Supporting Statement
Radioactive Drug Research Committee Report
On Research Use of Radioactive Drug;
Membership Summary and Study Summary - 21 CFR Part 361.1
OMB Number 0910-0053

A. Justification

1. **Circumstances Necessitating Information Collection**

The Food and Drug Administration (FDA) is requesting OMB approval of the information collection requirements contained in 21 CFR 361.1 These information collection requirements are:

21 CFR 361.1 (c)(2) – Requires recordkeeping by a Radioactive Drug Research Committee (RDRC). Each RDRC must meet at least once each quarter in which research activity has been authorized or conducted. Minutes of these meetings must be kept and must include the numerical results of votes on protocols involving use in human subjects.

21 CFR 361.1 (c)(3) – Requires reporting by an RDRC. Each RDRC must submit an annual report to the FDA that includes the names and qualifications of its members and of any consultants used by the RDRC (reported on Form FDA 2914 - Membership Summary), and a summary of each study conducted during the preceding year (reported on Form FDA 2915 – Study Summary). Additionally, this regulation requires that a RDRC submit a special summary of information at the time any study is approved that involves more than 30 research subjects or research subjects under 18 years of age (reported on Form FDA 2915 – Study Summary).

21 CFR 361.1 (c)(4) – Requires reporting by an RDRC. Each RDRC must report changes in membership and applications for new members to the FDA as soon as, or before, vacancies occur (reported on Form FDA 2914 – Membership Summary).

21 CFR 361.1 (d)(5) – Requires recordkeeping by an RDRC. Each RDRC must obtain the consent of research subjects or their legal representatives in accordance with 21 CFR 50, and must obtain from each female subject of childbearing potential a statement in writing that she is not pregnant,

or must confirm that she is not pregnant based on a pregnancy test, before she may participate in any study.

21 CFR 361.1 (d)(8) – Requires reporting by an RDRC. An RDRC must report to the FDA all adverse reactions probably attributable to the use of a radioactive drug in a research study.

These regulations implement provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355 (i)), which require the Secretary, DHHS, to promulgate regulations that permit drugs that have been generally recognized as safe and effective to be used solely for basic scientific research use. Title 21, Code of Federal Regulations, Part 361.1, sets forth specific regulations regarding the establishment and composition of RDRCs and their role in approving and monitoring research studies utilizing radiopharmaceuticals. No study involving administration of a radioactive drug to research subjects under 21 CFR 361.1 is permitted without the authorization of a FDA approved RDRC (21 CFR 361.1 (d)(7)). The research that may be undertaken with a radiopharmaceutical drug under 21 CFR 361.1 must be intended to obtain basic information and not to carry out a clinical trial for safety or efficacy. The types of basic research permitted are specified in the regulation, and include studies of metabolism, human physiology, pathophysiology, or biochemistry.

21 CFR 361.1 designates certain research uses of radioactive drugs as generally recognized as safe and effective (GRAS/E). When a drug is designated as GRAS/E, it is not a new drug as defined by the Food, Drug, and Cosmetic Act. When a new drug is used in humans and the drug is not yet approved for marketing, a Notice of Claimed Investigational Exemption for a New Drug (IND) application is required. An IND is not needed to study a drug that is not a new drug. A RDRC can determine that a radioactive drug to be used in a research study is not a new drug if the conditions of its use as specified in the investigator’s protocol meet the requirements of 21 CFR 361.1. Approval of research studies by an RDRC eliminates the need for submission of an IND to the FDA.

Types of research studies not permitted under this regulation are also specified, and include those intended for immediate therapeutic, diagnostic, or similar purposes or to determine the

safety or effectiveness of the drug in humans for such purposes (i.e., to carry out a clinical trial for safety or efficacy). These studies require submission of an IND under 21 CFR 312.1 and the associated information collection are covered in OMB Control Number0910-0014.

2. **How, by Whom, and for What Purpose Information Used**

FDA's approval of a RDRC is based on assessment of the qualifications of committee members and assurance that all necessary fields of expertise are covered (reported on Form FDA 2914 – Membership Summary)). Following approval, FDA periodically reviews the composition of the RDRCs. Approval may be withdrawn at any time the requirements of 21 CFR 361.1 are not met.

The FDA monitors an RDRC's activities by reviewing its annual reports (reported on Forms FDA 2914 and 2915), by periodic review of meeting minutes and study protocols, and through on-site inspections. The purpose of this monitoring is to determine whether the research studies are being conducted in accordance with the regulation and to assure the safety of human subjects. Monitoring by the FDA also allows for the identification of studies that initially complied with the requirements of 21 CFR 361.1 but which have evolved into clinical trials or other research studies that are not permitted under 21 CFR 361.1. and that require the submission of an IND.

3. **Consideration of Information Technology**

FDA encourages the electronic submission of Forms FDA 2914 and 2915 when feasible as well as the other reporting submissions in these regulations.

4. **Identification of Duplication**

The FDA is the only federal agency responsible for regulating the activities required by 21 CFR 361.1. The Nuclear Regulatory Commission (NRC), and some state and federal agencies such as the Department of the Army also regulate the possession and use of radioactive materials and other radiation sources (x-ray) necessary to conduct some of these RDRC studies. However, their responsibility is primarily related to occupational radiation safety and not the human use of the radiolabeled drug, and is therefore not considered duplicative.

5. **Small Businesses**

Collection of this information does not involve small businesses. Most Committees are affiliated with large institutions. However, FDA and the Center for Drug Evaluation and Research provide general assistance to the research community.

6. **Consequences of Less Frequent Information Collection**

The composition of the Committee membership is reported to the FDA on Form FDA 2914 (Membership Summary) yearly along with the annual report. Changes in membership may occur at any time during the year, and must be reported (also on Form FDA 2914) as soon as, or before, vacancies occur on the Committee. Less frequent reporting could allow unqualified members to serve on RDRCs for extended periods of time thereby placing the safety of human research subjects at risk as these RDRCs continue to evaluate and approve research protocols.

Approved study protocols are reported to the FDA on Form FDA 2915 (Study Summary) in the annual report. Less frequent reporting could result in safety risks to human subjects due to a delay in the detection of studies that are inappropriate under 21 CFR 361.1.

7. **Inconsistencies with 21 CFR 1320.6**

This information collection is consistent with the requirements of 5 CFR 1320.6.

8. **Consultation Outside FDA**

In the Federal Register of September 21, 2007 (72 FR 54044), FDA requested comments on the proposed collection of information. No comments were received.

9. **Payment or Gift**

No payment or gift has been provided.

10. **Confidentiality Provisions**

The contents of submitted Forms FDA 2914 (Membership Summary) and FDA 2915 (Study Summary) are available for public disclosure unless confidentiality is requested by the investigator and it is evident from the report(s) that the material contains trade secret or confidential commercial information as defined in 21 CFR 20.61. When confidentiality is requested and justified, the forms will be marked as not releasable and will be maintained in a manner similar to other confidential information. Data will be secured in a locked area with access limited to appropriate FDA personnel. Applicable confidentiality will be maintained as long as the data are maintained.

11. **Sensitive Questions**

No questions of a private or sensitive nature are asked.

12. **Total Hour Burden to Respondents**

The estimated annual burden for this information collection is 4,759 hours.

Table 1 -- Estimated Annual Reporting Burden

21 CFR Section	Form	No. Of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
361.1(c)(3) 361.1(c)(4)	FDA 2914 FDA 2914	80	1.0	80	1	80
361.1 c)(3)	FDA 2915	50	6.8	340	3.5	1,190
361.1(d)(8)		50	6.8	340	0.1	34
Total						1,304

\1\There are no capital costs or operating and maintenance costs associated with this collection

Table 2 -- Estimated Annual Recordkeeping Burden

21 CFR Section	Form	Number of Record Keepers	Annual Frequency per Record Keeping	Hours per Record Keeper	Total Hours
361.1(c)(2)		80	1 per quarter= 4 per year	10	3,200
361.1(d)(5)		50	6.8	0.75	255
Total					3455

The information entered on Form FDA 2914 (Membership Summary) and Form FDA 2915 (Study Summary) is extracted from data maintained by the RDRCs for their operation and from reports to the institutions with which the RDRCs are affiliated.

Information on study subjects required on Form FDA 2915 (Study Summary) is extracted from written orders (prescriptions) or the subject's medical records. These records are normally maintained in the practice of medicine (i.e., patient identification, diagnostic and therapeutic orders, evidence of informed consent, tests and test results, etc.). Time burden estimates are based on a measurement of clerical, administrative, and professional resources required for the collection and compilation of the data. It is estimated to take 1 hour per respondent annually to complete form FDA 2914 (Membership Summary). There are 80 respondents totaling 80 burden hours. It is estimated to take 3.5 hours per report to complete form FDA 2915 (Study Summary). Approximately 340 reports are submitted annually totaling 1190 burden hours.

The minutes of the meetings, which must be kept in compliance with 21 CFR 361.1(c)(2), are normal records of RDRC proceedings and are accepted by the FDA for inspection without any further compilation. The time to prepare these minutes varies, depending upon the number of protocols a RDRC has to review/discuss and vote on, and depending upon how an RDRC is structured. However, an average time to prepare minutes (writing/dictating, typing, proofreading) specifically related to studies conducted under this regulation can be estimated to take about 10 hours annually per recordkeeper. Records must be kept for 80 RDRCs totaling 800 burden hours.

13. **Total Annual Cost to Respondent**

Using an average salary of $60 per hour (clerical and professional salaries combined), the total estimated cost to the respondents is $128,520.

14. **Annualized Cost to FDA**

The estimate of the cost to the government is $72,850 per year. This figure is based on past experience, a current re-evaluation, and the cost of the following activities:

(1) Preparing letters to RDRCs;
(2) Printing Forms FDA 2914 and 2915;
(3) Clerical time for processing and mailing documents at $20.00 per hour; and
(4) Administrative and professional review time at $60 per hour

Table 3 – Estimated Cost to the Federal Government						
Item	Printing	Clerical Time (hrs)	Clerical Cost	Prof. Time (hrs)	Prof. Cost	Total Cost
Letter	$0	20	$400	320	$19,200	$19,600
2914 2915	$20 $100			250 800	$15,000 $48,000	$15,020 $48,100
Total	$120	20 hrs	$400	1370 hrs	$82,200	$82,720

15. **Explanation for Program Changes or Adjustments**

Change due to Agency miss-calculations in calculating Recordkeeping burden

16. **Publication of Information Collection Results**

FDA does not intend to publish results of the information collection.

17. **Display of OMB Approval Date**

FDA is not seeking an exemption from display of the OMB control number and date.

18. **Exceptions to "Certification for Paperwork Reduction Act Submissions."**

There are no exceptions to the certification statement found in Item 19 (Certification for Paperwork Reduction Act Submissions) of OMB Form 83-I.