

## § 21.33

## 21 CFR Ch. I (4–1–11 Edition)

### § 21.33 Medical records.

(a) In general, an individual is entitled to have access to any medical records about himself in Privacy Act Record Systems maintained by the Food and Drug Administration.

(b) The Food and Drug Administration may apply the following special procedures in disclosing medical records to an individual:

(1) The agency may review the records to determine whether disclosure of the record to the individual who is the subject of the records might have an adverse effect on him. If it is determined that disclosure is not likely to have an adverse effect on the individual, the record shall be disclosed to him. If it is determined that disclosure is very likely to have an adverse effect on the individual, he may be requested to designate, in writing, a representative to whom the record shall be disclosed. Such representative may be a physician, other health professional, or other responsible person who would be willing to review the record and discuss it with the individual.

(2) The availability of the record may be subject to any procedures for disclosure to an individual of medical records about himself under part 20 of this chapter, in addition to or in lieu of the procedures in paragraph (b)(1), that are not inconsistent with § 21.41(f).

### Subpart D—Procedures for Notification of and Access to Records in Privacy Act Record Systems

#### § 21.40 Procedures for submitting requests for notification and access.

(a) An individual may request that the Food and Drug Administration notify him whether a Privacy Act Record System contains records about him that are retrieved by reference to his name or other personal identifier. An individual may at the same time, or after receiving notification that such a record about him exists, requests that he be given access to the record.

(b) An individual desiring notification or access to records shall mail or deliver a request for records in any Food and Drug Administration Privacy Act Records System to the FDA Pri-

vacancy Act Coordinator (HFI-30), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

(c) Requests shall be in writing and shall name the Privacy Act Record System or Systems concerning which the individual requests notification of whether there are records about him that are retrieved by reference to his name or other personal identifier. To help assure a prompt response, an individual should indicate that he is making a “Privacy Act Request” on the envelope and in a prominent manner in the letter.

(d) An individual who merely wishes to be notified whether a Privacy Act Record System contains a record about him ordinarily need not provide any verification of his identity other than his name. The mere fact that the Food and Drug Administration has a record about an individual in any of its Privacy Act Records Systems would not be likely to constitute a clearly unwarranted invasion of personal privacy. Where mere disclosure of the fact that a record about the individual exists would be a clearly unwarranted invasion of personal privacy, further verification of the identity of the individual shall be required.

(e) An individual who requests that he be given access to a copy of records about himself, if any exist, should indicate whether he prefers (1) to have copies of any such records mailed to him in accordance with § 21.43(a)(1), which may involve a fee under § 21.45, including information to verify his identity under § 21.44 or (2) to use the procedures for access in person under § 21.43(a)(2).

(f) A request for notification and access may be submitted under this subpart concerning any Privacy Act Record System that is exempt under § 21.61, as indicated in the notice for the system. An individual seeking access to records under § 21.65(b)(2) to investigatory records compiled for law enforcement purposes other than criminal law enforcement purposes should submit a description of the right, benefit, or privilege that he believes he was denied as the result of the Food and Drug Administration’s maintenance of the records. Where the system is exempt under § 21.61, and access to the requested records is not granted

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under § 21.65, the request shall be handled under the provisions of part 20 of this chapter (the public information regulations).

[42 FR 15626, Mar. 22, 1977, as amended at 46 FR 8458, Jan. 27, 1981; 50 FR 52278, Dec. 23, 1985]

### § 21.41 Processing of requests.

(a) An individual or his guardian under § 21.75 shall not be required to show any justification or need to obtain notification under § 21.42 or access to a record under § 21.43.

(b) The Food and Drug Administration will determine whether a request by an individual for records about himself is appropriately treated as a request under this subpart, or under the provision of part 20 of this chapter (the public information regulations), or both. Where appropriate, the Food and Drug Administration will consult with the individual concerning the appropriate treatment of the request.

(c) The FDA Privacy Act Coordinator (HFI-30) in the Freedom of Information Staff shall be responsible for the handling of Privacy Act requests received by the Food and Drug Administration. Requests mailed or delivered to any other office shall be promptly redirected to the FDA Privacy Act Coordinator. Where this procedure would unduly delay the agency's response, however, the agency employee who received the request should consult with the FDA Privacy Act Coordinator and obtain advice as to whether the employee can respond to the request directly.

(d) Upon receipt of a request by the FDA Privacy Act Coordinator, a record shall promptly be made that a request has been received and the date.

(e) A letter in accordance with § 21.42 responding to the request for notification shall issue as promptly as possible after receipt of the request by the Food and Drug Administration. Upon determination by the Freedom of Information Staff that a request for access to records is appropriately treated as a request under part 20 of this chapter rather than part 21, or under both parts, the time limitations prescribed in § 21.41 shall apply. In any case, access to available records shall be provided as promptly as possible.

(f) Except as provided in § 21.32, an individual's access to records about him/herself that are retrieved by his/her name or other personal identifiers and contained in any Privacy Act Record System may only be denied by the Associate Commissioner for Public Affairs or his or her designate. An individual shall not be denied access to any record that is otherwise available to him/her under this part except on the grounds that it is exempt under § 21.65(a)(2), that it was compiled in reasonable anticipation of court litigation of formal administrative proceedings, or to the extent that it is exempt or prohibited from disclosure because it includes a trade secret or commercial or financial information that is privileged or confidential information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy of another individual.

(g) The FDA Privacy Act Coordinator shall ensure that records are maintained of the number, status, and disposition of requests under this subpart, including the number of requests for records exempt from access under this subpart and other information required for purposes of the annual report to Congress under the Privacy Act. These temporary administrative management records shall not be considered to be Privacy Act Record Systems. All records required to be kept under this paragraph shall only include requesting individuals' names or personal identifiers for so long as any request for notification, access, or amendment is pending. The identity of individuals making request under this subpart shall be regarded as confidential and shall not be disclosed under part 20 of this chapter (the public information regulations) to any other person or agency except as is necessary for the processing of requests under this subpart.

[42 FR 15626, Mar. 22, 1977, as amended at 46 FR 8458, Jan. 27, 1981]

### § 21.42 Responses to requests.

(a) The FDA shall respond to an individual's request for notification as to whether a Privacy Act Record System contains records about him that are retrieved by his name or other personal