



DRS Human Research Review Committee Decision Tree for Exempt Approval

Research means “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to general knowledge. Activities which meet this definition constitute research, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities”. [45 CFR 46.102(d)] & 22 VAC 30-40-10.

Human research means "any systematic investigation which utilizes human participants who may be exposed to physical or psychological injury as a consequence of participation and which departs from the application of established and accepted therapeutic methods appropriate to meet the participant's needs."

Human Participant means "a living individual about whom an investigator (whether professional or student) conducting research obtains (i) data through intervention or interaction with the individual or (ii) identifiable private information. Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the participant or participant's environment that are performed for research purposes."

Systematic means “characterized by order and planning; not haphazard; a series of orderly actions”

For the purposes of these procedures, **general knowledge** is synonymous with generalizable knowledge which means that the intent of collecting the information is to learn and apply what is discovered to a wider group of individuals than those included in the study **and** to publish the results in an outside publication such as a journal, trade magazine, conference proceedings, or periodical.

Unless they are covered by some other provision, the following kinds of research are exempt from full committee review:

1. Research conducted in established or commonly accepted education settings, involving commonly used educational practices, such as:
 - a) Research on regular and special education instructional strategies; or
 - b) Research on the effectiveness of or the comparison among instructional techniques, curriculum or classroom management methods.
2. Research involving solely the use and analysis of the results of standardized psychological, educational, diagnostic, aptitude, or achievement tests, if information taken from these sources is recorded in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.
3. Research involving survey or interview procedures, unless responses are recorded in such a manner that participants can be identified, directly or through identifiers linked to the participants; and either:
 - a) The participant's responses, if they become known outside the research, could reasonably place the participant at risk of criminal or civil liability or be damaging to the participant's financial standing, employability, or reputation; or
 - b) The research deals with sensitive aspects of the participants' own behavior, such as sexual behavior, drug or alcohol use, illegal conduct, or family planning.
4. Research involving solely the observation (including observation by participants) of public behavior, unless observations are recorded in such a manner that participants can be identified, directly or through identifiers linked to the participants, and either:
 - a) The observations recorded about the individual, if they become known outside the research, could reasonably place the human participant at risk of criminal or civil liability or be damaging to the participant's financial standing, employability or reputation; or
 - b) The research deals with sensitive aspects of the participant's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.
5. Research involving solely the collection or study of existing data, documents, records, or pathological or diagnostic specimens, if the sources are publicly available, or if the information taken from these sources is recorded in such a manner that participants cannot be identified, directly or through identifiers linked to the participants. Note: Based on the federal definition of “existing data”, research conducted on biological or pathological specimens obtained prospectively and/or taken strictly for research purposes or from future discarded clinical samples DOES NOT qualify for exempt review.

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