(§ 130.37)

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* § 130.37 **Consent for use of investigational new drugs (IND) on humans: statement of policy.**

(a) Section 505(i) of the act provides that regulations on use of investigational new drugs on humans shall impose the condition that investigators "obtain the consent of such human beings or their representatives, except where they deem it not feasible or, in their professional judgment, contrary to the best interests of such human beings."

(b) This means that the consent of such humans (or the consent of their representatives) to whom investigational drugs are administered primarily for the accumulation of scientific knowledge, for such purposes as studying drug behavior, body processes, or the course of a disease, must be obtained in all cases and, in all but exceptional cases, the consent of patients under treatment with investigational drugs or the consent of their representatives must be obtained.

(c) "Under treatment" applies when the administration of the investigational drug for diagnostic, therapeutic, or other purpose involves medical judgment, taking into account the individual circumstances pertaining to the patient to whom the investigational drug is to be administered.

(d) "Exceptional cases" as used in paragraph (b) of this section are those relatively rare cases in which it is not feasible to obtain the patient's consent or the consent of his representative, or in which as a matter of professional judgment exercised in the best interest of a particular patient under the investigator's care, it would be contrary to that patient's welfare to obtain his consent.

(e) "Patient" means the person under treatment.

(f) "Not feasible" is limited to cases wherein the investigator is not capable of obtaining consent because of inability to communicate with the patient or his representative; for example, the patient is in a coma or is otherwise incapable of giving consent, his representative cannot be reached, and it is imperative to administer the drug without delay.

(g) "Contrary to the best interests of such human beings" applies when the communication of information to obtain consent would seriously affect the patient's well-being and the physician has exercised a professional judgment that under the particular circumstances of this patient's case, the patient's best interests would suffer if consent were sought.

(h) "Consent" means that the person involved has legal capacity to give consent, is so situated as to be able to exercise free power of choice, and is provided with a fair explanation of pertinent information concerning the investigational drug, and/or his possible use as a control, as to enable him to make a decision on his willingness to receive said investigational drug. This latter element means that before the acceptance of an affirmative decision by such person the investigator should carefully consider and make known to him (taking into consideration such person's well-being and his ability to understand) the nature, expected duration, and purpose of the administration of said investigational drug; the method and means by which it is to be administered; the hazards involved; the existence of alternative forms of therapy, if any; and the beneficial effects upon his health or person that may possibly come from the administration of the investigational drug.

When consent is necessary under the rules set forth in this section, the consent of persons receiving an investigational new drug in Phase 1[1] and Phase 2[1] investigations (or their representatives) shall be in writing. When consent is necessary under such rules in Phase 3[1] investigations, it is the responsibility of investigators, taking into consideration the physical and mental state of the patient, to decide when it is necessary or preferable to obtain consent in other than written form. When such written consent is not obtained, the investigator must obtain oral consent and record that fact in the medical record of the person receiving the drug.

[1] As discussed in item 10 of Form FD 1571, which Form is set forth in § 130.3(a)(2).

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