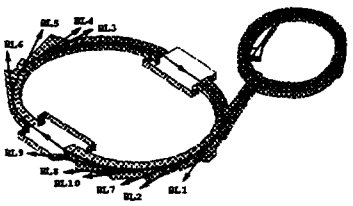

SSRL DIVISION MEMO

Date: March 31, 1994

To: Jerry Jobe

From: Katherine Cantwell KC

Subject: Angiography Program Files

Robin Chandler has completed the on-site inventory of the files relating to the angiography program at SSRL. Copies of the inventory are attached as well as a summary of the patients provided to me by the physicians and a note regarding the files at the VA Hospital.

The log books which are the primary source of information are located at Beam Line 17 at the NSLS at Brookhaven National Laboratory where they are in active use.

Robin spent about 5 hours on this project and I spent about an hour.

Let me know the next step.

HUMAN SUBJECT STUDIES AT THE STANFORD SYNCHROTRON RADIATION LABORATORY

From 1979 to 1989 there was a program at SSRL to develop non-invasive methods of coronary angiography. In the final stages of this program, a total of 6 human subjects were studied (one person was studied twice making 7 experimental runs with humans). Three in May 1986, 3 in April 1987 and 1 in March 1989. The program was headed by Drs. Robert Hofstadter (Physics Department - deceased) and Edward Rubenstein (Dept of Medicine - retired) of Stanford University.

The program then was moved to the National Synchrotron Light Source where a total of 12 more patients have been studied.

A new proposal has been submitted to SSRL and received the highest scientific rating from the SSRL Proposal Review Panel to re-start the angiography program at SSRL. This new effort is head by Dr. John Giacomini of the Palo Alto Veterans Hospital Medical Department.

Description of Angiography Experiment

These experiments involved the intravascular injection of non-radioactive iodine contrast agent. This is the same procedure that is used clinically in all angiography studies. The relevant parameters here are number of injections, injection volume, injection rates (milliliters/second) and the total volume of contract agent per study.

The patients were then exposed to the x-ray beam. The relevant parameter here is x-ray does as indicated by exposure per angiographic scan, and number of angiographic scans.

In addition, positioning scans were done at very low radiation doses (using a filter). The number of these and radiation exposure form each is another relevant parameter.

From: MX%"John.Giacomini@Forsythe.Stanford.EDU" 29-MAR-1994 19:12:25.90
To: K
CC:
Subj: Patient 7 and informed consents

Return-Path: <John.Giacomini@Forsythe.Stanford.EDU>
Received: from SLACMH.SLAC.Stanford.EDU (SERV03::SYSTEM) by SSRL01 (MX V3.3 VAX) with SMTP (DECnet); Tue, 29 Mar 1994 19:12:22 PST
Received: from Forsythe.Stanford.EDU by SERV03.SLAC.STANFORD.EDU (PMDF V4.2-12 #4747) id <01HAJZW6BFPC0013NK@SERV03.SLAC.STANFORD.EDU>; Tue, 29 Mar 1994 19:09:59 PST
Date: Tue, 29 Mar 1994 19:09:32 -0800 (PST)
From: John Giacomini <John.Giacomini@Forsythe.Stanford.EDU>
Subject: Patient 7 and informed consents
To: k@SSRL01.SLAC.Stanford.EDU
Message-ID: <01HAJZW6DUIA0013NK@SERV03.SLAC.STANFORD.EDU>
X-Envelope-to: k@SSRL01.SLAC.Stanford.EDU
Content-Transfer-Encoding: 7BIT

REPLY TO 03/28/94 13:28 FROM k@SSRL01.SLAC.STANFORD.EDU "KATHERINE CANTWELL, SSRL BITNET: K@SSRL750": Patient 7

Katherine--

As you have determined from speaking with Pat Ericson, I have been on clinical service, and out of town. I plan to contact Robin Chandler tomorrow. However, as I believe you learned from Ed Rubenstein, all of our patient logs are at the National Synchrotron Light Source in Brookhaven, NY. Bill Lavender, to whom the task has fallen to keep track and maintain these records is currently at Brookhaven, and will be there until at least April 15. As it is somewhat dangerous to ship these records, it might make more sense for someone at NSLS to audit the records there, particularly since

Lavender is currently at the facility.

Regarding the informed consents--we have located all of these except for the last two patients--Mr. Webb, and Mr. Harold Kimball. Mr. Kimball also continues to be followed by us. You had asked Pat Ericson to explain how an earthquake could destroy records--please understand that after the earthquake, the building was evacuated and sealed. Records (including hospital charts), and equipment were lost to us during the massive relocation which subsequently occurred. The fact that we were able to locate the consents which we did is actually fairly remarkable.

If it is necessary, we could contact Mr. Webb and Mr. Kimball, and ask them to write a letter affirming that they had participated in the study, and that we had obtained informed consent prior to the study.

Thanks.

John

To: k@SSRL01.SLAC.STANFORD.EDU

SLAC MEMORANDUM

Date: March 31st, 1994

To: Katherine Cantwell

From: Robin Chandler

Subject: DOE Human Experiment Inventory

Attached are the series inventories that I have prepared for the DOE Inventory. These descriptions include the materials currently on site at the SSRL facility. Please review and comment. I consider these to be draft until they are ready to be forwarded to the DOE. I spoke with John Giacomini on Wednesday 3/30/94 who relayed that the Stanford University Medical Center Veterans Hospital no longer has any experimental records for the angiography program. All records are maintained at the currently running experiment extension at BNL.

UCDOE 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

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

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

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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