

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.

Parent topic: PART 1335 - RESEARCH AND DEVELOPMENT CONTRACTING