ARROWHEAD REGIONAL MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD

EXEMPT HUMAN SUBJECTS RESEARCH

While all research involving human subjects must be reviewed by the appropriate IRB, federal regulations recognize certain types of research as being exempt from IRB oversight. Research meeting any of the following criteria will be confirmed by IRB review either during the IRB Meeting or expedited review of the initial application. There is no requirement for continuing review unless explicitly stated. The IRB retains the right to require full board review when warranted by the nature of the research and/or inclusion of vulnerable subject populations.

Criteria for Exempt Human Subjects Research

Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be exempt from IRB oversight. ***If you believe your project meets criteria for the exempt classification, please check all categories below that apply.***

1. **Education research**
   Research conducted in established or commonly accepted educational settings, involving normal educational practices not likely to adversely impact students' opportunity to learn or assessment of educators.

   Examples include: evaluating the use of accepted or revised standardized tests, testing or comparing a curriculum or lesson, a program evaluation of continuing education, etc.

2. **Surveys, interviews, educational tests, public observations**
   Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, if: (a) recorded information cannot readily identify the subject (directly or indirectly/linked); or (b) any disclosure of information outside the research would not reasonably place the subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation). [Educational test or observation of public behavior only include children when investigators do not participate in the activities being observed]

   Examples include: surveying teachers, nurses, or doctors about a technique or outcome, interviewing managers about a management style, conducting a focus group about an experience or opinion, etc.

3. **Benign Behavioral Interventions**
   Research involving benign behavioral interventions through verbal, written responses (including data entry or audiovisual recording from **adult** subjects who **prospectively agree**, if: (a) recorded information cannot readily identify the subject (directly or indirectly/linked); or (b) any disclosure of information outside the research would not reasonably place the subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation). [Benign interventions should be brief in duration, painless/harmless, not physically invasive, not likely to have a significant adverse lasting impact on subject, and do NOT include medical interventions,]

   Examples include: solving puzzles under various noise conditions, playing an economic game, being exposed to stimuli such as color, light or sound (at safe levels).

4. **Secondary use of identifiable private information or identifiable bio specimens**
   Secondary research with identifiable information/specimens collected for some other initial activity, if (a) biospecimens or information is publically available; or (b) information recorded so subject cannot readily be identified (directly or indirectly/linked) and investigator does not contact subject and will not re-

identify the subjects; or (c) collection and analysis involving investigator's use of identifiable health information when use is regulated by HIPAA 'health care operations' or 'research' or 'public health activities and purposes' with HIPAA Authorization or HIPAA waiver; or (d) research information collected by or on behalf of federal government using government generated or collected information obtained for non-research activities (may be subject to federal privacy laws).

Examples include: analyzing existing tissues samples or data set which were recorded by the investigator without identifiers.

5. **Federal research of demonstration projects**
   Research and demonstration projects supported by a Federal Agency/Dept. and designed to study, public benefit or service programs. Federal agencies must publish a list of projects covered by this exemption prior to research commencing.

6. **Taste and food quality evaluation**
   Research on taste and food quality evaluation and consumer acceptance studies, if: (a) wholesome foods without additives are consumed; or (b) 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 environmental contaminant at or below the level found to be safe, by the FDA or approved by the EPA or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

7. **Storage or maintenance of identifiable private information or identifiable biospecimens**
   Storage or maintenance of identifiable private information or identifiable biospecimens for secondary research for which broad consent is required. IRB may waive consent requirement or all requirements for broad consent must be met, and the IRB may not waive consent for use of identifiable material for any individual who refuses.

   This is a new exemption in the revised Common Rule that covers the storage or maintenance of identifiable private information or identifiable biospecimens for secondary research. Secondary research refers to research with materials originally obtained for nonresearch purposes or for research other than the current research proposal. The exemption can only be used when there is broad consent from the subjects for the storage, maintenance, and secondary research use of their identifiable materials.
   The use of exemption 7 in the revised Common Rule requires the IRB to conduct a limited review of specific requirements that pertain to the use of the exemption. The IRB is not asked to conduct a standard IRB review using all the criteria at 46.111. For Exemption 7, the IRB review is limited to the determinations described in 46.111(a)(8), which pertain to protections for privacy and confidentiality and broad consent.

8. **Secondary research use of identifiable private information or identifiable biospecimens**
   Secondary research involving use of identifiable private information or identifiable biospecimens for which broad consent was required. Privacy and confidentiality protections adequate; broad consent was obtained; documented or documentation waived return research results not allowed; refusals to consent must be tracked; the IRB may not waive consent for use of identifiable material for any individual who refuses.

   This is a new exemption in the revised Common Rule that covers the secondary research use of identifiable private information or identifiable biospecimens originally obtained for nonresearch purposes or for research other than the current proposal. There are four requirements that must be satisfied to use exemption 8: broad consent must be obtained from the subjects for the secondary research use of their identifiable materials, documentation or waiver of documentation of informed consent must be obtained, an IRB must conduct a limited review to make certain determinations relating to privacy and confidentiality protections and broad consent, and investigators cannot include the return of individual research results to subjects in the study plan. Note that this requirement does

not limit an investigator's ability to abide by any other legal requirement to return individual research results.

The use of Exemption 8 in the revised Common Rule requires the IRB to conduct a limited review of specific requirements that pertain to the use of the exemption. The IRB is not asked to conduct a standard IRB review using all the criteria at 46.111. For Exemption 8, the IRB conducts a limited review to determine whether the following criteria are met:

- *There are adequate privacy and confidentiality protections as required under 46.111(a)(7), and*
- *The research to be conducted is within the scope of the broad consent.*