The Radioactive Drug Research Committee: What It Is and What It Is Suppose To Do.

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Senior Manager - Radioactive Drug Research Committee program

Division of Medical Imaging and Hematology Products

Office Of Oncology Drug Products

Center for Drug Evaluation and Research

Food and Drug Administration

U.S. Public Health Service

Learning Objectives

Upon completion of this program participants will be able to:

1. Understand and contrast the regulatory pathways in the United States which authorize the study of radioactive drugs in humans.

2. Define the requirements for establishing a Radioactive Drug Research Committee.

3. Identify the function, membership requirements and responsibilities of a Radioactive Drug Research Committee in approving basic science research involving the use of certain radioactive drugs.

Self Assessment Questions

Have I learned?

1. The regulatory pathways in the United States for studying a radioactive drug in humans include:
   a) the IND or Investigational New Drug application,
   b) exemption from IND requirements, and
   c) the Radioactive Drug Research Committee or RDRC.

2. The regulations governing a RDRC can be found in 21 CFR 361.1
   http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/search/search.cfm?db=CFR&ID=361.1

Self Assessment Questions

Have I learned?

3. A RDRC approved research project is to be of a basic science nature, but which is not intended for immediate therapeutic, diagnostic, or similar purposes or to determine the safety and effectiveness of the radioactive drug in humans.

4. A radioactive drug that goes through the RDRC approval pathway is classed as GRAS/E (generally recognized as safe and effective) ONLY if it meets ALL of the requirements as defined in the regulations and is on a case by case bases for each radioactive drug reviewed and for each protocol submitted.

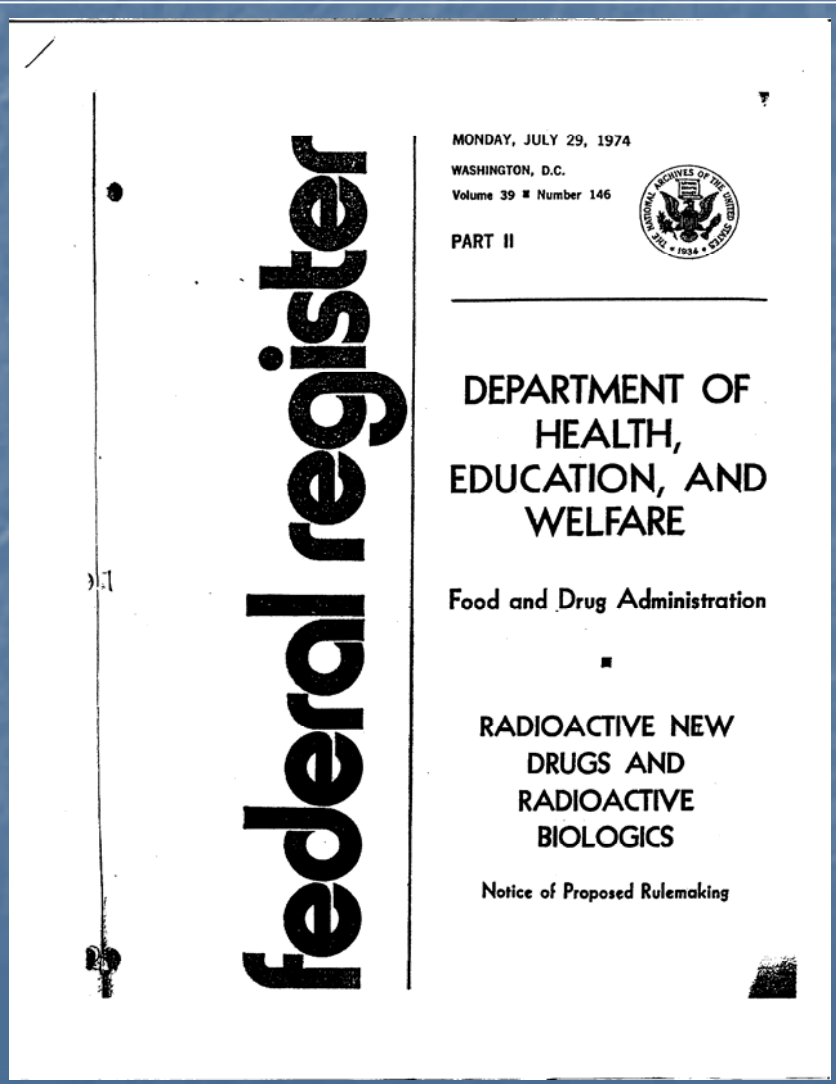
Self Assessment Questions

Have I learned?

5. A RDRC is composed of a minimum of 5 members, 3 of which are required and must include: 1) a physician recognized as a specialist in nuclear medicine, 2) a person qualified by training and experience to formulate radioactive drugs, and 3) a person with special competence in radiation safety and radiation dosimetry.

6. A RDRC is required to file an annual report by January 31 of each year which is to include the names and qualifications of the members and of any consultant and a study summary report for each study conducted during the preceding year.

A Little History



federal register

MONDAY, JULY 29, 1974
WASHINGTON, D.C.
Volume 39 ■ Number 146

PART II

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

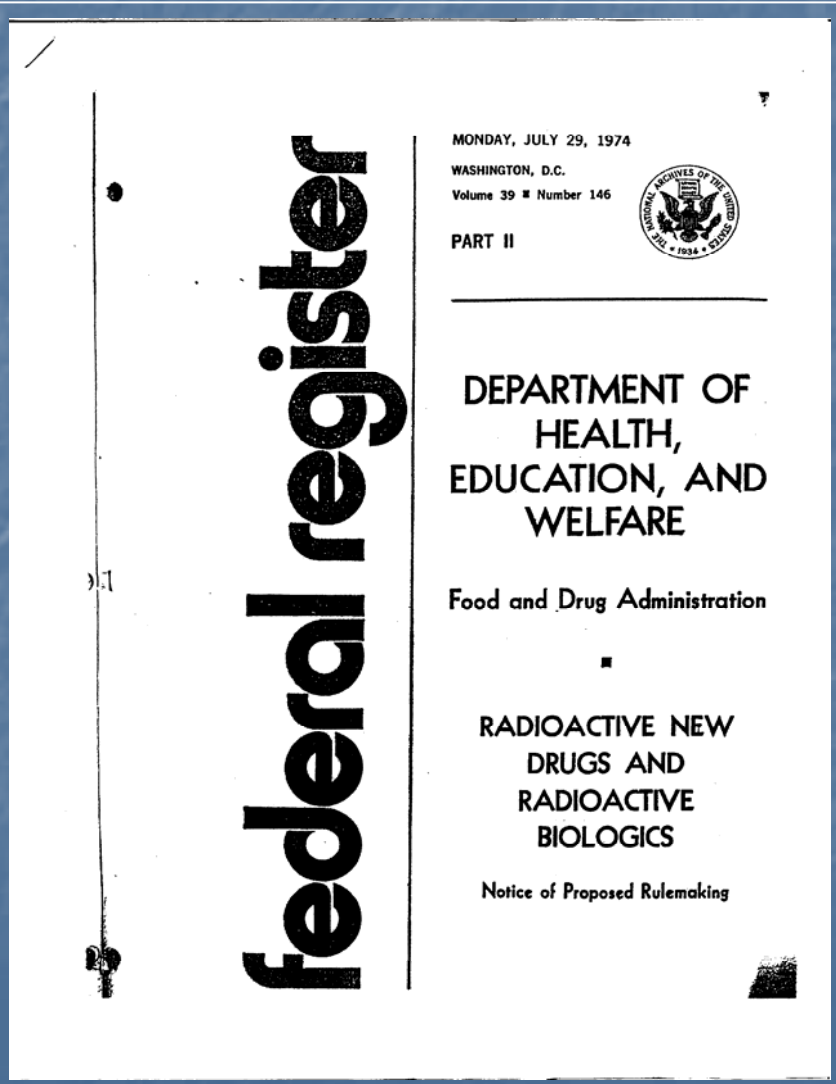
Food and Drug Administration

RADIOACTIVE NEW DRUGS AND RADIOACTIVE BIOLOGICS

Notice of Proposed Rulemaking

- Prior to 1975 AEC (Atomic Energy Commission) regulated reactor produced radioactive drugs
- January 8, 1963 Federal Register notice temporarily exempted radioactive new drugs for investigational use from requirements of § 312.1

A Little History (continued)



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PART II

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

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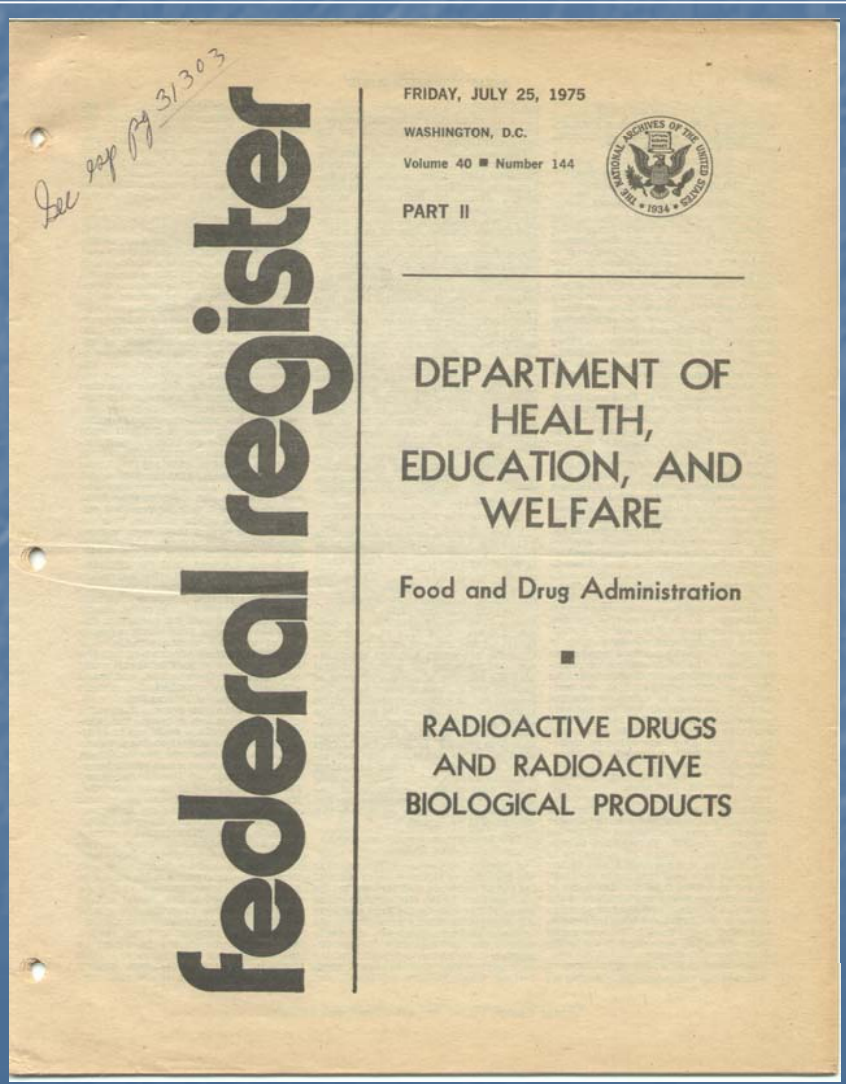
RADIOACTIVE NEW DRUGS AND RADIOACTIVE BIOLOGICS

Notice of Proposed Rulemaking

- The purpose of the exemption was to allow Federal agencies to explore ways to avoid unnecessary duplication of regulatory control
- AEC and FDA concluded ALL radioactive drugs should now be subject to the same clearance procedures as other drugs

A Little History (continued)



- FDA established regulations on August 25, 1975 to regulate ALL radioactive drugs
- Determined that all radioactive drugs are either New Drugs or GRAS/E Generally Recognized As Safe and Effective
- ALL radioactive drugs now subject to an IND, NDA or biological product license
- EXCEPT radioactive drugs used for certain research uses

The Regulation

- 21 CFR 361 Prescription Drugs for Human Use Generally Recognized as Safe and Effective and Not Misbranded: Drugs Used In Research

  § 361.1 Radioactive drugs for certain research uses.

Research under an RDRC

- Four conditions set in § 361.1

1. Basic Science Research
2. Pharmacological dose limit
3. Radiation dose limits
4. Radioactive Drug Research Committee

1. Basic Science Research

§ 361.1(a)

The research is considered Basic Science Research and done for the purpose of advancing scientific knowledge

- Intended to obtain basic information on
  1. Metabolism of a radioactive drug
     - Kinetics
     - Distribution
     - Dosimetry
     - Localization
  2. Human physiology, pathophysiology, or biochemistry.

- Not intended for immediate benefit to the study subject.
  - No therapy, diagnosis or preventative benefit

- Not intended to determine the safety and effectiveness of a radioactive drug as a therapy, diagnostic, or preventative medical product.

2. Pharmacological Dose Limit

§ 361.1(b)(2)

- The dose of active ingredient or combination of active ingredients to be administered shall be known not to cause *any clinically detectable pharmacological effect* in human beings.

3. Radiation Dose Limits

§ 361.1(b)(3)(i)

- Whole body, active blood-forming organs, lens of the eye, and gonads:
  Single dose..... 3 rem
  Annual and total dose commitment..... 5 rem

- Other organs:
  Single dose..... 5 rem
  Annual and total dose commitment..... 15 rem

3. Radiation Dose Limits Pediatric

§ 361.1(b)(3)(ii)

Subjects <18 years old = 10% of adult limits

- Whole body, active blood-forming organs, lens of the eye, and gonads:
  Single dose..... 0.3 rem
  Annual and total dose commitment..... 0.5 rem

- Other organs:
  Single dose..... 0.5 rem
  Annual and total dose commitment..... 1.5 rem

3. Radiation Dose Limits

§ 361.1(b)(3)(iii)

- To determine radiation dose limits are not exceeded:
  - ALL radioactive material whether essential or contaminant included in calculations,
  - Any X-ray procedure as integral part of study e.g.
    - Transmission scans – PET/SPECT
    - DEXA scans

3. Radiation Dose Limits

§ 361.1(b)(3)(iv)

- Numerical definition of dose based on absorbed fraction method:
  - MIRD (Medical Internal Radiation Dose), or ICRP (International Commission on Radiological Protection)

4. The RDRC

§ 361.1(c)(1)

Associated:

- With a medical institution

  or

- Committee established by a State authority to provide advice on radiation health matters.

Joint committees involving more than one medical institution are also acceptable.

an Approved RDRC

- Fulfills requirements for
  - Membership,
  - Function, and
  - Reporting
- Has an application that FDA accepted as meeting these criteria.
- FDA must approve application BEFORE an RDRC may approve research studies under § 361.1

Membership

Minimum of 5 members.

- Three required membership categories:
  1. A physician recognized as a specialist in nuclear medicine,
  2. A person qualified by training and experience to formulate radioactive drugs,
  3. A person with special competence in radiation safety and radiation dosimetry.
- Other voting members.
- Consultants.
- Non-voting members.

Functions (administrative)

Each Committee shall:

- Select a Chairperson who signs
  - Applications
  - Minutes
  - Reports
- Meet at least once each quarter
  - When research activity is authorized or conducted,
  - Meeting quorum is more than 50% of membership with representation from each of 3 required membership categories.
- Keep minutes of meetings with numerical results of votes.
  - No member can vote on a protocol in which they are an investigator.

Reports

Submit by January 31

- Annual Report
  - Membership Summary – FDA Form 2914
  - Study Summary – FDA Form 2915

- Special Summary report – FDA Form 2915
  - IMMEDIATELY submit to FDA when -
    - Study approved for >30 subjects
    - Study approved with subjects <18 years old
  - Justification statement for reason of the approval

FDA 2914

Membership Summary

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

RADIOACTIVE DRUG RESEARCH COMMITTEE (RDRC)

REPORT ON RESEARCH USE OF RADIOACTIVE DRUGS

MEMBERSHIP SUMMARY

Form Approved: OMB No. 0910-0053. Expiration Date: 2/29/08

DATE OF SUBMISSION

FOR FDA USE ONLY

NOTE: 21 CFR 361.1 Requires that an annual report be submitted by each RDRC. Use Form FDA 2914 to report names and qualifications of RDRC members and consultants. Also use Form FDA 2915 to add special summaries, as required.

Return COMPLETED form to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Oncology Drug Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

Attention: RDRC

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the address on the right. ▶

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Oncology Drug Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

A. GENERAL INFORMATION

1. RDRC COMMITTEE NUMBER
2. NAME OF INSTITUTION
3. RDRC CHAIRPERSON
   a. Name
   b. Address *(Include ZIP code)*
   c. E-mail Address
   d. Telephone No. *(Include Area Code)*
   e. Fax No. *(Include Area Code)*

B. REQUIRED MEMBERS *(Names and Qualifications)*

NOTE: Names must be listed. Qualifications previously submitted to FDA may be incorporated by reference to the appropriate submission. An individual may not be listed in more than one required specialty.

1. PHYSICIAN(S) RECOGNIZED AS SPECIALIST(S) IN NUCLEAR MEDICINE

	Name	Are qualifications attached?	If No, enter date of most recently submitted curriculum vitae
a.		☐ Yes ☐ No	
b.		☐ Yes ☐ No	
c.		☐ Yes ☐ No	

2. PERSON(S) QUALIFIED BY TRAINING AND EXPERIENCE TO FORMULATE RADIOACTIVE DRUGS

	Name	Are qualifications attached?	If No, enter date of most recently submitted curriculum vitae
a.		☐ Yes ☐ No	
b.		☐ Yes ☐ No	
c.		☐ Yes ☐ No	

3. PERSON(S) WITH SPECIAL COMPETENCE IN RADIATION DOSIMETRY

	Name	Are qualifications attached?	If No, enter date of most recently submitted curriculum vitae
a.		☐ Yes ☐ No	
b.		☐ Yes ☐ No	
c.		☐ Yes ☐ No	

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PSC Media Arts (301) 443-1090 E37

C. OTHER VOTING MEMBERS *(Names and Disciplines; Specialties)*

D. COMMITTEE CONSULTANTS *(i.e., Pediatrician) (Names and Disciplines; Specialties)*

E. NON-VOTING MEMBERS, IF ANY *(Names and Position Titles)*

F. STUDY SUMMARY TOTAL AND CHAIRPERSON SIGNATURE

1. NUMBER OF STUDY SUMMARIES SUBMITTED IN THIS REPORT
2. SIGNATURE OF RDRC CHAIRPERSON
3. DATE

FOR FDA USE ONLY

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FDA 2914

Membership Summary

Instructions for Completing Radioactive Drug Research Committee (RDRC) Report on Research Use of Radioactive Drugs -- Membership Summary (Form FDA 2914)

Basic research with radioactive drugs may be conducted without an Investigational New Drug Application (IND) when the research is conducted under a FDA-approved Radioactive Drug Research Committee (RDRC) and other conditions, as specified in the RDRC regulations, are met.

RDRC regulations are contained in Title 21, Code of Federal Regulations, Part 361.1 (21 CFR 361.1). Copies of the regulations and forms and further guidance regarding RDRC procedures are available from the FDA Center for Drug Evaluation and Research, Office of Oncology Drug Products, 5901-B Ammendale Road, Beltsville, MD 20705-1266. In addition, the regulations may be accessed at *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=361.1*. Microsoft Word versions of the forms (which can be filled out and saved on your computer) may be accessed at: *http://www.fda.gov/opacom/morechoices/fdaforms/FDA-2914.DOC* and *http://www.fda.gov/opacom/morechoices/fdaforms/FDA-2915.DOC*.

The following instructions address only the administrative aspects of preparing and submitting Form FDA 2914 (Membership Summary) for the following RDRC submissions:

1. **Original Application**
   An application for FDA approval of a RDRC consists of submission of Form FDA 2914 (Membership Summary), a current and dated curriculum vitae for each proposed committee member, and a statement that the RDRC agrees to comply with the requirements under 21 CFR 361.1.

2. **Annual Report**
   The annual report, due on or before January 31 of each year, consists of submission of Form FDA 2914 (Membership Summary) and Form FDA 2915 (Study Summary) for each study conducted during the preceding calendar year. A Form FDA 2915 (Study Summary) should be submitted even for studies that did not enroll any subjects in the preceding calendar year but have been previously approved by the RDRC and are still open and ongoing.

3. **Membership Changes**
   Changes in membership and applications for new members must be submitted as soon as, or before, vacancies occur on the committee and consists of submission of Form FDA 2914 (Membership Summary) and a current and dated curriculum vitae for each proposed committee member.

WHERE TO SEND THE SUBMISSION:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Oncology Drug Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

Specific instructions for filling out this report are on the next page.

FILLING OUT FORM FDA 2914

(Titles and numbers, when used, correspond to the item blocks on Form FDA 2914)

Section A. General Information

1. **RDRC Committee Number** -- Provide the committee number assigned by FDA when the RDRC was initially approved. Leave blank for original applications.
2. **Name of Institution** -- Provide the name of the medical institution to which the RDRC is affiliated. For annual reports and membership changes, if the name of the medical institution is different from that provided in the previous submission, please attach a cover letter specifying the old and new names.
3. **RDRC Chairperson**
   a. NAME..... Provide the name of the chairperson of the RDRC.
   b. ADDRESS..... Provide the address to which written correspondence from FDA should be directed. If this address is a post office box number, a street address must also be provided.
   c. E-MAIL..... Provide the e-mail address of the RDRC chairperson to which electronic correspondences from FDA should be directed.
   d. TELEPHONE NO.... Provide the telephone number where the RDRC chairperson is usually available during normal working hours. A telephone number must be provided.
   e. FAX NO..... Provide the fax number of the RDRC chairperson to which facsimile correspondences from FDA should be directed.

MEMBERSHIP *-- For original applications and annual reports, fill in sections B. through E. referenced below. For membership changes, fill in only those sections, B. through D., for which new members are proposed.*

Section B. Required Members -- Provide the names and qualifications of each required member:

1. Physician recognized as a specialist in nuclear medicine
2. Person qualified by training and experience to formulate radioactive drugs
3. Person with special competence in radiation safety and radiation dosimetry

If there are more than three members in a required speciality, attach a separate sheet.

Attach a current and dated curriculum vitae describing relevant degrees, training, and experience for each required member. If this is an annual report and qualifications have been previously submitted to FDA, provide the date(s) of the previous submission(s).

Section C. Other Voting Members -- Provide the names, disciplines, and specialties of other committee members.

Section D. Committee Consultants -- Provide the names, disciplines, and specialties of committee consultants.

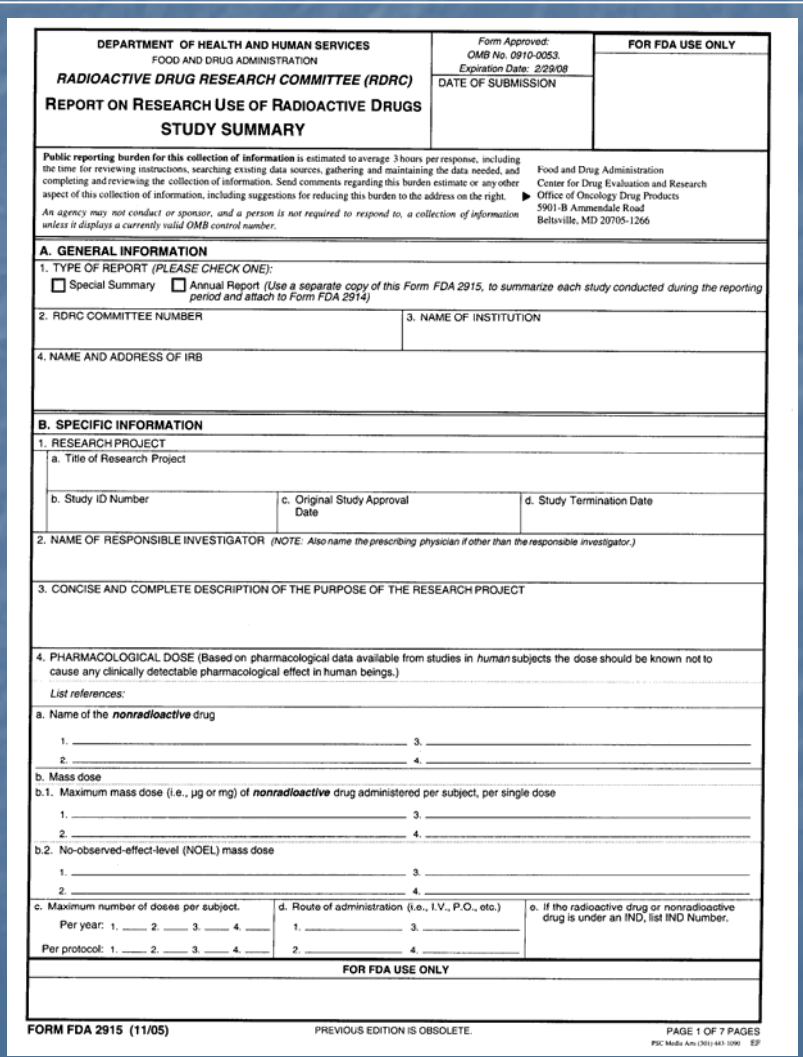
Section E. Non-Voting Members, if any -- Provide the names and position titles of non-voting committee members.

Section F. Study Summary Total and Chairperson Signature

1. *Number of Study Summaries Submitted in This Report* -- For annual reports, provide the number of studies included in the submission. For original applications and membership changes, leave blank.
2. *Signature of the RDRC Chairperson* -- The RDRC chairperson must sign the form.
3. *Date* -- Indicate the date the form is signed by the RDRC chairperson.

FDA 2915

Study Summary



DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

RADIOACTIVE DRUG RESEARCH COMMITTEE (RDRC)

REPORT ON RESEARCH USE OF RADIOACTIVE DRUGS
STUDY SUMMARY

Form Approved: OMB No. 0910-0053. Expiration Date: 2/29/08

DATE OF SUBMISSION

FOR FDA USE ONLY

Public reporting burden for this collection of information is estimated to average 3 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the address on the right.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Oncology Drug Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

A. GENERAL INFORMATION

1. TYPE OF REPORT *(PLEASE CHECK ONE)*:
☐ Special Summary ☐ Annual Report *(Use a separate copy of this Form FDA 2915, to summarize each study conducted during the reporting period and attach to Form FDA 2914)*

2. RDRC COMMITTEE NUMBER

3. NAME OF INSTITUTION

4. NAME AND ADDRESS OF IRB

B. SPECIFIC INFORMATION

1. RESEARCH PROJECT
a. Title of Research Project
b. Study ID Number
c. Original Study Approval Date
d. Study Termination Date

2. NAME OF RESPONSIBLE INVESTIGATOR *(NOTE: Also name the prescribing physician if other than the responsible investigator.)*

3. CONCISE AND COMPLETE DESCRIPTION OF THE PURPOSE OF THE RESEARCH PROJECT

4. PHARMACOLOGICAL DOSE (Based on pharmacological data available from studies in *human* subjects the dose should be known not to cause any clinically detectable pharmacological effect in human beings.)

List references:

a. Name of the ***nonradioactive*** drug
1. 2. 3. 4.

b. Mass dose
b.1. Maximum mass dose (i.e., µg or mg) of ***nonradioactive*** drug administered per subject, per single dose
1. 2. 3. 4.

b.2. No-observed-effect-level (NOEL) mass dose
1. 2. 3. 4.

c. Maximum number of doses per subject.
Per year: 1. 2. 3. 4.
Per protocol: 1. 2. 3. 4.

d. Route of administration (i.e., I.V., P.O., etc.)
1. 3. 2. 4.

e. If the radioactive drug or nonradioactive drug is under an IND, list IND Number.

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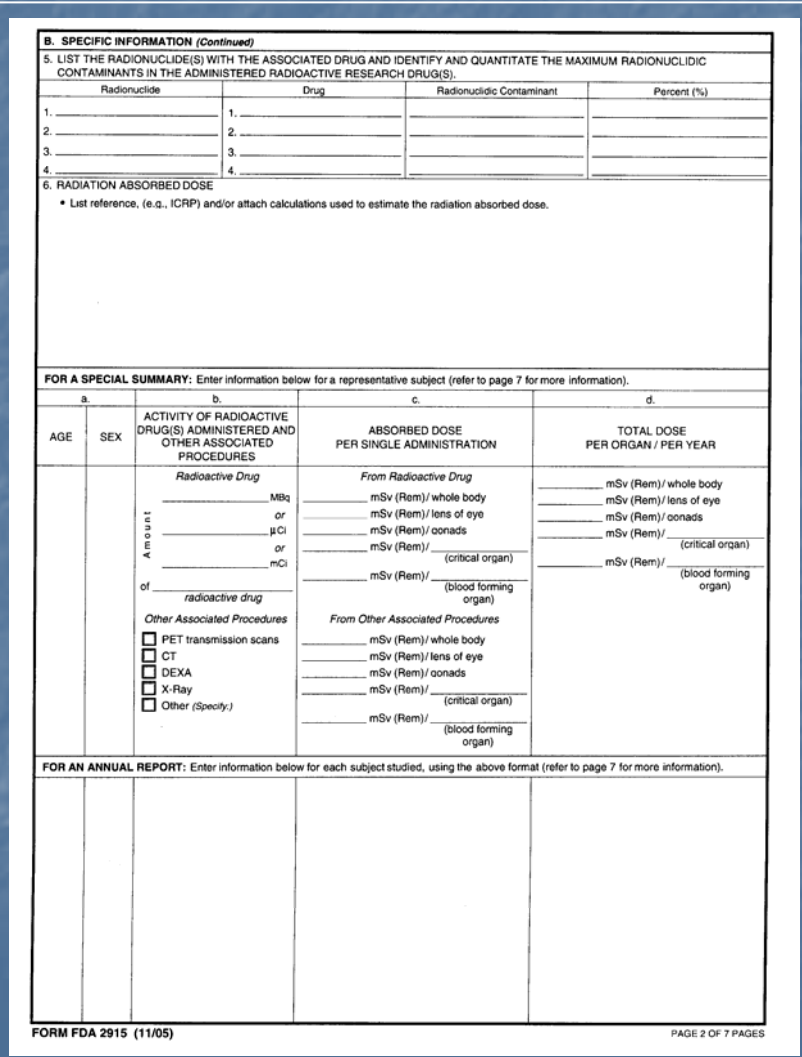

B. SPECIFIC INFORMATION *(Continued)*

5. LIST THE RADIONUCLIDE(S) WITH THE ASSOCIATED DRUG AND IDENTIFY AND QUANTITATE THE MAXIMUM RADIONUCLIDIC CONTAMINANTS IN THE ADMINISTERED RADIOACTIVE RESEARCH DRUG(S).

Radionuclide	Drug	Radionuclidic Contaminant	Percent (%)
1.	1.		
2.	2.		
3.	3.		
4.	4.		

6. RADIATION ABSORBED DOSE
- List reference, (e.g., ICRP) and/or attach calculations used to estimate the radiation absorbed dose.

FOR A SPECIAL SUMMARY: Enter information below for a representative subject (refer to page 7 for more information).

a. AGE	a. SEX	b. ACTIVITY OF RADIOACTIVE DRUG(S) ADMINISTERED AND OTHER ASSOCIATED PROCEDURES	c. ABSORBED DOSE PER SINGLE ADMINISTRATION	d. TOTAL DOSE PER ORGAN / PER YEAR
		Radioactive Drug Amount: _____ MBq *or* _____ µCi *or* _____ mCi of _____ *radioactive drug* *Other Associated Procedures* ☐ PET transmission scans ☐ CT ☐ DEXA ☐ X-Ray ☐ Other *(Specify.)*	*From Radioactive Drug* _____ mSv (Rem)/ whole body _____ mSv (Rem)/ lens of eye _____ mSv (Rem)/ gonads _____ mSv (Rem)/ _____ (critical organ) _____ mSv (Rem)/ _____ (blood forming organ) *From Other Associated Procedures* _____ mSv (Rem)/ whole body _____ mSv (Rem)/ lens of eye _____ mSv (Rem)/ gonads _____ mSv (Rem)/ _____ (critical organ) _____ mSv (Rem)/ _____ (blood forming organ)	_____ mSv (Rem)/ whole body _____ mSv (Rem)/ lens of eye _____ mSv (Rem)/ gonads _____ mSv (Rem)/ _____ (critical organ) _____ mSv (Rem)/ _____ (blood forming organ)

FOR AN ANNUAL REPORT: Enter information below for each subject studied, using the above format (refer to page 7 for more information).

FORM FDA 2915 (11/05) PAGE 2 OF 7 PAGES

FDA 2915

Study Summary

B. SPECIFIC INFORMATION *(Continued)*

6. RADIATION ABSORBED DOSE *(Continued)*

a. AGE	a. SEX	b. ACTIVITY OF RADIOACTIVE DRUG(S) ADMINISTERED AND OTHER ASSOCIATED PROCEDURES	c. ABSORBED DOSE PER SINGLE ADMINISTRATION	d. TOTAL DOSE PER ORGAN / PER YEAR

FORM FDA 2915 (11/05) PREVIOUS EDITION IS OBSOLETE. PAGE 3 OF 7 PAGES

B. SPECIFIC INFORMATION *(Continued)*

6. RADIATION ABSORBED DOSE *(Continued)*

a. AGE	a. SEX	b. ACTIVITY OF RADIOACTIVE DRUG(S) ADMINISTERED AND OTHER ASSOCIATED PROCEDURES	c. ABSORBED DOSE PER SINGLE ADMINISTRATION	d. TOTAL DOSE PER ORGAN / PER YEAR

e. NUMBER OF RESEARCH SUBJECTS STUDIED THIS REPORTING YEAR	
f. NUMBER OF RESEARCH SUBJECTS STUDIED THIS REPORTING YEAR UNDER 18 YEARS OF AGE	
g. CUMULATIVE NUMBER OF RESEARCH SUBJECTS STUDIED FROM INITIATION OF THIS PROTOCOL THROUGH END OF THIS REPORT	
h. TOTAL NUMBER OF RESEARCH SUBJECTS FOR WHICH THIS PROTOCOL IS APPROVED	

If additional space is needed, attach separate sheet(s)

7. CLAIM OF CONFIDENTIALITY

Contents of this report are available for public disclosure unless confidentiality is requested by the investigator and it is adequately shown by the investigator that the report constitutes a trade secret or confidential commercial information as defined in 21 CFR 20.61.

☐ I do not claim confidentiality.
☐ I claim confidentiality; justification is attached.

RETURN COMPLETED FORM TO:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Oncology Drug Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

Attention: RDRC

8. **CERTIFICATION**

The undersigned certify that the study outlined above complies with Title 21 CFR Section 361.1 and that the responses are true and accurate as outlined above.

SIGNATURE OF INVESTIGATOR	DATE
SIGNATURE OF CHAIRPERSON OF RADIOACTIVE DRUG RESEARCH COMMITTEE	DATE

FORM FDA 2915 (11/05) PAGE 4 OF 7 PAGES

FDA 2915

Study Summary

Instructions for Completing Radioactive Drug Research Committee (RDRC) Report on Research Use of Radioactive Drugs -- Study Summary (Form FDA 2915)

Basic research with radioactive drugs may be conducted without an Investigational New Drug Application (IND) when the research is conducted under a FDA-approved Radioactive Drug Research Committee (RDRC) and other conditions, as specified in the RDRC regulations, are met.

RDRC regulations are contained in Title 21, Code of Federal Regulations, Part 361.1 (21 CFR 361.1). Copies of the regulations and forms and further guidance regarding RDRC procedures are available from the FDA Center for Drug Evaluation and Research, Office of Oncology Drug Products, 5901-B Ammendale Road, Beltsville, MD 20705-1266. In addition, the regulations may be accessed directly at *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=361.1*. Microsoft Word versions of the forms (which can be filled out and saved on your computer) may be accessed at: *http://www.fda.gov/opacom/morechoices/fdaforms/FDA-2914.DOC* and *http://www.fda.gov/opacom/morechoices/fdaforms/FDA-2915.DOC*.

The following instructions address only the administrative aspects of preparing and submitting Form FDA 2915 (Study Summary) for the following RDRC submissions:

1. **Annual Report**
   The annual report, due on or before January 31 of each year, consists of submission of Form FDA 2914 (Membership Summary) and Form FDA 2915 (Study Summary) for each study conducted during the preceding calendar year. A Form FDA 2915 (Study Summary) should be submitted even for studies that did not enroll any subjects in the preceding calendar year but have been previously approved by the RDRC and are still open and ongoing.

2. **Special Summary**
   A special summary must be submitted to FDA at the time the RDRC approves research studies involving more than 30 subjects or involving subjects under the age of 18. A special summary consists of the submission of Form FDA 2915 (Study Summary) and a justification for the number of subjects or the inclusion of subjects under 18 years of age. In addition, provide the maximum radiation dose commitment for the organs listed in 21CFR361.1(b)(3)(i) by a representative subject.

WHERE TO SEND THE SUBMISSION:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Oncology Drug Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

ATTN: RDRC

Specific instructions for filling out this report begin on the next page.

FILLING OUT FORM FDA 2915

(Titles and numbers, when used, correspond to the item blocks on Form FDA 2915)

Section A. General Information

1. **Type of Report** -- Check the appropriate box indicating whether this is a special summary or an annual report. If this is a special summary, provide a justification for the need to study more than 30 subjects or to study subjects under the age of 18. Studies involving minors must be supported with review by a qualified pediatric consultant to the RDRC and documented in the special summary.
2. **RDRC Committee Number** -- Provide the committee number assigned by FDA when the RDRC was initially approved.
3. **Name of Institution** -- Provide the name of the medical institution to which the RDRC is affiliated.
4. **Name and Address of IRB** -- Provide the name and address of the Institutional Review Board (IRB) that approved the study protocol.

Section B. Specific Information

1. **Research Project** -- Check the appropriate box indicating whether this is a special summary or an annual report. If this is a special summary, provide a justification for the need to study more than 30 subjects or to study subjects under the age of 18. Studies involving minors must be supported with review by a qualified pediatric consultant to the RDRC and documented in the special summary.
   a. *Title of Research Project* -- Provide a unique and brief title of the research protocol that includes the name of the radioactive drug[1].
   b. *Study ID Number* -- Provide the unique number assigned to the research protocol by the Institution or RDRC for tracking purposes. A study ID number ***must*** be provided.
   c. *Original Study Approval Date* -- Provide the date the research protocol was approved by the RDRC for the first time.
   d. *Study Termination Date* -- Provide the date the research protocol was completed or terminated.
2. **Name of Responsible Investigator** -- Provide the name of the Principal Investigator and the name of the prescribing physician, if other than the Principal Investigator.
3. **Concise and Complete Description of the Research Project** -- Self-explanatory.
4. **Pharmacological Dose** -- This is the mass dose of the nonradioactive drug to be investigated that will not cause a clinically detectable pharmacologic effect in humans. Please cite relevant published literature or other valid human studies supporting the use of this dose. If necessary, attach a separate sheet.
   a. *Name of the Nonradioactive Drug* -- Provide the name of the nonradioactive drug being investigated. The use of the term "drug" in this section is synonymous with the terms moiety, active ingredient, compound, or ligand.
   b. *Mass Dose*
      b.1. *Maximum mass dose* -- This is the maximum amount of nonradioactive drug administered per subject per single dose at the expiration time of the radiolabeled drug to be administered. Indicate amount in terms of mass or weight expressed in units of µg or mg only.
      b.2. *No observed effect level (NOEL) mass dose* -- This is the pharmacologic dose of the nonradioactive drug that will not cause a clinically detectable pharmacologic effect in humans. This is not necessarily the administered dose.
   c. *Maximum number of doses per subject* -- Specify the number of administrations of the radioactive drug a research subject may receive per year and the total number of doses specified in the protocol.
   d. *Route of administration* -- Indicate the route of administration (e.g. I.V., P.O., etc.).
   e. *If the drug is under an IND, list IND Number* -- If the radioactive drug or the nonradioactive drug is being investigated under an Investigational New Drug Application (IND), identify the IND number.
5. **List the radionuclides with the associated drug and identify and quantitate the maximum radionuclide contaminants in the administered radioactive drug upon expiration.** -- Self-explanatory.

[1] The term "radioactive drug" is defined in 21 CFR 310.3(n) and includes a "radioactive biological product" as defined in 21 CFR 600.3(ee).

FDA 2915

Study Summary

FILLING OUT FORM FDA 2915 *(Continued)*

Section B. Specific Information *(Continued)*

6. **Radiation Absorbed Dose**

- All study summaries should list the specific reference(s) that were used to estimate the dose commitments (e.g., ICRP Publication 80 Table 3.2.1). For those radioactive drugs for which no reference(s) are available, list your assumptions and show your calculations. The report should include the dose contribution from the administered radioactive research drug and any other associated procedures (i.e., would not have occurred but for the study) contributing to the radiation absorbed dose.
- For a **special summary**, provide the maximum radiation dose commitment to the whole body, the critical organ, and each organ as specified in 21 CFR 361.1(b)(3)(i) received by a *representative* subject.
- For an **annual report**, provide the radiation dose commitment to the whole body, the critical organ, and each organ as specified in 21 CFR 361.1(b)(3)(i) received by *each* subject receiving the radioactive research drug during the reporting calendar year. For each subject, provide (a) Age and Sex; (b) the amount of radioactivity administered for each radioactive drug used in the study; (c) the absorbed dose to the whole body, the critical organ, and each organ specified in 21 CFR 361.1(b)(3)(i) per single administration for each radioactive drug and other procedures associated with the study; and (d) the resultant cumulative radiation dose to the subject for the whole body and organs referenced above within the calendar year.

a. *Age and Sex* -- Specify the age and sex for each individual research subject studied.

b. *Activity of Radioactive Drug(s) Administered and Other Associated Procedures* -- For each individual research subject identified in column a, provide the amount of radioactivity administered along with the name of each radioactive drug received. Express each amount of radioactivity in MBq, µCi, or mCi. FDA prefers you use the International System of Units (SI). Note: 37 MBq = 1mCi.

For other associated procedures (i.e., would not have occurred but for the study), identify the sources of radiation.

c. *Absorbed Dose per Single Administration* -- Provide the radiation absorbed dose in mSv [1 mSv = 100 mrem] for each target organ, e.g. whole body, lens of eye, gonads, and critical organ(s).

d. *Total Dose Per Organ/Per Year* -- Provide the total radiation dose from the radioactive drug and associated procedures per organ for a 12-month period of time, usually a calendar year, unless otherwise specified.

e. *Number of Research Subjects Studied this Reporting Year* -- Self-explanatory.

f. *Number of Research Subjects Studied this Reporting Year Under 18 years of Age* -- Self-explanatory.

g. *Cumulative Number of Research Subjects Studied from Initiation of this Protocol Through End of this Report* -- Self-explanatory.

h. *Total Number of Research Subjects for Which this Protocol is Approved* -- Self-explanatory.

7. **Claim of Confidentiality** -- Indicate whether or not you are claiming confidentiality. If confidentiality is claimed, attach a justification demonstrating that this report constitutes a trade secret or confidential information as defined in 21 CFR 20.61.

8. **Certification** -- The Principal Investigator and the RDRC chairperson must sign the form. Indicate the date(s) the form is signed by the Principal Investigator and by the RDRC chairperson.

Study Approval Functions

- The RDRC must determine that the research protocol meets the following requirements:

1. Radiation dosimetry parameters are as low as reasonably achievable (ALARA) (§ 361.1(d)(1)) and meet the limits specified in § 361.1(b)(3).

2. The amount of active ingredient(s) is known not to cause a clinically detectable pharmacological effect ***based on published data from human studies*** or from other valid human studies cited in the protocol (§ 361.1(d)(2)).

Study Approval Functions
(cont.)

- The RDRC must determine that the research protocol meets the following requirements:

3. Study investigators are qualified by training and experience to conduct the study (§ 361.1(d)(3)).

4. The medical facility is properly licensed to possess and handle radioactive materials (§ 361.1(d)(4)).

Study Approval Functions
(cont.)

- The RDRC must determine that the research protocol meets the following requirements:

5. The selection and consent of research subjects is appropriate (i.e., age limitations and pregnancy exclusion) (§ 361.1(d)(5)).

6. The quality of the radioactive drug to be administered meets appropriate standards (i.e., pyrogen and sterility testing, radiochemical and radionuclidic purity) as needed for safety and be of such uniform and reproducible quality as to give significance to the research study conducted (§ 361.1(d)(6)).

Study Approval Functions
(cont.)

- The RDRC must determine that the research protocol meets the following requirements:

7. The research protocol design has scientific worth and is based on a sound rationale (§ 361.1(d)(7)).

8. The protocol includes provisions for the reporting of adverse events to the RDRC and then immediately to the FDA (§ 361.1(d)(8)).

Study Approval Functions
(cont.)

- The RDRC must determine that the research protocol meets the following requirements:

9. The protocol receives concurrent approval by an appropriate institutional review board (IRB) (§ 361.1(d)(9)).

10. Labeling requirements (§ 361.1(f)), assure the statements:
    - "Rx only“;
    - "To be administered in compliance with the requirements of Federal regulations regarding radioactive drugs for research use (21 CFR 361.1)"

Protocol Review Checklist

RDRC PROTOCOL REVIEW CHECKLIST: Criteria for the Evaluation of the Appropriateness of Research Studies under a RDRC

To approve a proposed research study, the RDRC must consider the following:

	YES	NO	N/A
1. Is the pharmacological dose within the following limits?			
A. The amount of active ingredient or combination of active ingredients shall be known to not cause any clinically detectable pharmacological effect in humans.			
* Sufficient documentation provided.			
B. If the same active ingredients (exclusive of the radionuclide) are to be administered simultaneously (e.g., under an IND or for a therapeutic use), the total amount of active ingredients including the radionuclide shall be known not to exceed the dose limitations applicable to the separate administration of the active ingredient excluding the radionuclide.			
*Sufficient documentation provided.			
2. Were pharmacological dose calculations based on data available from published literature or from other valid studies?			
3. Is the radiation dose within the following limits?			
A. Subject must receive the smallest radiation dose practical to perform the study.			
*Absorbed dose calculations based on biologic distribution data available from published literature or from other valid studies was provided.			
*An acceptable method of radioassay of the radioactive drug prior to its use was provided.			
*Adequate and appropriate instrumentation for the detection and measurement of the specific radionuclide will be utilized.			

1

	YES	NO	N/A
*The radioactive drug has the combination of half-life, type of radiation, radiation energy, metabolism, and chemical properties that results in the lowest dose to the whole body or specific orifices which is passable to obtain the necessary information.			
B. For adult subject: Under no circumstances may radiation dose from a single study or cumulatively from a number of studies conducted within 1 year exceed:			
*Whole body, active blood-forming organs, lens of eye, and gonads:			
Single dose 3 Rems			
Annual & total dose 5 Rems			
* Other organs:			
Single dose 5 Rems			
Annual & Total Dose 15 Rems			
C. For subject under 18 years of age: Radiation dose may not exceed 10 percent of dose set forth above.			
D. When determining total radiation doses and dose commitments must consider:			
*All radioactive material included in drug either as essential material or as significant contaminant or impurity.			
* X-ray procedures that are part of the research study.			
* Possibility of follow-up studies.			
E. Are the numerical definitions of dose based on absorbed fraction method of radiation absorbed dose calculation (e.g., system set forth by Medical Internal Radiation Dose Committee of the Society of Nuclear Medicine or by the International Commission on Radiological Protection)?			
*Sufficient documentation provided.			
4. Is the radiation exposure justified by the quality of the study being undertaken and the importance of the information it seeks to obtain?			

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Protocol Review Checklist

	YES	NO	N/A
5. Is each investigator qualified by training and experience to conduct the proposed research studies?			
6. Is the investigator's or institution's license to handle radioactive materials appropriate? Does the investigator meet the following requirements?			
A. For reactor-produced isotopes: The investigator or institution shall be licensed by the Nuclear Regulatory Commission or Agreement State to possess and use the specific radionuclides for research use or be a listed investigator under a broad license.			
B. For non-reactor-produced isotopes: The investigator or institution shall be licensed by other appropriate State or local authorities, when required by state or local law.			
7. Is the use of human subjects appropriate and does it meet the following requirements?			
A. Number of subjects should not exceed 30.			
B. Research must be reviewed and approved by an institutional review board and consent must be obtained from the subjects or legal representatives.			
C. Research subjects must be at least 18 years of age and legally competent.			
D. Exceptions to preceding requirement only permitted if:			
*Investigator can demonstrate that: 1) the study presents a unique opportunity to gain information not currently available; 2) requires use of subjects less than 18 years of age; 3) is without significant risk to subjects.			
*RDRC review is supported with review by qualified pediatric consultant.			
E. Female subjects of childbearing potential must: 1) state in writing that they are not pregnant or 2) on basis of pregnancy test be confirmed as not pregnant.			

3

	YES	NO	N/A
8. Does the radioactive drug meet appropriate chemical, pharmaceutical, radiochemical, and radionuclidic standards of identity, strength, quality and purity?			
Were the radioactive materials for parenteral use prepared in sterile and pyrogen-free form?			
9. Is the research design appropriate in that:			
A. Scientific knowledge and benefit is likely to result from the study and the research shall be based upon sound rationale derived from appropriate animal studies or published literature;			
B. Scientific knowledge and benefit should be of sound design such that information of scientific value may result.			
C. Will the radiation dose be sufficient and no greater than necessary for purpose of the study?			
D. The projected number of subjects shall be sufficient and no greater than necessary and should reflect the fact that the study is intended to obtain basic research information and not intended for other purposes.			
10. Is the packaging, label, and labeling of the radioactive drug in compliance with Federal, State, and local law regarding radioactive materials?			
Is the label of the immediate container and shielded container, if any, in compliance with RDRC requirements?			

Revised: 10/03

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FDA monitoring of RDRCs

FDA conducts periodic reviews of approved committees by:

- Review of the annual report,
- Review of meeting minutes,
- Review of full protocols for certain studies,
- On-site inspections.

Ways to Study Radioactive Drugs in Human Subjects

- 21 CFR 312 — Investigational New Drug Application
- 21 CFR 312.2 — Exempt from IND requirements
- 21 CFR 361 — Prescription Drugs for Human Use Generally Recognized as Safe and Effective and Not Misbranded: Drugs Used In Research

  § 361.1 Radioactive drugs for certain research uses.

New Drug or GRAS/E

- NEW DRUGS
  - Subject to new drug requirements of the FD&C Act, includes submission of an IND (unless exempt)

- GRAS/E – Generally Recognized As Safe and Effective*
  - Determined by FDA
  - Not subject to the new drug requirements of the FD&C Act (no IND required)
  - 21 CFR 361.1 was established to specify the conditions of use under which drugs for certain research uses would be considered GRAS/E

*General recognition of safety exists only when the mass of the drug to be administered has no clinically detectable pharmacological effect in humans based on experience or studies in human beings.

Purpose of RDRC vs IND Research

RDRC

- The research is intended to obtain basic information regarding:
  - Metabolism of the radioactively labeled drug
    - Kinetics
    - Distribution
    - Dosimetry
    - Localization
  - Human physiology, pathophysiology, biochemistry
- The research is **NOT** intended for immediate therapeutic, diagnostic, or similar purposes, or to determine the safety and effectiveness of the drug in humans for such purposes (i.e., to carry out a clinical trial)

IND

- Intent of the research is not restricted
- Can include:
  - Research involving therapeutic, diagnostic, or preventative benefit to the subject
  - Study of safety and efficacy (a clinical trial)
  - Basic research that does not meet the requirements of § 361.1
  - Basic research that meets the requirements of § 361.1

Review, Approval, and Oversight

RDRC and IND

- **Institutional Review Board (IRB)**
  - 21 CFR 56
  - Responsibilities include:
    - Review of initial research and subsequent changes
      - Authority to approve, require modification in, or disapprove research activities
      - Authority to suspend or terminate approval of research
      - Approval must be obtained prior to implementation
    - Continuing review of ongoing research
  - Criteria for approval:
    - Minimization of risks to subjects; risks are reasonable in relation to anticipated benefits
    - Equitable selection of subjects
    - Compliance with the informed consent requirements of 21 CFR 50, including subpart D if some subjects are children
    - Adequate provision for monitoring data to ensure safety of subjects
    - Protection of rights and welfare of vulnerable subjects
    - Adequate provisions to protect privacy and confidentiality

Review, Approval, and Oversight (cont.)

RDRC

Radioactive Drug Research Committee

- Approved, monitored by FDA
- Responsible for ensuring that the requirements of § 361.1 are met:
  - Qualified study investigators
  - Proper licensure for radioactive materials
  - Appropriate selection and consent of research subjects
  - Appropriate quality of radioactive drug administered
  - Sound research protocol design
  - Reporting of adverse events
  - Approval by an IRB
  - Labeling

IND

FDA

- Reviews:
  - Protocols, protocol changes
  - Study investigators
  - CMC, Pharmacology/Toxicology, PK
  - Information amendments
- Primary objective of the review:
  - To assure the safety and rights of subjects
  - To assess the scientific quality of the clinical investigations
- Ability of sponsor to proceed:
  - First 30 days
  - Ongoing studies

Review, Approval, and Oversight (cont.)

	RDRC	IND
Reporting to FDA	• Annual Report – Study Summary – Membership Summary • Special Summary • Adverse events • If requested – Meeting minutes – Full protocols	• Annual Report • New protocols • Protocol changes • New investigators • Information amendments • Adverse events
Monitoring by FDA	• FDA monitors the activities of the approved RDRCs	• FDA monitors the research
FDA enforcement actions	• Notifications of deficiencies • On-site inspections • Withdrawal of approval of an RDRC	• On-site inspections • Full or partial clinical hold • Termination of an IND

Dosing

	RDRC	IND
Pharmacological dose	**Limited** • Amount of active ingredient must be known not to cause any clinically detectable pharmacological effect in humans, based on published literature or other valid human studies	**Not limited** • Evaluated for safety on a case-by-case basis • Initial dose can be chosen based on animal and/or human data
Radiation dose	**Limited** • Smallest dose with which it is practical to perform the study without jeopardizing the benefits to be obtained from the study • Single dose and annual/total dose limits	**Not limited** • Evaluated for safety on a case-by-case basis

Study Subjects

	RDRC	IND
Informed Consent (21CFR 50)	• Required, including Subpart D	• Required, including Subpart D
Number of Subjects	• Sufficient but no greater than necessary for the purpose of the study • Should Reflect that the study is intended to obtain basic research information (usually <30)	• No Limit
Subjects <18 years of age	• Permitted only in special situations described in § 361.1(d)(5)	• Permitted
Women of child bearing potential	• Must state in writing that she is not pregnant, or be confirmed as not pregnant	• Permitted

Adverse Event (AE) Reporting

RDRC

- Investigator must immediately report to RDRC all AEs associated with use of the radioactive drug in the research study
  - Serious – FDA recommends 2 business days
  - All others – FDA recommends 5 business days
- RDRC must immediately report to FDA all adverse events probably attributable to use of the radioactive drug in the research study
  - Serious – FDA recommends 7 business days
  - All others – FDA recommends 15 business days

IND

- Sponsor must review all information relevant to the safety of the drug from any source, foreign or domestic
  - Clinical trials
  - Literature
  - Animal studies
  - Commercial marketing
  - Unpublished papers
  - Reports from foreign regulatory authorities
- Safety reports
  - Serious/unexpected: file within 15 days of receipt
  - Unexpected fatal or life-threatening: file within 7 days of receipt
- Annual reports

RDRC Trivia

- How many RDRCs have been approved by FDA?
- Which States have the most approved RDRCs?
- Which States have never had an approved RDRC?
- Which States have the most RDRCs which are currently considered “active”?

RDRC Trivia - Answers

- How many RDRCs have been approved by FDA?
  - 201
- Which States have the most approved RDRCs?
  - California & New York = 20
  - Michigan = 14
  - Illinois & Massachusetts = 12
  - Pennsylvania & Texas = 11
  - Next closest = 8
- Which States have never had an approved RDRC?
  - Alaska, Delaware, Hawaii, Mississippi, Montana, Nevada, New Mexico, Wyoming
- Which States have the most RDRCs which are currently considered "active"?
  - California & New York = 11
  - Massachusetts & Texas = 5

RDRC Trivia

As of December 31, 2005

State	Total number of RDRCs chartered per State	Total number of RDRCs "inactive" per State	Total number of RDRCs "active" per State
Alabama	5	4	1
Arizona	2	1	1
Arkansas	1	0	1
California	20	9	11
Colorado	3	2	1
Connecticut	4	3	1
Florida	4	4	0
Georgia	2	1	1
Idaho	1	1	0
Illinois	12	10	2
Indiana	3	2	1
Iowa	1	0	1
Kansas	2	2	0
Kentucky	1	0	1
Louisiana	3	2	1
Maine	1	0	1
Maryland	5	2	3
Massachusetts	12	7	5
Michigan	14	10	4
Minnesota	4	0	4
Missouri	5	4	1
Nebraska	2	1	1
New Hampshire	1	1	0
New Jersey	4	4	0
New York	20	9	11
North Carolina	3	1	2
North Dakota	1	0	1
Ohio	7	4	3
Oklahoma	1	1	0
Oregon	1	1	0
Pennsylvania	11	7	4
Rhode Island	4	4	0
South Carolina	2	2	0
South Dakota	1	1	0
Tennessee	3	0	3
Texas	11	6	5
Unknown	1	1	0
Utah	1	0	1
Vermont	1	1	0
Virginia	4	3	1
Washington	2	1	1
Washington, DC	8	7	1
West Virginia	2	1	1
Wisconsin	5	3	2
Totals =	201	123	78

RDRCs in the United States

Quantity of RDRCs by State for 2005 Reporting Year

RDRC #	RDRC Committee Name	State	Quantity
5	????	????	1
63	University of Alabama at Birmingham Birmingham, Alabama	Alabama	1
76	VA Medical Center Birmingham, Alabama	Alabama	2
140	University of South Alabama Mobile, Alabama	Alabama	3
154	Princeton Baptist Medical Center Birmingham, Alabama	Alabama	4
183	Carraway Methodist Medical Center Birmingham, Alabama	Alabama	5
99	University of Arizona Health Sciences Center Tucson, Arizona	Arizona	1
201	Banner Good Samaritan Medical Center Phoenix, Arizona	Arizona	2
109	University of Arkansas for Medical Sciences Little Rock, Arkansas	Arkansas	1
20	Stanford University School of Medicine Stanford, California	California	1
28	VA San Diego Healthcare System San Diego, California	California	2
36	Los Angeles County University of Southern California Medical Center (LAC+USC Medical Center) Los Angeles, California	California	3
38	Ernest Orlando Lawrence Berkeley National Laboratory Berkeley, California	California	4
41	University of California, Los Angeles - UCLA Los Angeles, California	California	5
47	University of California, San Diego San Diego, California	California	6
54	Harbor-UCLA Research & Education Institute Torrance, California	California	7
59	Loma Linda University Medical Center Loma Linda, California	California	8
60	Veterans Affairs Medical Center, Sepulveda, California	California	9
62	VA Greater Los Angeles Healthcare System Los Angeles, California	California	10
71	University of California San Francisco San Francisco, California	California	11
72	University of California at Berkeley Berkeley, California	California	12
82	Naval Regional Medical Center San Diego, California	California	13
92	University of California - Davis Medical Center Sacramento, California	California	14
96	Letterman Army Medical Center Presidio of San Francisco, California	California	15
98	Jerry L. Pettis Memorial Veterans Medical Center Loma Linda, California	California	16
108	VA Medical Center Long Beach, California	California	17

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Quantity of RDRCs by State for 2005 Reporting Year

RDRC #	RDRC Committee Name	State	Quantity
156	University of California - Irvine Irvine, California	California	18
164	Scripps Clinic and Research Foundation La Jolla, California	California	19
198	Biomedical Research Institute of America San Diego, California	California	20
130	VA Medical Center Denver, Colorado	Colorado	1
135	University of Colorado Health Sciences Center Denver, Colorado	Colorado	2
139	Fitzsimons Army Medical Center Aurora, Colorado	Colorado	3
120	Yale-New Haven Hospital New Haven, Connecticut	Connecticut	1
126	VA Connecticut Healthcare System (West Haven, CT) Department of Veterans Affairs West Haven, Connecticut	Connecticut	2
131	University of Connecticut Health Center Farmington, Connecticut	Connecticut	3
196	Saint Francis Hospital & Medical Center Hartford, Connecticut	Connecticut	4
74	VA Medical Center Bay Pines, Florida	Florida	1
129	University of Florida Gainesville, Florida	Florida	2
136	Mt. Sinai Medical Center Miami Beach, Florida	Florida	3
182	The University of South Florida Affiliated Hospitals Tampa, Florida	Florida	4
40	Emory University Atlanta, Georgia	Georgia	1
73	Medical College of Georgia Augusta, Georgia	Georgia	2
158	VA Medical Center Boise, Idaho	Idaho	1
4	Humana Hospital - Michael Reese Chicago, Illinois	Illinois	1
43	The Methodist Medical Center of Illinois Peoria, Illinois	Illinois	2
67	University of Chicago Chicago, Illinois	Illinois	3
97	Edward Hines, Jr. VA Medical Center Hines, Illinois	Illinois	4
117	University of Illinois at Chicago Chicago, Illinois	Illinois	5
138	Northwestern Memorial Hospital Chicago, Illinois	Illinois	6
148	The Children's Memorial Hospital Chicago, Illinois	Illinois	7
157	Evangelical Health Systems - Christ Hospital and Medical Center Oaklawn, Illinois	Illinois	8
159	Loyola University Medical Center Maywood, Illinois	Illinois	9

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RDRCs in the United States

Quantity of RDRCs by State for 2005 Reporting Year

RDRC #	RDRC Committee Name	State	Quantity
165	VA Medical Center North Chicago, Illinois	Illinois	10
178	Evanston Hospital Evanston, Illinois	Illinois	11
188	Victory Memorial Hospital Waukegan, Illinois	Illinois	12
14	Indiana University Medical Center Indianapolis, Indiana	Indiana	1
137	Methodist Hospital of Indiana Indianapolis, Indiana	Indiana	2
190	West Pharmaceuticals Services, Inc. / GFI Research Center Evansville, Indiana	Indiana	3
48	University of Iowa Iowa City, Iowa	Iowa	1
8	University of Kansas Medical Center Kansas City, Kansas	Kansas	1
68	Innovex Inc. Lenexa, Kansas (formerly Clinical Research Foundation-America, Lenexa, Kansas and originally Quincy Research Center, Kansas City, Kansas)	Kansas	2
151	University of Kentucky Lexington, Kentucky	Kentucky	1
6	Ochsner Clinic New Orleans, Louisiana	Louisiana	1
87	Overton Brooks VA Medical Center Shreveport, Louisiana	Louisiana	2
179	Louisiana State University Health Sciences Center in Shreveport Shreveport, Louisiana	Louisiana	3
173	Maine Medical Center Portland, Maine	Maine	1
18	National Institutes of Health Bethesda, Maryland	Maryland	1
31	Francis Scott Key Medical Center Baltimore, Maryland	Maryland	2
33	University of Maryland Medical Systems Baltimore, Maryland	Maryland	3
42	Johns Hopkins Medical Institutions Baltimore, Maryland	Maryland	4
66	Prince George's General Hospital and Medical Center Cheverly, Maryland	Maryland	5
2	Brigham and Women's Hospital Boston, Massachusetts	Massachusetts	1
16	Beth Israel Deaconess Medical Center Boston, Massachusetts	Massachusetts	2
30	New England Medical Center Boston, Massachusetts	Massachusetts	3
32	Massachusetts General Hospital Boston, Massachusetts	Massachusetts	4

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Quantity of RDRCs by State for 2005 Reporting Year

RDRC #	RDRC Committee Name	State	Quantity
57	Massachusetts Institute of Technology Cambridge, Massachusetts	Massachusetts	5
79	Children's Hospital, Boston Boston, Massachusetts	Massachusetts	6
80	New England Deaconess Hospital Boston, Massachusetts	Massachusetts	7
88	Worcester Foundation for Experimental Biology Shrewsbury, Massachusetts	Massachusetts	8
118	University Hospital Boston, Massachusetts	Massachusetts	9
163	University of Massachusetts Medical School Worchester, Massachusetts	Massachusetts	10
172	VA Medical Center West Roxbury, Massachusetts	Massachusetts	11
177	New England Medical Center Boston, Massachusetts	Massachusetts	12
45	The University of Michigan Ann Arbor, Michigan	Michigan	1
85	Bronson Methodist Hospital Kalamazoo, Michigan	Michigan	2
95	VA Medical Center Allen Park, Michigan	Michigan	3
107	Wayne State University Detroit, Michigan	Michigan	4
110	Hurley Medical Center Flint, Michigan	Michigan	5
112	St. John Hospital and Medical Center Detroit, Michigan	Michigan	6
115	Wayne County General Hospital Eloise, Michigan	Michigan	7
125	William Beaumont Hospital Royal Oak, Michigan	Michigan	8
133	Detroit Receiving Hospital and University Health Center Detroit, Michigan	Michigan	9
141	Harper-Grace Hospitals Detroit, Michigan	Michigan	10
162	Grace Hospital (purchased Mt. Carmel Mercy Hospital on April 1, 1991) Detroit, Michigan	Michigan	11
181	Department of Veterans Affairs Healthcare System Ann Arbor, Michigan	Michigan	12
186	Children's Hospital of Michigan Detroit, Michigan	Michigan	13
192	Henry Ford Hospital Detroit, Michigan	Michigan	14
17	Mayo Clinic Rochester, Minnesota	Minnesota	1
132	Hennepin County Medical Center Minneapolis, Minnesota	Minnesota	2
145	University of Minnesota Minneapolis, Minnesota	Minnesota	3
174	Veterans Administration Medical Center, Minneapolis Minneapolis, Minnesota	Minnesota	4
27	Veterans Administration Medical Center St. Louis, Missouri	Missouri	1

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RDRCs in the United States

Quantity of RDRCs by State for 2005 Reporting Year

RDRC #	RDRC Committee Name	State	Quantity
49	Bothwell Regional Health Center Sedalia, Missouri	Missouri	2
122	Washington University St. Louis, Missouri	Missouri	3
152	Saint Louis University St. Louis, Missouri	Missouri	4
155	St. Luke's Hospital of Kansas City Kansas City, Missouri	Missouri	5
64	University of Nebraska Medical Center Omaha, Nebraska	Nebraska	1
171	Creighton University Omaha, Nebraska	Nebraska	2
149	Dartmouth-Hitchcock Medical Center Hanover, New Hampshire	New Hampshire	1
55	Newark Beth Israel Medical Center Newark, New Jersey	New Jersey	1
86	VA Medical Center East Orange, New Jersey	New Jersey	2
150	UMDNJ-New Jersey Medical School Newark, New Jersey	New Jersey	3
187	Cooper Hospital / University Medical Center Camden, New Jersey	New Jersey	4
1	Columbia Presbyterian Medical Center New York, New York	New York	1
12	Brookhaven National Laboratory Upton, New York	New York	2
15	State of New York Department of Health Albany, New York	New York	3
19	Veterans Administration Hospital Albany, New York	New York	4
25	The State University of New York at Buffalo Buffalo, New York	New York	5
83	VA Medical Center Northport, New York	New York	6
89	Albany Medical Center Hospital Albany, New York	New York	7
101	New York University Medical Center New York, New York	New York	8
102	The Rockefeller University Hospital New York, New York	New York	9
103	North Shore University Hospital Manhasset, New York	New York	10
105	Memorial Sloan-Kettering Cancer Center New York, New York	New York	11
123	VA Medical Center Brooklyn, New York	New York	12
128	The Mary Imogene Bassett Hospital Cooperstown, New York	New York	13
146	VA Medical Center Bronx, New York	New York	14
160	SUNY at Stony Brook Stony Brook, New York	New York	15
180	The Mount Sinai Medical Center New York, New York	New York	16
191	University of Rochester Rochester, New York	New York	17
194	St. Luke's - Roosevelt Hospital Center New York, New York	New York	18

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Quantity of RDRCs by State for 2005 Reporting Year

RDRC #	RDRC Committee Name	State	Quantity
199	Montefiore Medical Center Bronx, New York	New York	19
200	New York Presbyterian Hospital and Weill Medical College of Cornell University New York, New York	New York	20
3	Duke University Medical Center Durham, North Carolina	North Carolina	1
116	VA Medical Center Fayetteville, North Carolina	North Carolina	2
175	Wake Forest University Health Sciences Winston Salem, North Carolina	North Carolina	3
119	University of North Dakota Grand Forks, North Dakota	North Dakota	1
84	VA Medical Center Cleveland, Ohio	Ohio	1
93	University of Cincinnati Medical Center & Children's Hospital Medical Center Cincinnati, Ohio	Ohio	2
104	Medical College of Ohio Toledo, Ohio	Ohio	3
147	University Hospitals of Cleveland Cleveland, Ohio	Ohio	4
166	The Cleveland Clinic Foundation Cleveland, Ohio	Ohio	5
193	Greater Cincinnati Radioactive Drug Research Committee Cincinnati, Ohio	Ohio	6
195	Kettering Medical Center Network Kettering, Ohio	Ohio	7
35	The University of Oklahoma Health Sciences Center Oklahoma City, Oklahoma	Oklahoma	1
7	VA Medical Center Portland Division Portland, Oregon	Oregon	1
9	Milton S. Hershey Medical Center, Pennsylvania State University Hershey, Pennsylvania	Pennsylvania	1
10	University of Pennsylvania Philadelphia, Pennsylvania	Pennsylvania	2
22	Lancaster Osteopathic Hospital Lancaster, Pennsylvania	Pennsylvania	3
37	Temple University Philadelphia, Pennsylvania	Pennsylvania	4
39	Pinnacle Health Systems at Harrisburg Hospital and Polyclinic Hospital Harrisburg, Pennsylvania	Pennsylvania	5
69	VA Medical Center Coatsville, Pennsylvania	Pennsylvania	6
70	Thomas Jefferson University Hospital Philadelphia, Pennsylvania	Pennsylvania	7
111	Montefiore Hospital Pittsburgh, Pennsylvania	Pennsylvania	8
113	Lankenau Medical Research Center Wynnewood, Pennsylvania	Pennsylvania	9
143	Presbyterian-University of Pennsylvania Medical Center Philadelphia, Pennsylvania	Pennsylvania	10

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RDRCs in the United States

Quantity of RDRCs by State for 2005 Reporting Year

RDRC #	RDRC Committee Name	State	Quantity
161	University of Pittsburgh Pittsburgh, Pennsylvania	Pennsylvania	11
34	Roger Williams Medical Center Providence, Rhode Island	Rhode Island	1
114	VA Medical Center Providence, Rhode Island	Rhode Island	2
167	Rhode Island Hospital Providence, Rhode Island	Rhode Island	3
176	Womens and Infants Hospital of Rhode Island Providence, Rhode Island	Rhode Island	4
77	VA Medical Center Charleston, South Carolina	South Carolina	1
153	William Jennings Bryan Dorn VA Medical Center Columbia, South Carolina	South Carolina	2
106	Veterans Administration Center Sioux Falls, South Dakota	South Dakota	1
13	Vanderbilt University Nashville, Tennessee	Tennessee	1
94	University of Tennessee Health Science Center, Memphis Memphis, Tennessee	Tennessee	2
170	University of Tennessee Medical Center Knoxville, Tennessee	Tennessee	3
21	The University of Texas, MD Anderson Cancer Center Houston, Texas	Texas	1
44	University of Texas, Southwestern Medical School Dallas, Texas	Texas	2
46	University of Texas Medical Branch Galveston, Texas	Texas	3
51	The Methodist Hospital Houston, Texas	Texas	4
56	University of Texas Health Science Center at San Antonio San Antonio, Texas	Texas	5
61	Audie L. Murphy Memorial Veterans Administration Hospital San Antonio, Texas	Texas	6
75	VA Medical Center Dallas, Texas	Texas	7
81	Texas Tech University Health Sciences Center Lubbock, Texas	Texas	8
124	NASA-Johnson Space Center Houston, Texas	Texas	9
144	The University of Texas Houston Health Science Center Houston, Texas	Texas	10
197	Baylor College of Medicine Houston, Texas	Texas	11
78	University of Utah, Radiological Health Department Salt Lake City, Utah	Utah	1
26	Medical Center Hospital of Vermont Burlington, Vermont	Vermont	1

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Quantity of RDRCs by State for 2005 Reporting Year

RDRC #	RDRC Committee Name	State	Quantity
11	University of Virginia Health Sciences Center Charlottesville, Virginia	Virginia	1
58	Virginia Commonwealth University / Medical College of Virginia Richmond, Virginia	Virginia	2
90	Naval Regional Medical Center Portsmouth, Virginia	Virginia	3
127	St. Mary's Hospital Richmond, Virginia	Virginia	4
121	VA Puget Sound Health Care System Seattle, Washington	Washington	1
184	University of Washington Medical Center Seattle, Washington	Washington	2
23	Walter Reed Army Medical Center Washington, DC	Washington, DC	1
24	George Washington University Hospital Washington, DC	Washington, DC	2
29	The Washington Hospital Center Washington, DC	Washington, DC	3
50	Veterans Administration Medical Center Washington, DC	Washington, DC	4
53	Georgetown University Medical Center Washington, DC	Washington, DC	5
134	Children's National Medical Center Washington, DC	Washington, DC	6
168	National Institutes of Mental Health Neurosciences Center at St. Elizabeth's Hospital Washington, DC	Washington, DC	7
169	MedStar Research Institute Washington, DC	Washington, DC	8
142	West Virginia University Medical Center Morgantown, West Virginia	West Virginia	1
185	West Virginia University Morgantown, West Virginia	West Virginia	2
52	Froedtert Memorial Lutheran Hospital Milwaukee, Wisconsin	Wisconsin	1
65	Clement J. Zablocki VA Medical Center Milwaukee, Wisconsin	Wisconsin	2
91	University of Wisconsin Medical School & Wm. S. Middleton Memorial Veterans Hospital Madison, Wisconsin	Wisconsin	3
100	University of Wisconsin Medical School Madison, Wisconsin	Wisconsin	4
189	Covance Clinical Research Unit, Inc. Madison, Wisconsin	Wisconsin	5

Background fill = "Active Committee"
Background fill = "Inactive Committee"

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FDA RDRC program website

Information about the FDA Radioactive Drug Research Committee program can be found at:

http://www.fda.gov/cder/regulatory/RDRC/

Or contact

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