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STANFORD UNIVERSITY

Stanford Linear Accelerator Center
Business Services Division, MS 02

2575 Sand Hill Road
Menlo Park, CA 94025
(415) 926-4245 (phone)
(415) 926-4999 (fax)

April 5, 1994

Mr. Ralph Kopenhaver:
Environment Safety & Support Division
Oakland Field Office
Department of Energy
1301 Clay Street, Room 700N
Oakland, California 94612 - 5208

Subject: Human Radiation Experiments Records Inventory

Dear Mr. Kopenhaver:

In accordance with our telephone conversation of March 17, 1994, the attached records inventory sheets covering records held at SLAC are submitted for your information. As we discussed, we will safeguard the records and await further instructions from you.

If you have any questions, please call me at (415) 926-4245.

Sincerely,

Jerry L. Jobe
Associate Director
Business Services Division

JLJ:laj

Enclosures a/s

cc: W. Von Flue
K. Cantwell
R. Chandler

REPOSITORY DOE - OAK
COLLECTION ES+H OFFICE ~~BLDG~~ 120
BOX No.
FOLDER ANNIOGRAPHY

0021295

USDOE Human Experiment Inventory Form

1. Name of Facility: Stanford Synchrotron Radiation Laboratory (SSRL)

2. Responsible Office: SSRL ESH Office

3. Contact Name: Ian Evans

4. Contact Telephone: (415) 926-3110

5. Series Title: Safety Administration Files for Angiography Program Experiment 456B

6. Inclusive Dates: 1981 - 1990

7. Access Restrictions: None

8. Percent Classified: 0

9. Medium: Paper

10. Description of Records: Experimental safety records for angiography program including engineering drawings and rough sketches for modification of SSRL facility for experiment, angimono drums, and Beam Line IV Angiography Examination Room; internal memoranda from SLAC lab director, SSRL assoc. director and legal counsel regarding safety procedures for experiment; Angiography Safety Plan; Meeting Minutes of Angiography Safety Committee; Stanford University Human Subjects in Medical Research Panel approval of experiment; structural calcs and schematics for angiography equipment; DOE policy and regulations on protection of Human Subject Experiments; DOE approval of experiment meeting safety requirements; SLAC Radiation Committee approval of experiment; tenative run schedule for experiment; blank informed consent information and form for patients; final reviews by SSRL admnistration to ensure safety for human subjects in experiment prior to initial run; memoranda concerning successful first run with safety suggestions for second run of experiment; SSRL memo to DOE informing of second series of angiography experiment;

11. Scheduled: DOE Record Schedule 1, item 3: Medical Research Project Case File: permanent

12. Informational Analysis: The records reflect the SSRL facility experimental review process, particularly focusing on the observation of environmental, safety and health policies and procedures for experiments involving human subjects.

13. Informational Ranking: Number One

14. Location of Records:

SSRL
2575 Sand Hill Road, Bldg 120, Room 211
Menlo Park, CA 94309

15. Type of Record: Administration Safety Files

16. Arrangement: By Experiment and within file chronologically

17. Volume: 2" (linear ft) or one file

18. Category: Experiment; Radiation

19. Title of Experiment: Transvenous Coronary Angiography in Humans Using Synchrotron Radiation, Experiment 456B

20. Principal Investigator: Edward Rubenstein (now retired) was Pi when the experiment was at SSRL; John Giacomini has become the Pi while experiment at BNL

21. Investigator's Affiliation: Stanford University School of Medicine

22. Description (Experiment): Study of the use of a dual-beam dual-detector synchrotron radiation system for transvenous coronary angiography in a human subject. This system eliminates the need for rapid beam switching, increases x-ray fluence by a factor of about 2.5, and makes it possible to record high and low energy images simultaneously, thus excluding artifacts arising from time subtraction.

23. Dates of Experiments: 1986-1989 (SSRL); 1990-present (BNL)

24. Conducted by: Several scientists including Rubenstein, E.; Hughes, E.; Hofstadter, R.; Giacomini, J.; Gordon, H. J.; Thompson, A. C.; Brown, G.; Thomlinson, W.; and Zeman, H.

25. Locations of Experiment:

1986-1989:
SSRL
2575 Sand Hill Road
Menlo Park, CA 94309

1990 - present:
Brookhaven National Lab
Long Island, NY

26. Cross References to other records; experiments:
Logbooks for SSRL experiment are currently in active use at BNL location.

SSRL Administrative files for SSRL experiment located at SSRL.

27. Comments: none

28. Name of person completing form:
Robin Chandler

29. Telephone: 926-2411

30. Date: 3/30/94

0021298

USDOE Human Experiment Inventory Form

1. Name of Facility: Stanford Synchrotron Radiation Laboratory (SSRL)

2. Responsible Office: Director's Office

3. Contact Name: Katherine Cantwell

4. Contact Telephone: (415) 926-3191

5. Series Title: SSRL Experiment 1046/456B Administrative Files: 2nd Proposal Extension

6. Inclusive Dates: 1986-1992

7. Access Restrictions: None

8. Percent Classified: 0

9. Medium: Paper

10. Description of Records: Laboratory administrative experimental files including copies of patient consent forms for original SSRL Angiography experiment; original proposal review; papers written on Transvenous Coronary Angiography using Synchrotron Radiation; proposal to SSRL for continued study; proposal rating; end of run summary form; extension request; extension approval; and memoranda regarding status of further extension.

11. Scheduled: No

12. Informational Analysis: The records reflect the SSRL facility experimental review process, indicating the procedures by which an experiment is approved for running time at the laboratory. Additionally, the records reflect programmatic concerns for scientific value of proposal and observation of environmental, safety and health policies and procedures.

13. Informational Ranking: Number One

14. Location of Records:

SSRL
2575 Sand Hill Road, Bldg 69, Room 310
Menlo Park, CA 94309

15. Type of Record: Laboratory Administration

16. Arrangement: By Experiment and within file chronologically

17. Volume: 2" (linear ft) or one file

18. Category: Experiment; Radiation

19. Title of Experiment: Transvenous Coronary Angiography in Humans Using Synchrotron Radiation, Experiment 456B

20. Principal Investigator: Edward Rubenstein (now retired) was Pi when the experiment was at SSRL; John Giacomini has become the Pi while experiment at BNL

21. Investigator's Affiliation: Stanford University School of Medicine

22. Description (Experiment): Study of the use of a dual-beam dual-detector synchrotron radiation system for transvenous coronary angiography in a human subject. This system eliminates the need for rapid beam switching, increases x-ray fluence by a factor of about 2.5, and makes it possible to record high and low energy images simultaneously, thus excluding artifacts arising from time subtraction.

23. Dates of Experiments: 1986-1989 (SSRL); 1990-present (BNL)

24. Conducted by: Several scientists including Rubenstein, E.; Hughes, E.; Hofstadter, R.; Giacomini, J.; Gordon, H. J.; Thompson, A. C.; Brown, G.; Thomlinson, W.; and Zeman, H.

25. Locations of Experiment:

1986-1989:
SSRL
2575 Sand Hill Road
Menlo Park, CA 94309

1990 - present:
Brookhaven National Lab
Long Island, NY

26. Cross References to other records; experiments:
Logbooks for SSRL experiment are currently in active use at BNL location.
Additional administrative files and safety files for SSRL experiment at SSRL.

27. Comments: Patient consent forms are incomplete. According to John Giacomini, a principal investigator for the experiment, two of the consent forms for the original seven volunteers for the experiment at SSRL, were destroyed during the damage inflic ted by the Loma Prieta Quake in October 1989. Giacomini has been in contact with the individuals who are willing to write affirming their willing participation in the program.

28. Name of person completing form:
Robin Chandler

29. **Telephone:** 926-2411

30. **Date**: 3/30/94

USDOE Human Experiment Inventory Form

1. Name of Facility: Stanford Synchrotron Radiation Laboratory (SSRL)

2. Responsible Office: Director's Office

3. Contact Name: Katherine Cantwell

4. Contact Telephone: (415) 926-3191

5. Series Title: SSRL Experiment 456B Administrative Files

6. Inclusive Dates: 1979-1988

7. Access Restrictions: None

8. Percent Classified: 0

9. Medium: Paper

10. Description of Records: Laboratory administrative experimental files which include the original proposal of experiment and addendum; proposal review records which include letters of intent and proposal referee's critiques; proposal for continued study; safety memoranda; forms indicating changes in spokespersons; and experimental run summary forms.

11. Scheduled: No

12. Informational Analysis: The records reflect the SSRL facility experimental review process, indicating the procedures by which an experiment is approved for running time at the laboratory. Additionally, the records reflect programmatic concerns for scientific value of proposal and observation of environmental, safety and health policies and procedures.

13. Informational Ranking: Number One

14. Location of Records:

SSRL
2575 Sand Hill Road, Bldg 69, Room 310
Menlo Park, CA 94309

15. Type of Record: Laboratory Administration

16. Arrangement: By Experiment and within file chronologically

17. Volume: 2" (linear ft) or one file

0021302

18. Category: Experiment; Radiation

19. Title of Experiment: Transvenous Coronary Angiography in Humans Using Synchrotron Radiation, Experiment 456B

20. Principal Investigator: Edward Rubenstein (now retired) was Pi when the experiment was at SSRL; John Giacomini has become the Pi while experiment at BNL

21. Investigator's Affiliation: Stanford University School of Medicine

22. Description (Experiment): Study of the use of a dual-beam dual-detector synchrotron radiation system for transvenous coronary angiography in a human subject. This system eliminates the need for rapid beam switching, increases x-ray fluence by a factor of about 2.5, and makes it possible to record high and low energy images simultaneously, thus excluding artifacts arising from time subtraction.

23. Dates of Experiments: 1986-1989 (SSRL); 1990-present (BNL)

24. Conducted by: Several scientists including Rubenstein, E.; Hughes, E.; Hofstadter, R.; Giacomini, J.; Gordon, H. J.; Thompson, A. C.; Brown, G.; Thomlinson, W.; and Zeman, H.

25. Locations of Experiment:

1986-1989:
SSRL
2575 Sand Hill Road
Menlo Park, CA 94309

1990 - present:
Brookhaven National Lab
Long Island, NY

26. Cross References to other records; experiments:
Logbooks for SSRL experiment are currently in active use at BNL location.
Safety files for SSRL experiment located at SSRL.

27. Comments: none

28. Name of person completing form:
Robin Chandler

29. Telephone: 926-2411

30. Date: 3/30/94

0021303