Section 1115 of the Social Security Act gives the Secretary of Health and Human Services authority to approve experimental, pilot, or demonstration projects that are found by the Secretary to be likely to assist in promoting the objectives of the Medicaid program.

Section 1115a establishes the Center for Medicare and Medicaid Innovation.

2018 Exempt Category 5:
Research and Demonstration Projects
After 21 Jan 2019

START

Research on a public benefit or service program?

- **YES**
  - Are prisoners the target of the project?
    - **NO**
      - Conducted or Supported by a federal department or agency?
        - **YES**
          - Designed IAW the intent of the regulation?
            - **YES**
              - Qualifies as exempt under Category 5.
            - **NO**
              - NO
        - **NO**
          - Designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.
          - Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants.
          - The research or demonstration project must be published on federally accessible website prior to commencing the research involving human subjects.

- **NO**
  - Does not qualify under this category.

Or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects).