PART 1335 - RESEARCH AND DEVELOPMENT CONTRACTING

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1335.001 Definitions.

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Parent topic: SUBCHAPTER F - SPECIAL CATEGORIES OF CONTRACTING

1335.001 Definitions.

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains:

(1) Data through intervention or interaction with the individual, or

(2) Identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. “Private information” includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (*i.e.,* the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Research means a systematic investigation, including research, development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported

under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

1335.006 Contracting methods and contract type.

(a) Insert provision 1352.235-70, *Protection of Human Subjects,* in all solicitations where research services under the contract might involve the use of human subjects. The provision is mandatory where human subjects may be used in performance of the award and may not be modified without consultation with Program Counsel.

(b) Insert clause 1352.235-71, *Protection of Human Subjects - Exemption,* in all contracts where the agency has determined based on documentation submitted by the offeror in response to provision 1352.235-70, *Protection of Human Subjects,* that the research involving human subjects is exempt from the requirements of 15 CFR part 27 and does not require Institutional Review Board (IRB) review. The provision is mandatory where an appropriate agency official has determined that the research involving human subjects to be carried out in performance of the award is exempt from 15 CFR part 27, and may not be modified without consultation with Program Counsel.

(c) Insert clause 1352.235-72, *Protection of Human Subjects - Institutional Approval,* in all contracts where the agency has determined based on documentation submitted by the offeror in response to provision 1352.235-70, *Protection of Human Subjects,* that the research involving human subjects is not exempt from the requirements of 15 CFR part 27 and requires review by a cognizant Institutional Review Board (IRB). The provision is mandatory where an appropriate Agency official has determined that the research involving human subjects to be carried out in performance of the award is not exempt from 15 CFR part 27 and requires review by a cognizant IRB, and may not be modified without consultation with Program Counsel.

(d) Insert clause 1352.235-73, *Protection of Human Subjects - After Initial Contract Award,* in all contracts where at the time of award no research involving human subjects is anticipated, but where decisions made in the course of the research may necessitate the addition of research involving human subjects to the work performed. The provision is mandatory where it is possible that the use of human subjects may be required in performance of the award but is not anticipated at the time of award, and may not be modified without consultation with Program Counsel.

1335.014 Government property and title.

The designee authorized to determine that the policies in FAR 35.014(b)(1)-(4) will not apply regarding title to equipment purchased by nonprofit institutions of higher learning and nonprofit organizations whose primary purpose is the conduct of scientific research is set forth in CAM 1301.70.

1335.016 Broad agency announcement.

1335.016-70 DOC procedures for the use of broad agency announcements.

Procedures for the use of broad agency announcements within the Department of Commerce are set forth in CAM 1335.016.

1335.017 Federal funded research and development centers.

1335.017-2 Establishing or changing an FFRDC.

The designee authorized to approve the establishment of an FFRDC, or change its basic purpose and mission, is set forth in CAM 1301.70.

1335.017-4 Reviewing FFRDCs.

The designee authorized to approve the continuation or termination of the sponsorship of an FFRDC is set forth in CAM 1301.70.