Is the research or demonstration project conducted or approved by the Department or Agency Head?

- **Yes**: Research is exempt under 45 CFR 46.101(b)(5) from all 45 CFR part 46 requirements.*
- **No**: Go to Chart 8

Does the research or demonstration project involve only the study, evaluation, or examination of:

- Public benefit or service *programs*;
- *Procedures* for obtaining benefits or services under public or service programs;
- Possible *changes in or alternatives to* public benefits or service *programs* or to *procedures* for obtaining benefits or services under public benefit or service programs;
- Possible changes in *methods or levels of payment* for benefits or services under those public benefit or service programs?

*Note: See OHRP guidance on exemptions at http://www.hhs.gov/ohrp/policy/index.html#exempt for further description of requirements for this exemption.*

Adapted from: http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c6