**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 CFR361.1 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 | c. E-mail Address |
|---|---|
| b. Address *(Include ZIP code)* | 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* |
|---|---|---|---|
| | | ☐ Yes ☐ No | |
| | | ☐ Yes ☐ No | |
| | | ☐ 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* |
|---|---|---|---|
| | | ☐ Yes ☐ No | |
| | | ☐ Yes ☐ No | |
| | | ☐ 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* |
|---|---|---|---|
| | | ☐ Yes ☐ No | |
| | | ☐ Yes ☐ No | |
| | | ☐ Yes ☐ No | |

**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**

## 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) and maybe accessed at the following web address:
*http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=361.1*

Guidance regarding RDRC procedures is available from the FDA Center for Drug Evaluation and Research, Office of Oncology Drug Products, 5901-B Ammendale Road, Beltsville, MD 20705-1266. Information about the FDA RDRC program is available at the RDRC web site at the following web address:
*http://www.fda.gov/cder/regulatory/RDRC/default.htm*

Access to RDRC reporting Forms (2914 -Membership Summary and 2915 -Study Summary) in both Adobe Acrobat and Microsoft Word versions, which can be filled out and saved on your computer, can be obtained through the RDRC web site or from the following FDA Forms website:
*http://www.fda.gov/opacom/morechoices/fdaforms/default.html*

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** (21 CFR 361.1 (c)(4) Approval)An application for FDA approval of RDRC consists of submission of Form FDA 2914 (Membership Summary), current and dated curriculum vitae for each proposed committee member, and statement that the RDRC agrees to comply with the requirements under 21 CFR 361.1.

2 **Annual Report** (requirement – 21 CFR 361.1 (c)(3) Reports)
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** (21 CFR 361.1 (c)(4) Approval)
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 current and dated curriculum vitae for each proposed new committee member. The submitted Form FDA 2914 Membership Summary should include the names of all members of the RDRC.

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**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

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*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.

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***MEMBERSHIP**—For original applications and annual reports and membership changes, fill in sections B. through E. referenced below.*

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**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 specialty, 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 of the most recent previous submission for each listed member.

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

Attach current and dated curriculum vitae for each other voting member. If this is an annual report and qualifications have been previously submitted to FDA, provide the date of the most recent previous submission for each listed member.

**Section D. Committee Consultants** -- Provide the names, disciplines, and specialties of committee consultants. Provide a current and dated CV for each consultant used by the committee during the annual report cycle.

**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 Study Summaries 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.