PURPOSE and SCOPE

The purpose of this worksheet is to provide support for Designated Reviewers granting exemption determinations. This worksheet is to be used. It does not need to be completed or retained.

1 GENERAL EXCLUSIONS FROM EXEMPTIONS (Check if **"Yes"**. If either is checked, the research is not exempt.)	
☐	The research is FDA-regulated.[i]
☐	The research involves Prisoners and is conducted or funded by DHHS or Dept. of Defense (DOD).
☐	The research involves Prisoners, and is inappropriate for the prison population being studied or involves interactions with Prisoners.
2 The research falls into one or more of the following categories (One or more categories must be checked.)	
☐	1. Research conducted in established or commonly accepted educational settings, involving normal educational practice. (Both the procedures involve normal education practices and the objectives of the research involve normal education practices.)
☐	2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, 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; and (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. In addition:
	☐ If the research involves children and is conducted, funded, or subject to regulation by DHHS, Dept. of Defense (DOD), Dept. of Education (ED), or Environmental Protection Agency (EPA), the procedures are limited to (1) the observation of public behavior when the investigator(s) do not participate in the activities being observed and (2) the use of educational tests. **("N/A" if the research does not involve children or is not conducted, funded, or otherwise subject to regulation by these agencies.)**
☐	3. Research involving the use of educational tests[ii], survey procedures, interview procedures, or observation of public behavior that is not exempt under section 2 above, if: (i) the Human Subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
☐	4. [iii] Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens if the information is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. **(For research conducted, funded, or otherwise subject to regulation by any federal agency, "existing" means "existing at the time the research is proposed." Otherwise, it means "existing at the time the research is proposed or will exist in the future for non-research purposes.")**
☐	5. Research and demonstration projects which are conducted by or subject to the approval of Dept. or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (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. In addition: (Check if **"Yes"**. All must be checked)
	☐ The program under study delivers a public benefit[iv] or service[v].
	☐ The research or demonstration project is conducted pursuant to specific federal statutory authority.
	☐ There is no statutory requirement that the project be reviewed by an IRB.
	☐ The project does not involve significant physical invasions or intrusions upon the privacy of subjects.
	☐ The funding agency concurs with the exemption.
☐	6. [vi]Taste and food quality 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 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 Dept. of Agriculture.
3 Criteria for approval of exempt research (Check if **"Yes"**)	
☐	The research involves no more than Minimal Risk to subjects. **(Must be checked.)**
☐	Selection of subjects is equitable. **(Must be checked.)**
☐	If there is recording of identifiable information: **(If checked, the following must be checked.)**
	☐ There are adequate provisions to maintain the confidentiality of the data.
☐	There are interactions with subjects: **(if checked, the following must be checked.)**
	☐ There will be a consent process.
	☐ The consent process will disclose that the activities involve research.
	☐ The consent process will disclose the procedures to be performed.
	☐ The consent process will disclose that participation is voluntary.
	☐ The consent process will disclose the name and contact information for the investigator.
	☐ There are adequate provisions to maintain the privacy interests of subjects. [vii]

[i] The organization's policy is to not grant exemptions to FDA-regulated research in category (6).
[ii] Includes cognitive, diagnostic, aptitude, and achievement tests.
[iii] "If these sources are publicly available" was removed because public data cannot be private, and if there is no collection of private identifiable information, there can be no Human Subjects.
[iv] For example, financial or medical benefits as provided under the Social Security Act.
[v] For example, social, supportive, or nutritional services as provided under the Older Americans Act.
[vi] Note that for FDA-regulated research exemption (6) is an exemption from IRB review in 21 CFR §56, but unlike DHHS regulations is not an exemption from FDA requirements for consent in 21 CFR §50. If an organization's policy is to grant exemptions to FDA-regulated research in category (6), then additional criteria for such exemptions would be that consent will be obtained in accordance with 32 CFR §50.20 and §50.25, and the consent will be either documented in writing in accordance with 21 CFR §50.27 or waived in accordance with 21 CFR §56.109(c)(1).