

COURSE 13, TUTORIAL 1

PART 2

EXEMPTED RESEARCH UNDER THE FINAL RULE



As we discussed earlier, there are situations where human subject research is exempt from the Final Rule. Each exemption has a number of criteria and conditions that must be met to allow an exemption from the Final Rule's human subject protections. If you believe that your research falls under one of these exemptions, you must go to the Final Rule and determine if you meet the caveats and conditions that allow your research to be exempt.

EXEMPTIONS

The exempted research categories are:

EXEMPTION 1

Research conducted in an educational setting involving normal educational practice.

EXEMPTION 2

Research using educational tests, survey procedures; interviews; or observations of public behavior, unless subjects are identifiable and disclosure could place them at risk. This exemption for parts involving educational tests is applicable to children. However, this exemption for parts involving survey or interview procedures or observations of public behavior does not apply to research involving children, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

EXEMPTION 3

Research using educational tests, survey procedures; interviews; or observations of public behavior, if the subjects are

public officials or candidates for public office, federal law requires that confidentiality be maintained.

Each exemption has a number of criteria and conditions that must be met to allow an exemption from the Final Rule's human subject protections.

EXEMPTION 4

Research involving the collection or study of existing data, documents, records, pathological or diagnostic specimens; if these sources are publicly available or if the information is recorded in such a manner that subjects cannot be identified. Since 2008



There are eight research category exemptions to the Final Rule; each of which has a number of criteria and conditions that must be met.

guidance from OHRP, E4 is seldom applicable; most research with existing data or specimens is either non-exempt human subjects research or not human subjects research.

EXEMPTION 5

Research and demonstration projects that evaluate public benefit or service programs.

EXEMPTION 6

Research that evaluates taste and food quality; or consumer acceptance of foods.

Two new exemptions were added into the Final Rule. They are:

EXEMPTION 7

Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use.

EXEMPTION 8

Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use.

RESOURCES TO DETERMINE EXEMPTIONS

These are summaries of the exempted research categories. The Final Rule includes the criteria, caveats and conditions that are put in place to ensure the same level of human subject safety and confidentiality that would be safeguarded by the Final Rule in non-exempt human subject research. The U.S. Department of Health and Human Services' (HHS) Office for Human Research Protections (OHRP) offers an excellent set of Human Subject Regulations Decision Charts which will allow you to determine if your proposal meets all criteria for any particular exempted research and, whether or not your proposal will need approval from an Institutional Review Board (IRB). These charts can be found on the HHS's OHRP website. Web links to the site as well to a PDF of the flow charts can be found in the Links section of this tutorial.