	Category *Most applicable to CCMR	Description	Conditions/Allowances/Limitations
1	EDUCATION	Research in Established or Commonly Accepted Education Settings that Involves Normal Educational Practices	Not likely to adversely impact students' opportunity to learn or assessment of educators
2	SURVEYS, INTERVIEWS*	Research only includes Educational Tests, Surveys, Interviews, Public Observation if at least **ONE** of the following criteria met: (i) Information is recorded with identifiers & IRB conducts Limited Review (ii) Recorded information cannot readily identify the subject (directly or indirectly/linked) (iii) Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation)	• Data collection only • May include visual or auditory recording • Limited IRB review is required for criterion (i) to ensure that adequate provisions exist to protect the privacy of subjects and to maintain the confidentiality of their data.
3	BENIGN BEHAVIORAL INTERVENTIONS*	Research involving Benign Behavioral Interventions through verbal, written responses, (including data entry or audiovisual recording) from adult subject who prospectively agrees* (unclear on how this should be obtained) and **ONE** of following met: (i) Recorded information cannot readily identify the subject (directly or indirectly/linked) (ii) Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation) (iii) Information is recorded with identifiers & IRB conducts Limited Review *Prospective agreement must be meaningful, but it is not the same as a requirement for explicit consent. For example, individuals who are simply made aware that research data will be collected as they voluntarily complete a computer task may be understood as having agreed to participate. It is not yet clear how this will be implemented in the VA.	• May not include medical interventions • Subject prospectively agrees • Intervention must be: ❑ Brief in duration ❑ Painless/Harmless ❑ Not physically invasive ❑ Not likely to have significant adverse lasting impact ❑ Not likely to be offensive or embarrassing ❑ No deception unless participant prospectively agrees • PI can get confirmation from CCMR Veterans Research Engagement Committee (VREC) that intervention meets all these criteria to present to IRB. • Limited IRB review is required for criterion (iii) to ensure that adequate provisions exist to protect the privacy of subjects and to maintain the confidentiality of their data.

	Category *Most applicable to CCMR	Description	Conditions/Allowances/Limitations
4	SECONDARY RESEARCH*	Secondary research for which consent is not required: use of identifiable Information or identifiable biospecimen that have been or will be collected for some other 'primary' or 'initial' activity, if **ONE** of following criteria met: (i) Biospecimens or information is publicly available (ii) Information recorded so subject cannot readily be identified (directly or indirectly/linked); Investigator does not contact subjects and will not re-identify the subjects (iii) Collection and analysis involving Investigators' use of Identifiable Health Information when use is regulated under HIPAA as "health care operations" or "research" or "public health activities and purposes" (iv) Research information collected by or on behalf of federal government using government generated or collected information obtained for non-research activities	• Allows both retrospective and prospective secondary use • HIPAA still applies: HIPAA protections include authorization or waiver of authorization • If research generates identifiable private information it is subject to specified federal privacy laws
5	PUBLIC BENEFIT	Research and demonstration projects supported by a Federal Agency/Dept. AND designed to study, public benefit or service programs.	Must be posted on a federal web site
6	FOOD	Taste and Food Quality	
7	BROAD CONSENT: REPOSITORY	Storage or maintenance of identifiable private information or identifiable biospecimens for secondary research for which broad consent is required	• IRB may waive consent requirement • All requirements for Broad Consent must be met and refusals to consent must be tracked; the IRB may not waive consent for use of identifiable material for any individual who refuses
8	BROAD CONSENT: SECONDARY RESEARCH	Secondary research involving use of Identifiable Private Information or Identifiable Biospecimens for Which Broad Consent was Required	• Broad Consent obtained • Documentation or waiver of documentation of IC • IRB may not waive consent for use of identifiable material for any individual who refuses • IRB limited review - privacy and confidentiality protections adequate • Return research results not allowed • Refusals to consent must be tracked