GRANT NO: DAMD17-94-J-4376

TITLE: "Positron Emitter I124 Iododeoxyuridine as a Tracer to Follow DNA Metabolism on Scans and in Tumor Samples in Advanced Breast Cancer"

PRINCIPAL INVESTIGATOR(S): Teresa Ann Gilewski, M.D.

CONTRACTING ORGANIZATION: Sloan-Kettering Institute for Cancer Research
New York, New York 10021

REPORT DATE: September 1995

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for public release; distribution unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.
Positron Emitter 1124 Iododeoxyuridine as a Tracer to Follow DNA Metabolism on Scans and in Tumor Samples in Advanced Breast Cancer

Teresa Ann Gilewski, M.D.

Sloan-Kettering Institute for Cancer Research
New York, New York 10021

U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

Approved for public release; distribution unlimited
**GENERAL INSTRUCTIONS FOR COMPLETING SF 298**

The Report Documentation Page (RDP) is used in announcing and cataloging reports. It is important that this information be consistent with the rest of the report, particularly the cover and title page. Instructions for filling in each block of the form follow. It is important to stay within the lines to meet the formatting requirements.

**Block 1a.** Leave Blank (Title Only).

**Block 2.** Report Date. Full publication date including day, month, and year, if available (e.g. 1 Jan 86). Must cite at least the year.

**Block 3.** Type of Report and Date Covered. State whether report is interim, final, etc. If applicable, enter inclusive report dates (e.g. 10 Jun 80 - 30 Jun 80).

**Block 4.** Title and Subtitle. A title is taken from the part of the report that provides the most meaning and complete information. When a report is composed of more than one volume, it may be sub-titled, add volume number, and include subtitle for the specific volume. On classified documents enter the title classification in parentheses.

**Block 5.** Heading Numbers. To include contract and grant numbers, may include program element number(s), project number(s), task number(s), and work unit number(s). Use the following list:

- C - Contract
- G - Grant
- PP - Program
- WU - Work Unit
- Acc - Accession No.

**Block 6.** Author(s). Name(s) of person(s) responsible for writing the report, performing the research, or credited with the content of the report. Whether or compiler, this should follow the name(s).

**Block 7.** Performing Organization Name(s) and Address(es). Self-explanatory.

**Block 8.** Preparing Organization Report Number. Enter the unique alphanumeric report number as assigned by the organization preparing the report.

**Block 9.** Receiving/Monitoring Agency Name(s) and Address(es). Self-explanatory.

**Block 10.** Accession Number. (If known)

**Block 11.** Supplementary Notes. Enter information not included elsewhere such as: frequency and/or periodicity with... Trans. of..., To be published in... Effective report is revised, include a statement that the new report supersedes or replaces the dated report.

**Block 12a.** Distribution/Availability Statement. Denotes public availability or limitations. Cite any availability to the public. Enter additional limitations or special markings in all capitals (e.g. NOFORN, REL, ITAR).

- DOD - See DoDD 5230.26, "Distribution Statements on Technical Documents."
- DOE - See authorities.
- NTIS - Leave blank.

**Block 12b.** Distribution Code.

- DOD - Leave blank.
- DOE - Enter DOE distribution categories from the Standard Distribution for Unclassified Scientific and Technical Reports.
- NASA - Leave blank.
- NTIS - Leave blank.

**Block 13.** Abstract. Include a brief (Maximum 200 words) factual summary of the most significant information contained in the report.

**Block 14.** Subject Terms. Keywords or phrases identifying major subjects in the report.

**Block 15.** Number of Pages. Enter the total number of pages.

**Block 16.** Price Code. Enter appropriate price code (NTIS only).


**Block 20.** Limitation of Abstract. This block must be completed to assign a limitation to the abstract. Enter either UL (unlimited) or SAR (same as report). An entry in this block is necessary if the abstract is to be limited. If blank, the abstract is assumed to be unlimited.

---

*U.S.GPO:1993-0-350-779*
FOREWORD

Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the US Army.

Where copyrighted material is quoted, permission has been obtained to use such material.

Where material from documents designated for limited distribution is quoted, permission has been obtained to use the material.

Citations of commercial organizations and trade names in this report do not constitute an official Department of Army endorsement or approval of the products or services of these organizations.

In conducting research using animals, the investigator(s) adhered to the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and Use of Laboratory Animals of the Institute of Laboratory Resources, National Research Council (NIH Publication No. 86-23, Revised 1985).

For the protection of human subjects, the investigator(s) adhered to policies of applicable Federal Law 45 CFR 46.

In conducting research utilizing recombinant DNA technology, the investigator(s) adhered to current guidelines promulgated by the National Institutes of Health.

In the conduct of research utilizing recombinant DNA, the investigator(s) adhered to the NIH Guidelines for Research Involving Recombinant DNA Molecules.

In the conduct of research involving hazardous organisms, the investigator(s) adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.

PI - Signature ___________________________ Date ___________
SUMMARY

Grant # DMAD 17-94-J-4376

"Positron emitter I\textsuperscript{124} iododeoxyuridine as a tracer to follow DNA metabolism on scans and in tumor samples in advanced breast cancer."

The objectives of this study are: (1) to determine whether the biologic activity of locally advanced Stage III breast cancer as measured by I\textsuperscript{124}I-iododeoxyuridine (IUDR) uptake on positron emission tomography (PET) scans pre and post chemotherapy can be correlated with the clinical response as determined by physical examination and conventional radiographic studies, (2) to demonstrate that incorporation of IUDR is into the DNA contained within the tumor and that it correlates with the subsequent tumor response and proliferative activity of the tumor, (3) to further assess the biologic activity of tumor sites and clinical response by using a program which fuses PET scan images on computed tomography (CT) scans, magnetic resonance imaging (MRI) or SPECT bone scans.

Patients with Stage III breast cancer will have a complete extent of disease evaluation including routine radiographic studies. A PET scan with IUDR will be obtained within 2 weeks prior to therapy and after 4 cycles of chemotherapy. Whole body emission scans will be performed 24 hours after intravenous injection of 8 mCi of IUDR. Tumor biopsies will be obtained on the day of the PET scan and assessed for incorporation of IRdR into DNA. Flow cytometry and Ki-67 stains will also be obtained. Fusion imaging will generate resliced PET images that correspond to appropriate original CT, MRI or SPECT bone scan images.

There has been an unforeseen delay in the construction of the site for the positron emission tomography (PET) scan. It is expected that the PET scan will be operational in November 1995.