

**U.S. Army Public Health Center (APHC)
Office of Human Protections Submitter Pre-Decision Tool***

Date: _____

Project Title: _____ Project Lead(s): _____

Organization/Unit: _____

<i>Answer all questions in order and follow instructions provided in "Public Health Practice (PHP) or Research Decision Matrix" columns based on your responses. Additional instructions on reverse.</i>	Yes	No	Public Health Practice or Research Decision Matrix		Submitter Rationale Required	Reviewer Comments <i>If applicable / not required</i>
			If Yes, then	If No, then		
1. Legal Authority: Is there general or specific legal or other authorization (via statute, regulation, official tasker or other law) or corresponding governmental duty that underlies the project? What legal authority allows you to do this project? Specify all authorities in submitter rationale.			Activity may be PHP	Activity may be research		
2. Specific Intent: Is the intent of the activity to support an existing public health program or public health need? <i>If the activity is designed to test a hypothesis or generalize the findings or acquired knowledge beyond the activity's participants; it may be research.</i>			Activity may be PHP	Activity may be research		
3. Foundations of Human Subjects Research: Does your project involve living individuals, personal identifiers, or biological specimen?			Activity may be research	Activity may be PHP		
4. Subject Participation: Does your project involve persons who are required to participate in the activity or did not specifically volunteer to participate?			Activity may be PHP	Activity may be research		
5. Methodology #1: Does the project involve access, collection, or analysis of identifiable personal data? (ie. Personally Identifiable Information (PII) & Protected Health Information (PHI))			Activity may be research	Activity may be PHP		
6. Methodology #2: Is the project designed to introduce non-standard or experimental elements or methods to the activity involving subjects?			Activity may be research	Activity may be PHP		
7. Conclusion: Do your responses conclude that your project is likely public health practice, human subjects research, or other? Put an 'X' through the appropriate box. See additional information in the Instructions under #2.		Other	Activity may be PHP	Activity may be Research		

By signing and dating below, I concur with the responses provided above and approve the activity as scientifically sound as described in the attached documents.

Division Manager/equivalent _____ Date: _____
Print Name Signature

Directorate Director/equivalent _____ Date: _____
Print Name Signature

*Checklist adapted from Hodge JG and Gostin LO. *Public health practices vs. research: A report for public health practitioners including cases and guidance for making distinctions.* A report for the Council of State and Territorial Epidemiologists, 2004; online at <http://www.vdh.virginia.gov/OFHS/policy/documents/2012/irb/pdf/Public%20Health%20Practice%20versus%20Research.pdf>

U.S. Army Public Health Center (APHC) Office of Human Protections (OHP) Submitter Pre-Decision Tool Instructions

After developing your project plan, use the Submitter Pre-Decision Tool to characterize your project. The Human Protections Administrator (HPA) and/or the Public Health Review Board (PHRB) may or may not agree with your conclusion. One of tool's purposes is to aid in your understanding of the differentiation between public health practice (PHP) and research.

1. Read each question and put an X in each Yes or No box that applies and follow the corresponding instructions. *Note; the term 'project and activity' refers to the reason you are submitting this Submitters Pre-Decision Tool, whether it is a public health or research project, protocol, surveillance activity, program evaluation, etc.
2. Answer each question and provide a brief rationale for each decision.

Legal Authority. State specific tasking organization requesting project and attach tasking letter and/or give regulatory authority for project. Whenever possible, quote specific paragraph and line number(s) from Army Regulations (AR) such as; AR 40-5 'Army Public Health Program', or Department of Army (DA) Pamphlet (PAM) such as; DA PAM 40-11 'Army Public Health Program'. See the following links for official DA administrative publications: 40 Series Collection (Medical): <https://armypubs.army.mil/ProductMaps/PubForm/AR.aspx>; other regulation series (e.g. E series) may be also apply.

Public Health Practice. If your responses affirm that your activity (or some part thereof) is likely public health practice, the activity is not subject to the Common Rule: <http://www.hhs.gov/ohrp/humansubjects/commonrule/index.html>. Public health practice projects are not research as defined by section 219.101, title 32, Code of Federal Regulations, and do not require Institutional Review Board review or approval: http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title32/32cfr219_main_02.tpl. However, the project must still be conducted consistent with principles of law and ethics designed to protect individuals and their privacy while furthering the public's health. For guidance on the impact of the HIPAA Privacy Rule on public health practice, see HIPAA Privacy Rule and Public Health: Guidance from CDC and DHHS, available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/m2e411a1.htm>

Human Subjects Research. If your responses affirm that your activity (or some part thereof) is, or is likely, human subjects research, specific regulations guidance will apply. The APHC Office of Human Protections will provide further guidance. For additional guidance and a helpful flow chart, please see the Guidelines for the Conduct of Research Involving Human Subjects published by the Office for Human Subjects Research at NIH, available at: <https://irbo.nih.gov/confluence/pages/viewpage.action?pagelid=36241835&preview=%2F36241835%2F38961821%2FDecision+Tree+-+Is+the+Activity+Research+Involving+Human+Subjects.pdf> and the MRMC Human Research Protection Office Policies and Procedures found at https://mrhc.amedd.army.mil/index.cfm/collaborate/research_protections/hrpo/policies

3. In addition to this Submitters Pre-Decision Tool, complete the project plan template (available on the OHP SharePoint site at: <https://tiny.army.mil/r/pS49J/OHPToolsTemplates> and any supporting documents, (e.g., Tasking memo, Command letter, Operation Order (OPORD), Memorandum of Agreement (MOA)/ Understanding (MOU)).
4. Submit your data protection plan to the Information Management Division (IMD) for review and approval. *APHC Memorandum 25-1-5 gives IMD (Information Assurance) the responsibility to oversee personally identifiable information (PII) and/or protected health information (PHI) protection; to fulfill that responsibility, IMD will review and approve data protection plans prior to submitting the project to the HPA and PHRB. Copy and paste your completed data protection plan (section 4.3 only) into an e-mail and submit to Nora Wallace at: nora.s.wallace.civ@mail.mil (410.417.0140). The subject line of the e-mail should include; 'data protection plan approval', the project title (at least in part) and the project lead's last name. Ms. Wallace will either approve or disapprove and request revisions via e-mail. In the event that Ms. Wallace is not available, she will designate a POC via an e-mail out of office message. Please include the approved data protection plan e-mail message when submitting the packet to the OHP.*

For an urgent matter, such as an EPICON that must deploy immediately, please contact Dawn Gyory, HPA at 410.417.2611/ dawn.m.gyory.civ@mail.mil or Amy Millikan Bell, PHRB Chair at 410.436.8447/ amy.m.millikanbell.civ@mail.mil for instructions.

5. Obtain the signature of the Division Manager / equivalent after incorporating any revisions / feedback.
6. Obtain the signature of the Directorate Director / equivalent after incorporating any revisions / feedback.
7. Reviewer Comment Column: This section is for signatories to provide feedback to the project lead if necessary. The signatories are not required to provide comments.
8. Submit the package to the OHP SharePoint site at: <https://tiny.army.mil/r/ZON4/OHPSubmitaProject> no later than **26 days before the PHRB monthly meeting**. The PHRB meets the second Monday of every month, unless that day is a Federal holiday, in which case they will meet the following Monday.
9. The HPA will do an initial review to determine if PHRB review is required and 1) if the project is time sensitive, a tentative determination will be made by the HPA, with a follow-up to the next PHRB for information or confirmation, 2) if the project is not time-sensitive, it will go before the PHRB at the next meeting. The PHRB calendar is available at: <https://tiny.army.mil/r/pS49J/OHPToolsTemplates> under Tools and Templates - PHRB Monthly Calendar Document Due Dates.
10. The Office of Human Protections will provide a written response on the Determination Template noting the final determination as PHP, Research or Other. Appropriate reasons for the decision will be annotated below the determination. The HPA and the PHRB Chair will sign the Determination. The signed determination, the Submitters Pre-Decision Tool, and all relevant project documents will be returned to you (and cc'd to all signatories) as soon as possible.
11. New research and non-emergency public health projects cannot start without the Institutional Official's approval and the HPA's determination.

If you have additional questions or need clarification please contact the Office of Human Protections personnel or the PHRB Chair:

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