AR 40-7, Use of Investigational Drugs and Devices in Humans and the Use of Schedule I Controlled Drug Substances, 4 Jan 91

Interim Management Control Evaluation. *AR 40-7 is under revision. This evaluation should be used until publication of the revised AR 40-7 that will include an evaluation of key management controls.*

Appendix C
Management Control Evaluation

C-1. Function. The function covered by this checklist is the administration of the use of investigational new drugs and devices and the use of Schedule I controlled substances. This evaluation should be used at the following levels: MACOM.

C-2. Purpose. The purpose of this checklist is to assist assessable unit managers and subject matter experts in evaluating the key management controls listed below. It is not intended to cover all controls.

C-3. Instructions. Answers must be based on the actual testing of key management controls (e.g., document analysis, direct observation, sampling, simulation, other). Answers which indicate deficiencies must be explained and corrective action indicated in supporting documentation. These management controls must be evaluated at least once every three years. Certification that this evaluation has been conducted must be accomplished on DA Form 11-2-R (Management Control Evaluation Certification Statement).

C-4. Test Questions.

a. Is AR 40-7 readily available for reference?

b. Are investigators fully qualified as experts (review of CV) in the clinical study of investigational drugs or devices?

c. Is the investigator's brochure (drug or device information) available?

d. Are annual progress reports required by the sponsor and continuing review reports required by the IRB of record submitted in a timely manner?

e. Are research protocols complete with background, hypothesis, objectives, military significance and methodology, and in DA or E6 formats as appropriate?

f. Are literature references cited to support the research protocol?

g. Are human use protocols written to include ICH prescribed content and do they include a copy of informed consent, case report forms and study specific procedures?

h. Do animal use protocols include animal use approval, justification for animal/species use, description of animal facilities, and evidence of compliance?

i. Is there evidence that the sponsor has provided clinical monitoring of the investigational new drug or device research protocol in accordance with 21 CFR 312 or 21 CFR 812.46, respectively, and the ICH Guideline for Industry E6 Good Clinical Practice: Consolidated Guidance?

Encl

j. Are the requirements for the protection of human participants identified in 21 CFR 50, 32 CFR 219 and AR 70-25 being followed?

k. Does the hospital or research facility have appropriate standing operating procedures for the conduct of clinical trials? At a minimum, procedures should be available for:

(1) Scientific review of research protocols.

(2) Local human use review of research protocols.

(3) Training and education of research staff in Good Clinical Practice (GCP).

(4) Control and accountability of investigational products.

(5) Maintenance of regulatory files.

(6) Laboratory procedures (appropriate certification).

(7) Study specific procedures.

(8) Adverse event reporting.

(9) Periodic reporting and final reports.

(10) Informed consent process.

(11) Participant recruitment.

(12) Participant record maintenance.

l. Are procedures in place for emergency use of investigational products?

m. Are financial contracts with commercial sponsors signed?

n. Are procedures in place to ensure that participation in research does not conflict with 10 U.S.C 980?

o. Are final reports submitted at the conclusion of research activities?

p. For activities that use Schedule I controlled substances, are procedures in place to ensure the following:

(1) Has DEA Form 225 been completed?

(2) Is the Certificate of Registration available?

(3) Are the controlled substances correctly stored?

(4) Are security measures evident?

(5) Are dispensing records maintained correctly?

(6) Do only appropriate personnel have access?

(7) Can only authorized investigator(s) prescribe the controlled substance(s)?

(8) Do written records provide an audit trail of receipt, disposal, inventory and distribution?

C-5. Supersession. No prior version of this checklist has been published.

C-6. Comments. Help make this a better tool for evaluating management controls. Submit comments to: Commander, USAMMDA, ATTN: MCMR-UMR, Fort Detrick, MD 21702.