AUTHORIZATION TO ADMINISTER RADIATION IN RESEARCH INVOLVING HUMAN SUBJECTS

Rad Authorization No.:
Clinical Research Study No.:

Date:

Title:

From: Chair, NIH Radiation Safety Committee

To:

Action Item No.:

The NIH Radiation Safety Committee and, if applicable, the NIH Radioactive Drug Research Committee have approved your Application for Authorization to Administer Radiation for Research with Human Subjects; a copy of the approved application is attached. Final authorization for you to proceed is dependent upon approval of the Clinical Research Study by the IRB responsible for overseeing your proposed study. You are reminded that this approval is for work to be conducted in accordance with the statements in the protocol and your application as well as any additional conditions that may have been imposed by the Committee.

Please ensure that all NIH radiation safety rules and procedures, U.S. Nuclear Regulatory Commission requirements, and FDA regulations are followed in working with this material. Any adverse reactions due to the administration of this material must be reported immediately to the Chairperson(s) of the NIH Radiation Safety Committee and/or the NIH Radioactive Drug Research Committee.

Renewals: Reviews and renewals of Rad Authorizations are now coupled to the over-all review of Clinical Research Studies. The RSC requires Triennial review of all Rad Authorizations. These shall include the protocol, a new Form 88-23(a), “APPLICATION FOR AUTHORIZATION TO ADMINISTER RADIATION FOR RESEARCH WITH HUMAN SUBJECTS” (contact the Executive Secretary of the Radiation Safety Committee for a new, up-to-date form at the time of application), and informed consent statement.

All submissions to the RSC should be concurrent with applications to IRBs and include Form NIH-1195, “CLINICAL RESEARCH STUDY REVIEW APPLICATION.”

Amendments: An application for an amendment to the Rad Authorization must be submitted if there are changes in the procedures approved herein, including number or age of subjects, maximum activity per dose to be administered, patient population, maximum number of doses per quarter or per year, change or departure of the Authorized User. Review by the Radioactive Drug Research Committee may also be required in certain cases. Simple amendments may be requested via memorandum if there is not a substantial change in the information previously submitted on Form 88-23(a), e.g., a request for change of Authorized User or P.I. (call the Executive Secretary of the Committee if in doubt).

Signatures: All Applications to the RSC must be signed by all Authorized User(s) and P. I.

NOTE: Investigators should ensure that a completed final copy of the application is forwarded to Protocol Services for final processing after approval by the Radiation Safety Committee and IRB. A complete protocol includes form 88-23(a), “Application for Authorization to Use Radiation in Human Subjects” as well as the protocol and informed consent statements. FINAL copies must be submitted which reflect any changes made to satisfy stipulations of both Committees. A copy of this approval is being provided to Protocol Services to indicate that the Radiation Safety Committee has reviewed and approved the application. The final version of form 88-23(a) must have sign-off approval by a representative of the RSC.

If you have any questions regarding these matters, please contact the Executive Secretary of the Committee at 496-2253.

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Lance A. Liotta, M.D., Ph.D., Chair, NIH Radiation Safety Committee