APPLICATION FOR AUTHORIZATION
TO USE RADIATION IN RESEARCH
INVOLVING HUMAN SUBJECTS
Form **NIH 88-23(a)**

Attached is a Form 88-23(a) for your use. The NIH's policy on who may submit an application the Radiation Safety Committee is reproduced below.

APPLICATION POLICIES FOR AUTHORIZATION TO USE RADIATION IN RESEARCH INVOLVING HUMAN SUBJECTS

Studies that require x rays, radionuclides, or both, with the resulting exposure to ionizing radiation indicated solely for research, should be considered at two levels: 1) Complex high dose procedures central to the protocol involved and 2) Standard procedures often used in the practice of medicine.

The following table specifies the background required of an applicant PI or AI submitting a protocol using those modalities at the levels indicated.

	Level #1 Procedures that are complex or high dose is central to the protocol	Level #2 Standard procedures often used in medical practice
Radiological examination	RSC Authorized credentialed clinician[1] or a credentialed clinician with a relevant specialty board certification[2]	Credentialed clinician
Radionuclide use	RSC Authorized clinician	Credentialed clinician with the actual procedure under supervision of an RSC Authorized clinician

[1] The RSC authorizes clinicians based upon the "Applications for Authorization To Administer Radioactive Material for Research With Human Subjects"

[2] Such as cardiology, gastroenterology, or nuclear medicine

All studies involving research irradiation, whether at Level 1 or Level 2, must be reviewed by the RSC with a single exception: radiotherapy protocols involving external beam radiation from non-NRC licensed sources need only be reviewed by the RSC when requested by the IRB.

Reminders for completion of application:

1. Fill out all parts of form completely.

2. Applications must be signed by applicant consistent with the above guidelines of the Committee as well as the PI.

3. Be sure to include literature citations and other information sufficient to support dosimetry calculations.

Revised November 1990
Minor Revision September, 1992
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Action Requested

____ New Application

____ Amend Existing Rad Authorization

____ Triennial Review of Rad Authorization

NIH 88-23(a)

APPLICATION FOR AUTHORIZATION TO USE RADIATION IN RESEARCH INVOLVING HUMAN SUBJECTS

PLEASE TYPE OR PRINT LEGIBLY

(Radiation Safety Committee Use Only)

Action Item No. –

Rad Authorization No.

Clinical Project No. _____–_____–_____

Applicants*					
Name	Institute	Division/ Branch/Lab	Bldg./Room	**SIGNATURE**	Date
Principal Investigator(s) (If different than applicant)					

* Refer to current *Application Policies for Authorization to use Radiation in Research Involving Human Subjects.*

TITLE OF RESEARCH PROJECT: _____

_____

CLINICAL PROJECT NO. _____ RAD AUTHORIZATION NO. _____

Material to Be Administered									
Radionuclide		Compound	Maximum activity per single administration (mCi)	Maximum number of administrations per subject:		Method of administration			Maximum quantity of active drug or compound per single administration (:g or mg)
				Quarterly	Yearly	IV	Oral	Other	
1.									
2.									
3.									
4.									
5.									

REGULATORY STATUS OF RADIOPHARMACEUTICAL:

(If more than one radiopharmaceutical is to be administered, use the supplemental forms reproduced in attachment A to indicate the regulatory status of each.)

Radioactive Research Drug (Regulated under 21 CFR 361)

Absence of pharmacologic effect ____ has / ____ has not been demonstrated. (Data available from studies in humans relating to any pharmacologic effect must be included in protocol.)

Investigational New Drug

Approved IND No. _____(Attach copy of approval letter.)

Amendment to above IND No. sent to FDA on _____(Attach copy of letter to FDA.)
(Date)

Application for IND submitted to FDA on _____
(Date)

Application for IND not yet submitted to FDA

FDA approved drug

Other (Explain): _____

STUDY POPULATION					
Normal Control Subjects		Research Patients		Total Number of Subjects	
Yearly	For Duration of Study	Yearly	For Duration of Study	Yearly	For Duration of Study

Age: _____ to _____ years
(Minimum) (Maximum)

Sex: _____ Male _____ Female

____ ____
(Yes) (No)

Data bank on NORMAL CONTROL SUBJECTS for similar studies has been reviewed and will be used to the maximum extent possible in order to minimize radiation exposure to additional NORMAL CONTROL SUBJECTS.

____ ____
(Yes) (No)

The limited life expectancy (specify) _____of the proposed RESEARCH PATIENTS should be considered in evaluating the risks of radiation exposure to these patients.

PREGNANCY STATUS OF RESEARCH SUBJECTS:

The applicant accepts responsibility for determining the pregnancy status prior to each administration by (a) obtaining a signed and recorded statement regarding pregnancy status from the subject; (b) performing a pregnancy test (with date and results of test recorded in the subject's record); or (c) making a direct entry into the subject's record as to why the test is not indicated.

SUBJECT PARTICIPATION IN OTHER STUDIES INVOLVING RADIATION EXPOSURE:

Subjects ____ are / ____ are not enrolled in other studies (protocols) that result in radiation exposure. If so, list other protocols:

Clinical Project No.	Rad Authorization No.	Title

The nature of these studies should be discussed in the protocol, including the agents, doses (activity and radiation dose), and risks. Dosimetry must be included on subsequent pages of this application, e.g., on supplemental Tabulations of Radiation Doses to Subjects.

INSTITUTE INSTITUTIONAL REVIEW BOARD (IRB) APPROVAL:

____ Protocol submitted to IRB for review on _____ and not yet approved.
(Date)

____ Protocol was approved by IRB on _____ by _____, _____.
(Date) (Name of Chairman, IRB) (Institute)
(Please include a copy of approval memo or other document with signature and minutes from meeting at which the protocol was approved.)

RADIOACTIVE DRUG RESEARCH COMMITTEE (RDRC) APPROVAL:

____ Application to RDRC not required. ____ Application approved by RDRC on _____.
(Date)

____ Signature of RDRC Chairman appears on approval memo or other document dated _____.
(Please include copy of document with application.)

RADIATION SAFETY COMMITTEE (RSC) APPROVAL: (FOR RSC USE ONLY)

____ Application approved by RSC ____ with / ____ without stipulations on _____.
(Date)

____ Final review of application completed by Executive Secretary, RSC, or other person

(_____) on _____.
(Title) (Date)

_____ _____
(Signature of Reviewer) (Date)

TABULATION OF RADIATION DOSES TO SUBJECTS

(Detailed dosimetry or referenced data must be included with application or attached hereto.)

1. Tabulation of radiation doses to subjects from (check one):

   _____ Proposed radiopharmaceutical or radiographic procedure, OR

   _____ Ancillary study not part of this protocol

   _____

   (Name of radiopharmaceutical, radiographic procedure, or ancillary study)

   (See notes below)

	Radiation Dose to Organ (Rem)		
Organ	Per single administration	Per quarter (13 weeks)	Per year
Red Bone Marrow			
Lens of the Eye			
Gonads, Ovaries			
Gonads, Testes			
Breast			
Lung			
Thyroid			
Bone			
Bladder Wall*			
Heart			
Brain			
Spleen			
Kidneys			
Liver			
Total Body			

*Specify voiding schedule _____
(If different from those on which assumptions underlying dosimetry are based, discuss effect of differences on validity of dosimetry estimates.)

NOTES:

1. If more than one agent or radiation source is to be used, fill out additional copies of this tabulation (see attachment B).

2. If radiographic studies are involved, indicate primary site(s) or organs to be irradiated and include skin or "entrance" dose.

3. Estimates of doses for the organs and tissues listed in the table should be as accurate as possible. If this is inappropriate for some sites, e.g., for those that are distant from the irradiated site in radiographic studies, note the basis for dose estimates in the protocol or leave blank, as appropriate.

2. Total radiation doses to subjects from participation in this study (summation of doses from this Authorization and other procedures):

	Total Radiation Dose to Organ (Rem)		
Organ	Per single administration	Per quarter (13 weeks)	Per year
Red Bone Marrow			
Lens of the Eye			
Gonads, Ovaries			
Gonads, Testes			
Breast			
Lung			
Thyroid			
Bone			
Bladder Wall			
Heart			
Brain			
Spleen			
Kidneys			
Liver			
Total Body			

NOTE

This page need not be completed if only *one* agent or source of radiation is involved.

ATTACHMENT A

REGULATORY STATUS OF RADIOPHARMACEUTICAL WHEN MORE THAN ONE AGENT IS INVOLVED

Name of Radioactive Drug _____

Radioactive Research Drug (Regulated under 21 CFR 361)

Absence of pharmacologic effect ____ has ____ has not been demonstrated. (Data available from studies in humans relating to any pharmacologic effect must be included in protocol.)

Investigational New Drug (IND)

Approved IND No. _____ (Attach copy of approval letter.)

Amendment to above IND No. sent to FDA on _____ (Attach copy of letter to FDA.)
(Date)

Application for IND submitted to FDA on _____
(Date)

Application for IND not yet submitted to FDA

Drug for which a New Drug Application has been approved by the FDA

Other (Explain): _____

Name of Radioactive Drug _____

Radioactive Research Drug (Regulated under 21 CFR 361)

Absence of pharmacologic effect ____ has ____ has not been demonstrated. (Data available from studies in humans relating to any pharmacologic effect must be included in protocol.)

Investigational New Drug (IND)

Approved IND No. _____ (Attach copy of approval letter.)

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(Date)

Application for IND submitted to FDA on _____
(Date)

Application for IND not yet submitted to FDA

Drug for which a New Drug Application has been approved by the FDA

Other (Explain): _____

Name of Radioactive Drug _____

Radioactive Research Drug (Regulated under 21 CFR 361)

Absence of pharmacologic effect ____ has ____ has not been demonstrated. (Data available from studies in humans relating to any pharmacologic effect must be included in protocol.)

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(Date)

Application for IND not yet submitted to FDA

Drug for which a New Drug Application has been approved by the FDA

Other (Explain): _____

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(Date)

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(Date)

Application for IND not yet submitted to FDA

Drug for which a New Drug Application has been approved by the FDA

Other (Explain): _____

ATTACHMENT B

EXTRA COPIES OF "TABULATION OF RADIATION DOSES TO SUBJECTS"

FOR USE WHEN MULTIPLE SOURCES OF RADIATION ARE INVOLVED

TABULATION OF RADIATION DOSES TO SUBJECTS

(Detailed dosimetry or referenced data must be included with application or attached hereto.)

1. Tabulation of radiation doses to subjects from (check one):

   _____ Proposed radiopharmaceutical or radiographic procedure, OR

   _____ Ancillary study not part of this protocol

_____

(Name of radiopharmaceutical, radiographic procedure, or ancillary study)

(See notes below)

	Radiation Dose to Organ (Rem)		
Organ	Per single administration	Per quarter (13 weeks)	Per year
Red Bone Marrow			
Lens of the Eye			
Gonads, Ovaries			
Gonads, Testes			
Breast			
Lung			
Thyroid			
Bone			
Bladder Wall*			
Heart			
Brain			
Spleen			
Kidneys			
Liver			
Total Body			

*Specify voiding schedule _____

(If different from those on which assumptions underlying dosimetry are based, discuss effect of differences on validity of dosimetry estimates.)

NOTES:

1. If more than one agent or radiation source is to be used, fill out additional copies of this tabulation (see attachment B).

2. If radiographic studies are involved, indicate primary site(s) or organs to be irradiated and include skin or "entrance" dose.

3. Estimates of doses for the organs and tissues listed in the table should be as accurate as possible. If this is inappropriate for some sites, e.g., for those that are distant from the irradiated site in radiographic studies, note the basis for dose estimates in the protocol or leave blank, as appropriate.

TABULATION OF RADIATION DOSES TO SUBJECTS

(Detailed dosimetry or referenced data must be included with application or attached hereto.)

1. Tabulation of radiation doses to subjects from (check one):

_____ Proposed radiopharmaceutical or radiographic procedure, OR

_____ Ancillary study not part of this protocol

_____

(Name of radiopharmaceutical, radiographic procedure, or ancillary study)

(See notes below)

	Radiation Dose to Organ (Rem)		
Organ	Per single administration	Per quarter (13 weeks)	Per year
Red Bone Marrow			
Lens of the Eye			
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Bone			
Bladder Wall*			
Heart			
Brain			
Spleen			
Kidneys			
Liver			
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(If different from those on which assumptions underlying dosimetry are based, discuss effect of differences on validity of dosimetry estimates.)

NOTES:

1. If more than one agent or radiation source is to be used, fill out additional copies of this tabulation (see attachment B).

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