

## Exemption Category 5

Research and demonstration projects that are conducted or supported by a Federal department or agency, 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), and that are 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.

### Must have a contract or other agreement

### Must be posted on a Federal website

Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

### Examples of studies that may be eligible for exemption under category 5:

### Examples of studies that may *not* be eligible for exemption under category 5:

- ◆ Study sponsored by the Department of Housing and Urban Development to assess the effectiveness of a housing subsidy program.
- ◆ Study sponsored by the Department of Health & Human Services to examine barriers to obtaining new Medicare benefits.

- ◆ FDA regulated research.
- ◆ Studies that are not conducted or supported by a Federal department or agency.

This exemption covers a limited scope of federally funded or supported research. Researchers seeking this exemption for studies that are not federally funded or supported must demonstrate that the study is subject to and has received approval by the appropriate federal department or agency head.