and/or PHI is serious violation of the trust placed in investigators by the subjects of research studies. The DoD has policies regarding the protection of PII and PHI in all forms (paper, electronic, at rest, while in transit, *etc*.). Explain how the data in your possession will be protected at all times.

17. HIPAA Authorization: As referenced in the HIPAA Privacy Rule an DoD 6025.18- and select the appropriate choice from the list of values.

18. Signature: self-explanatory