



Request for Exempt Determination Review

Office of the Assistant Secretary of Defense for Health Affairs (HA)/TRICARE Management Activity (TMA)

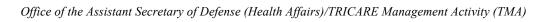
Human Research Protection Program Office

770 Arlington Boulevard, Suite 5101

Falls Church, VA 22042

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

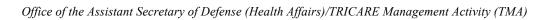
1. Project Title	-		
2. Principal Investigator (PI)			
Name (include rank) Title			
Affiliation (vendor, command, installation, etc.)			
Work email Worl	c phone		
3. Government Project Manager			
Name (include rank) Title			
Affiliation (vendor, command, installation, etc.)			
Work email Worl	c phone		
4. Training Attestation		Yes	No
Have all investigators and key personnel completed the required Co	ollaborative 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 app	pear to be affected by the		
research, or a financial interest in any entity whose financial intere	sts 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 res	earch reasonably place			
participants at risk of criminal or civil liability or be damagi	ng to participants' financial			
standing, employability or reputation?				
Does any part of the research require deception or incomp	olete disclosure of			
information to participants?				Ш
Will <u>prisoners</u> (or their data and/or specimens) be particip	ants in this research?			
For studies proposed under Category 1, will the research b	e conducted outside of			
commonly accepted educational settings or deviate from r	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 p	articipates in the activities			
being observed?				
For research proposed under Category 4, will any of the da	ata, 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 s	pecimens 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 <u>Categories 1-5</u> , 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			Review	
Board (IRB) review. Do not complete this template.				
9. Research Methods and Activities (Check all that apply.	Attach a copy of all applicabl	e material	ls/docume	nts.)
Audio, video, digital or image recording	Record review (which m	ay include	protected	l health
	information (PHI))			
Bio-specimen		existing at	t time of	
Existing data, not publicly available	application)			
☐ Existing data, publicly available ☐ Surveys, questionnaires		or intervie	ews (one-o	n-one)
Focus groups	Surveys, questionnaires	or intervie	ws (group)
Internet or email data collection	☐ Taste testing			
Observation of participants (including field notes)	Other (specify):			
Oral history (does <u>not</u> include medical history)				

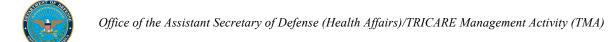






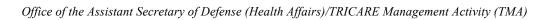
10. Summary of the Research				
Briefly summarize the purpose and proce			ed activity, preferably in non-technical language: and reference "Exempt Determination Review, Section 10, Summary of	
Describe how the proposed research mos	ats the criteria fo	r 044	emption. Reference the exemption categories (see	
			emption. Reference the exemption categories (see	
instruction sheet) and the categories' cor If your response exceeds the space available, please the Research, Criteria for Exemption."			and reference "Exempt Determination Review, Section 10, Summary of	
the Research, efficial for Exemption.				
Provide the estimated start and end date	s of the project:	Si	tart: End:	
Provide the estimated start and end date:	s of the project.	31	tart.	
11. Participant Population	Specify age range of possible participants to years of age			
Demographics				
Adults			Non-English speaking	
Children (<18 years)			Unknown (e.g., secondary analysis – de-identified)	
Active Duty		Pregnant women, human fetuses, neonates		
Prisoners			Other (specify):	

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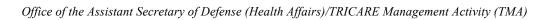
12. Participant Identification, Recruitment and Selection		
Describe how potential participants will be identified (e.g., advertisements, record review, p	ersonal cor	ntact). Explain
how investigators will gain access to this population:		
If your response exceeds the space available, please attach additional 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 Participants."	Review, Sectio	n 13, Incentives to







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) <i>etc</i> . (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."			

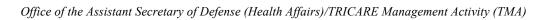






15. Privacy of Participants (continued)	Yes	No
Does the study require access to personally identifiable information (PII)?		
If "Yes", then describe the PII involved in the study: List the information source(s) (e.g., educational	records, i	nedical
records, surveys, databases).		
If your response exceeds the space available, please attach additional pages and reference "Exemption Determination Review Participants, PII."	ı, Section 15,	Privacy of
16. Confidentiality of Data		
Explain how electronic and hard copy information is handled, stored, secured, and transmitted/tran	sported. A	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, Sc. Confidentiality of Data."	ection 16,	
Indicate what will happen to the identifiable data at the end of the study. Study-related records sho	ould be re	tained
for a period of at least three (3) years after the study has been discontinued. Other regulations m	ay require	e 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		
I dentinable data will not be collected		

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.7. Health Insurance Portability and Accountability Act (HIPA)	A) Authorization
Nill individually identifiable PHI subject to the HIPAA Privacy Ri	ule requirements be accessed, used or disclosed in this
tudy?	
□No	
Yes	
All information provided in this Application and t	1 7 0
and accurate. I understand that Exempt Determin	
inure to the benefit of the Principal Investigator o	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