**Section 1005.150 Institutional Review Board Applications**

a) Applications for IRB review shall be submitted to the Department electronically unless otherwise requested by the IRB.

b) Applications involving human subjects research shall include the following documentation:

1) A proposal including, but not limited to, the following:

A) The names and curriculum vitae of the principal investigator and co-principal investigators;

B) An abstract of the project;

C) A full description of the project's purpose, methodology, protocol and duration;

D) The number of subjects, the amount of time required for each subject's participation, and a detailed description of the interaction with the subjects;

E) The procedures for obtaining informed consent and the informed consent forms;

F) The questionnaires, testing and measurement instruments;

G) Letters, scripts, posters, notices, flyers, written materials and advertisements to be used for subject recruitment;

H) A duly executed unaffiliated investigator agreement for each investigator who is not an employee or who is not working on behalf of the Department;

I) Proof that each investigator has completed required training in the protection of human research subjects; and

J) The Department resources to be used;

2) Identification of funding resources for the research proposal;

3) Any certifications and assurances regarding the protection of human research subjects, privacy and confidentiality that are required by law or regulation; and

4) Any other information necessary to the IRB review procedure.

c) The IRB will review the application, in accordance with Section

1005.110 and 45 CFR 46.

(Source: Added at 38 Ill. Reg. 19251, effective September 10, 2014)