Institutional Review Board
Checklist: Exempt & Limited IRB Review

NUMBER | HRP-312

IRB Number:	
Protocol Name:	
Investigator:	

. Once completed, return this checklist to the IRB manager.

	1. General Exclusions from Exemptions (Check if "Yes". If any are checked, the research is NOT exempt.)
☐	The research is FDA- regulated.
☐	The research involves Prisoners, conducted or funded by DHHS or Dept. of Defense (DOD), and is NOT aimed at involving a broader subject population that only incidentally includes prisoners.
☐	The research involves interactions with prisoners.

2018 Requirements

Note: This checklist is for Exempt determinations on or after 1/21/19.

2. The research falls into one or more of the following categories. (One or more categories must be checked.)

	New Citation	Exemption Category Description	Limited IRB Review *	Conditions/Allowances/Limitations
☐	104(d)(1) 1	Educational Research: Research in established or commonly accepted education settings that involves normal educational practices	N/A	Not Likely to adversely impact students' opportunity to learn or assessment of educators.
☐	104(d)(2) 2	Research only includes educational test, surveys, interviews, public observation if at least one of the following criteria met:	N/A	Data collection only; may include visual or auditory recording; may NOT include intervention
		☐ Recorded information cannot readily identify the subject (directly or indirectly/linked); OR	N/A	Surveys & Reviews: No Children; Educational tests or observations of public behavior: Can only include children when investigators do not participate in activities being observed.
		☐ Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation); OR	N/A	Surveys & Reviews: No Children; Educational tests or observations of public behavior: Can only include children when investigators do not participate in activities being observed.
		☐ Information is recorded with identifiers & IRB conducts Limited IRB Review. (Must complete section 4 below.)	Privacy and Confidentiality Review *	NO Children
☐	104(d)(3) 3	New Benign Behavioral Intervention: Research involving benign behavioral interventions (BBI) through verbal, written responses, (including data entry or audiovisual recording) from adult subjects	N/A	NO Children; May not include medical interventions; Subject prospectively agrees;

	3	who prospectively agrees and ONE of the following met:		BBI must be: ☐ Brief in duration ☐ Painless/harmless ☐ Not physically invasive ☐ Not likely to have a significant adverse lasting impact on subjects ☐ Unlikely that subjects will find interventions offensive or embarrassing No deception unless participant prospectively agrees
		☐ Recorded information cannot readily identify the subject (directly or indirectly/linked): OR	N/A	
		☐ Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation); OR	N/A	
		☐ Information is recorded with identifiers & IRB conducts Limited IRB Review. (Must complete section 4 below.)	Privacy and Confidentiality Review *	
☐	104(d)(4) 4	Secondary research for which consent is not required: Use of identifiable information or identifiable biospecimens that have been or will be collected for some other "primary" or "initial" activity, if ONE of following criteria met:		No Primary collection from subjects for the research; allows both Retrospective and Prospective Secondary use.
		☐ Biospecimens or information is publically available; OR	N/A	Must be publically available
		☐ Information recorded so subject cannot readily be identified (directly or indirectly/linked); investigator does not contact subjects and will not re-identify the subjects; OR	N/A	
		☐ Collection and analysis involving investigators use of identifiable health information when use is regulated by HIPAA "health care operations" or "research" or "public health activities and purposes"; OR	N/A	HIPAA still applies; HIPAA protections include authorization or waiver of authorization; Federal guidance needed on how to apply this criterion
		☐ Research information collected by or on behalf of federal government using government generated or collected information obtained for non-research activities.	N/A	If research generates identifiable private information, it is subject to specified federal privacy laws.
☐	104(d)(5) 5	Research and demonstration projects supported by a Federal Agency/Dept. AND designed to study, public benefit or service programs.	N/A	Must be posted on a federal web site.
☐	104(d)(6) 6	Taste and Food quality	N/A	

☐	104(d)(7) 7	Storage or maintenance of identifiable private information or identifiable biospecimens for secondary research for which broad consent is required. **The Avera IRB will not be authorizing broad consent so this these two exemptions will not be used locally**	➢ Board consent is obtained ➢ Documented or documentation waived ➢ If there is a change made for research purposes in the wat material stored or maintained, privacy and confidentiality review	All requirements for Broad Consent met; MUST TRACK REFUSALS – as the IRB may not waive consent for use of identifiable material for any individual who refuses.
☐	104(d)(8) 8	Secondary research involving use of identifiable private information or identifiable biospecimens for which broad consent was required. **The Avera IRB will not be authorizing broad consent so this these two exemptions will not be used locally**	➢ Privacy and confidentiality review & ➢ Research is within the scope of the broad consent & ➢ PI does not plan to return research results	Privacy and confidentiality protections adequate; broad consent was obtained; documented or documentation waived. No plan to return research results; MUST TRACK REFUSALS as the IRB may not waive consent for use of identifiable material for any individual who refuses.

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. That is, the research is appropriate for the population being studied. (Must be checked)	
☐	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 of the investigator.
	☐	There are adequate provisions to maintain the privacy interests of subjects.

4. *Limited IRB Review

Exempt 2 (surveys/interviews) and Exempt 3 (benign behavioral interventions) where disclosure of the subjects' responses outside the research reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, education advancement, or reputation requires a "Limited IRB review" of the confidentiality measures. Limited IRB Review may be done via expedited review by the Chair, or an experienced IRB member designated by the Chair.

The new rule outlines some exempt categories that require an increased level of review by the IRB for data security and privacy protections.

The exempt categories subject to limited IRB review are:

- Exempt (d)(2) research involving tests, surveys, interviews, public observations that are identifiable

- Exempt (d)(3) research involving benign behavioral interventions (BBI) that are identifiable (directly or through links) and the responses may be damaging to the subject's reputation, financial standing, employability, educational advancement, criminal or civil liability.

Limited review .111(a)(7) for data security and privacy is applicable to exempt categories 2 and 3.

- The extent to which identifiable private information is or has been de-identified and the risk that such de-identified information can be re-identified;
- The use of information;
- The extent to which the information will be shared or transferred to a third party or otherwise disclosed or released;
- The likely retention period or life of the information;
- The security controls that are in place to protect the confidentiality and integrity of the information; and
- The potential risk of harm to individuals should the information be lost, stolen, compromised, or otherwise used in a way contrary to the contours of the research under the exemption.

☐ **This limited IRB review has determined that there are adequate provisions in place to protect the privacy of subjects and confidentiality of data if there is a change in the way the identifiable private information or identifiable biospecimens are stored or maintained.**

The research is:

☐ Eligible for Exempt review and APPROVED under the checked category above.

☐ Eligible for Exempt, and Limited Review (#2 or 3 above) and APPROVED under the checked category above.

☐ Not Eligible for Exempt review.

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(Reviewer) (Date)