



NATIONAL AERONAUTICS AND SPACE ADMINISTRATION
LEWIS RESEARCH CENTER
CLEVELAND, OHIO 44135



REPLY TO
ATTN OF: 1005

The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44106

Gentlemen:

During the past several weeks we have negotiated with you the Consortium Agreement between the Cleveland Clinic Foundation and the National Aeronautics and Space Administration covering use by CCF of the NASA Cyclotron for neutron Beam Radiotherapy. During that negotiation you have asked questions and expressed some concern about the procedures for handling possible requests by others for use of these facilities.

In recognition of the CCF investment in constructing a Patient Handling Facility we have, in the Consortium Agreement, provided for your exclusive use of this Patient Handling Facility during the term of this agreement. In connection with the jointly-financed vertical neutron beam in the patient treatment room, it is noted that, should a non-governmental third party request permission to use this vertical neutron beam for cancer therapy or cancer research, we would refer the inquirer to CCF with the advice that they arrange with CCF to participate in the ongoing program. It is understood and agreed that CCF and such parties will be treated equitably.

Sincerely,

A handwritten signature in cursive script, reading "Bruce T. Lundin", is written over the typed name.

Bruce T. Lundin
Director

CONSORTIUM AGREEMENT

This Consortium (Cooperative) Agreement is entered into this 22nd day of February, 1977, by and between the Cleveland Clinic Foundation, 9500 Euclid Avenue, Cleveland, Ohio, an Ohio corporation, not-for-profit, (hereinafter called "CCF") and National Aeronautics and Space Administration, Lewis Research Center, 21000 Brookpark Road, Cleveland, Ohio, an agency of the Federal Government (hereinafter called "NASA"), acting under the authority of Section 203(c)(6) of the Space Act of 1958, as amended, 42 USC 2451 et seq., and Public Law 94-278 Section 1102(b), 42 USC 225a.

WHEREAS, CCF has received a grant from the National Cancer Institute (hereinafter called "NCI") (Grant No. 1-P01-CA-197 20-01 entitled "Neutron Beam Radiotherapy") dealing with the treatment of cancer patients and related research through the use of the NASA cyclotron (hereinafter called the "Grant"); and

WHEREAS, CCF and NASA desire to enter into an agreement pursuant to which the NASA cyclotron may be utilized by CCF for treatment of cancer patients and related research as provided in the Grant; and

WHEREAS, CCF and NASA desire to establish an arrangement and relationship pursuant to which programmatic activity is carried out through a cooperative arrangement between CCF as the grantee institution and NASA as the cooperating institution.

NOW THEREFORE, in consideration of the mutual covenants, representations, warranties and conditions contained herein, the parties agree as follows:

1. Designations

For purpose of management of the Grant, CCF will be designated the grantee institution and NASA will be designated

2. Term of Agreement

The term of this Agreement shall commence October 1, 1976, and terminate September 30, 1979; provided however that the term hereof shall automatically continue from year to year thereafter unless either party gives at least ninety days advance written notice to the other of an intention not to continue the Agreement beyond its expiration date.

This Agreement may also be terminated by NASA in whole or in part, and without cost to the Government, if there has been a failure by CCF to comply with any term or condition of this Agreement, if said failure is not cured or complied with after specific written notice thereof has been given to CCF by NASA. This Agreement may also be terminated by NASA, in whole or in part, and without cost to the Government, if the cognizant Institutional Director at NASA Headquarters, or the Director of Lewis Research Center, determines that the national aeronautics and space program, the national defense, or the public welfare require the termination of the Agreement; and at least a 30-day advance notice in writing is given to CCF that such determination has been made. CCF may terminate this Agreement for any reason it deems appropriate by giving at least 30 days' advance written notice to NASA.

Termination or expiration of the Grant shall not operate to terminate this Agreement, but shall cause it to be reopened for renegotiation of its terms and conditions consistent with the changed relationship between the parties.

3. Times Cyclotron is Available for Use

NASA shall make available to CCF the use of the Lewis Research Center cyclotron and related facilities, for purposes of performing treatment of cancer patients and related research in accordance with and subject to the terms and conditions

excepted) during the hours from 8:00 a.m. to 4:00 p.m., and, in addition, to the extent practicable NASA will endeavor to make available similar hours on Fridays and other days and times, based on clinical need and upon reasonable advance notice from CCF. CCF shall have priority over other uses or users of the cyclotron during the assigned hours, except that its usage may be pre-empted in case of local or national emergency, as determined by the Director of NASA-LeRC, or his designee.

4. NASA Duties

NASA shall use its best efforts to cause the cyclotron to produce a high-powered beam of deuterons that produces neutrons, as described in the application for the Grant, which is capable of being delivered in both vertical and horizontal fashion at the treatment room (Room No. 1 of NASA-LeRC Building 49) on the Lewis Research Center premises. The CCF shall bear the expense of the facility modifications to produce the vertical beam. NASA shall be responsible for operation, maintenance and repair of the cyclotron facility, exclusive of the special support facilities for patients to be maintained by CCF staff or CCF's contractors, except as provided in para. 13. The cyclotron shall be capable of delivering a continuously available neutron beam as described above, on a best efforts basis.

5. CCF Patient Treatment Responsibilities and Indemnification

NASA and CCF shall monitor the deuteron beam current, alignment and focus and CCF shall have control of and be solely responsible for the generation of the neutron beam by stopping or passing the deuteron beam to the target, and CCF shall have control of and be solely responsible for use, and operation of the neutron beam from its point of reception in the treatment room.

beam and agrees to indemnify and hold the United States of America and its officers, agents, and employees harmless from and against any and all claims, suits, expenses, damages and liability arising as a result of the use of the cyclotron or other NASA facilities by CCF or its employees or patients and other visitors to the CCF cancer treatment center at LeRC. However, the foregoing indemnification and hold-harmless provision shall not apply with respect to NASA employees covered by the Federal Employees' Compensation Act or persons who are not employees, patients, or invitees of CCF, unless in either case the negligence of CCF, its officers, agents and employees proximately caused the damage or injury complained of.

CCF shall insure that CCF employees assigned to work at the LeRC and visitors to the cyclotron treatment center will comply with the same rules and regulations as NASA employees related to matters of safety in a radiation area. CCF shall be responsible for personal dosimetry of their patients and employees. Visitors and guests to the cyclotron facility shall also comply with NASA safety and health-physics regulations; their exposure while at LeRC will be monitored by NASA employees.

6. Payments

All funds to be paid pursuant to the Grant shall be paid directly to CCF by the National Institutes of Health hereinafter called "NIH". CCF shall make payments to NASA as follows:

(A) First year of the term hereof:

CCF shall pay NASA at the rate of \$55 per hour, or proportionately for fractions of an hour, for dedicated beam time. The concept of dedicated beam time shall be the following: (1) beam startup time, including

warmup, alignment and stabilization; (2) time

expended for physical and biological beam characterization measurements; (3) time for performance of dosimetry measurements, calibrations and intercomparisons; and (4) time during patient handling, set-up and treatment; and (5) other usages requested by one party and agreed to by the other. The CCF shall also reimburse NASA for personnel costs, including salary, fringe benefits, and applicable overhead expenses, for the services of NASA scientists and technicians; provided that the time charged and the effort performed shall not exceed \$60,000.

(B) Second and third years of the term hereof:

CCF shall pay NASA at the rate of \$60 per hour for dedicated beam time. CCF shall also reimburse NASA for personnel costs (salary, fringe benefits, and applicable overhead expense) at a rate not to exceed \$16,000 per year.

(C) Year(s) subsequent to the 3rd Year of the Agreement

Payment rates will be negotiated and determined prior to the end of the 3rd year of this agreement.

Except as stated above, no other payments shall be made by CCF to NASA for CCF's use of the cyclotron. During the period of the Grant, the specific amount of funds to be expended by NASA for the purposes described shall be based upon the budget of the

monthly or quarterly statements, as necessary, to CCF setting forth payments due it by CCF for the preceding period. CCF shall make payment of each such statement within thirty days of receipt thereof, with checks made payable to the order of the "National Aeronautics and Space Administration". Such periodic statements may include certain estimated costs; however at least once a year said estimates shall be adjusted to actual costs incurred, usually within 6 months after close of the NASA fiscal year.

7. Programmatic Responsibilities

During the period of the Grant, programmatic responsibilities of CCF and NASA shall be those as set forth in the Grant, a complete copy of which has been furnished to NASA and approved in writing. The Grant is however subject to modifications, amendments, continuations and renewals to which NASA must consent in writing in order to be bound. The principal investigator and responsible persons and their duties under the Grant are described in Exhibit A hereto.

8. Records on Expenditures and Audit

CCF shall maintain records on all expenditures made under the Grant. All costs incurred in the Grant will be subject to audit by the cognizant Federal audit agency. Upon request, the auditors of CCF and cognizant Federal auditors will be provided access to records supporting grant-related costs of NASA. NASA shall maintain such records under the Grant for all expenditures made and costs incurred, as required by relevant Federal Management Circulars and the Code of Federal Regulations and by the grantee.

9. Publications and Publicity

Each party hereto is free to publish the results of any research performed under terms of the Grant. Work in which

authored. NASA shall submit copies of any research papers to CCF at such time as they are submitted for publication and CCF shall reciprocate with their research papers. Publicity such as announcements, news releases, and press conferences, shall be coordinated between NASA and CCF by the Public Information Officers of each party.

10. Reporting

Each party will be responsible for progress reports (interim reports and terminal reports). The interim reports will be submitted by NASA to CCF on a schedule to be determined by the CCF project director. The terminal reports required by the Grant will be due by NASA to CCF within 45 days after the end of the Grant. The contents of the reports shall conform to the guidelines laid down by the NCI.

11. Assurances

CCF shall have responsibility for ensuring that all required assurances are obtained. These may include any or all of the following:

(A) Care and treatment of laboratory animals

CCF, if it uses warm-blooded animals in the grant-supported project, will comply with applicable portions of the Animal Welfare Act (P.L. 89-544, as amended) and will follow the guidelines prescribed in DHEW Publication No. 72-23 (NIH), "Guide for the Care and Use of Laboratory Animals".

(B) Civil rights and equal employment opportunity

CCF shall comply with Title VI of the Civil Rights Act of 1964, and Executive Order 11246. CCF will ensure that valid Assur-

Act of 1964 are on file with the Department of Health, Education and Welfare ("DHEW") (Form HEW 441) and, if any contracts are entered into, they will include paragraphs (1) through (7), Part II, Subpart B, Section 202, Executive Order 11246.

(C) Protection of human subjects

Under the provisions of DHEW Publication No. (NIH) 72-102, "The Institutional Guide Policy on Protection of Human Subjects" and in particular Section B, "Special Assurance", p. 13 et seq., CCF will, unless it has given a "General Assurance", obtain the necessary clearance from NCI for that part of any research carried on and involving human subjects.

12. Inventions

Rights to inventions made solely by NASA employees in the performance of work under this agreement shall be determined by NASA pursuant to Executive Order 10096 and implementing regulations. All other inventions made in the performance of work under this agreement shall be subject to the attached clause entitled "Property Rights in Inventions" (Exhibit "B" hereto).

13. CCF-Sponsored Facility Modifications

CCF may at its expense, construct and install in the treatment room and adjacent areas in the locations described on Exhibit C, hereto, fixtures and other facilities as may be necessary to carry out the program and work contemplated by this Agreement. NASA shall cooperate with CCF in providing access to

of any new utilities, shall be provided by NASA. CCF may also at its expense construct a new patient-handling facility building as described in Exhibit D hereto. After completion of construction, NASA will provide cleaning, security and routine maintenance services and all utility services, except PBX telephone service. For these services, CCF agrees to pay to NASA a monthly charge of \$0.30 per square foot, inside building dimensions, for calendar 1977; the charge shall increase 7% annually for each succeeding year of this Agreement. Construction of all additional utility lines or other utility facilities required by CCF shall be accomplished at CCF expense. Title to all real estate improvements, structures and fixtures, other than removable equipment and personal property, shall vest in NASA upon construction of the facilities by CCF. CCF shall have the right at any time to remove all items of removable equipment and personal property furnished by them. It is understood and agreed that all equipment concerned with generation, control, distribution, focusing and handling of the deuteron and neutron beams will be classified as non-removable fixtures. It is understood and agreed that during the term of this agreement the CCF shall have exclusive use of the patient handling facility. It is also understood and agreed that any request by a third party for use of the patient handling facility will be a matter of consultation between the parties and CCF will give appropriate consideration to such requests. The vertical neutron beam will not be used by any third party or for any non-governmental purpose outside the scope of the grant without consultation between the parties. NASA shall approve, in advance, any plans for new or modified facilities on the site of LeRC. Also the contractors and subcontractors of CCF performing construction work on the site of NASA-LeRC shall conform to practices

covering said work, furnishing of insurance certificates in the amounts and types ordinarily required by NASA prior to commencing work, and payment of Davis-Bacon Act minimum wages to the construction trades involved, as then determined by the Secretary of Labor, as well as all Center Safety and Security Requirements. All insurance certificates shall name the United States of America as an additional insured on the insurance policies involved. A copy of all contracts entered into by the CCF shall be submitted to the NASA Office of Chief Counsel for information prior to the start of work.

14. Assignment of Agreement Rights and Approval of NIH

Neither party may assign or transfer this Agreement or any of its rights or obligations hereunder. This Agreement may not be modified, amended or altered except by a writing signed on behalf of both parties hereto. This agreement is subject to the approval of the National Institutes of Health and shall not become effective until it has been approved by NIH.

15. Visitor and CCF Employee Clearances to Visit NASA-LeRC

The CCF agrees that it will join with NASA during the period of performance of this agreement in seeing that all CCF staff employees and visitors to the cyclotron treatment facility comply with the requirements of the attached clause (Exhibit "E" hereto) entitled Badges, Passes, Emergencies, Accidents and Traffic Procedures. Wherever the term the "contractor" or "contract" appears in this clause substitute "CCF" or "this agreement" respectively therefor.

IN WITNESS WHEREOF, the parties have caused this agreement to be executed on the year and date first appearing above.

THE CLEVELAND CLINIC FOUNDATION
9500 Euclid Avenue
Cleveland, Ohio 44106

by William S. Kiser,
(Title & Name)
Vice President

NATIONAL AERONAUTICS AND SPACE
ADMINISTRATION, LEWIS RESEARCH
CENTER
21000 Brookpark Road
Cleveland, Ohio 44135

by Bruce T. Lundin
Bruce T. Lundin, Director

This instrument was prepared by Edward A. Zak of the Office of Chief Counsel, NASA-Lewis Research Center, 21000 Brookpark Road, Cleveland, Ohio 44135, representing NASA and by Norman S. Jeavons of Baker, Hostetler, and Patterson, Union Commerce Building, Cleveland, Ohio 44115, representing the Cleveland Clinic Foundation.

| | |
|-----------------------|----------------------------|
| ANTONIO ANTUNEZ, M.D. | PRINCIPAL INVESTIGATOR |
| PAUL LAVIK, M.D. | CO-INVESTIGATOR |
| GWYNN JELDEN, M.D. | CO-INVESTIGATOR |
| WM. MacINTYRE, M.D. | CO-INVESTIGATOR CONSULTANT |
| CHERNAK, EDWARD | PHYSICIST |

EXHIBIT "A"

PROPERTY RIGHTS IN INVENTIONS
(November 1972) (NPR 9.105(a))

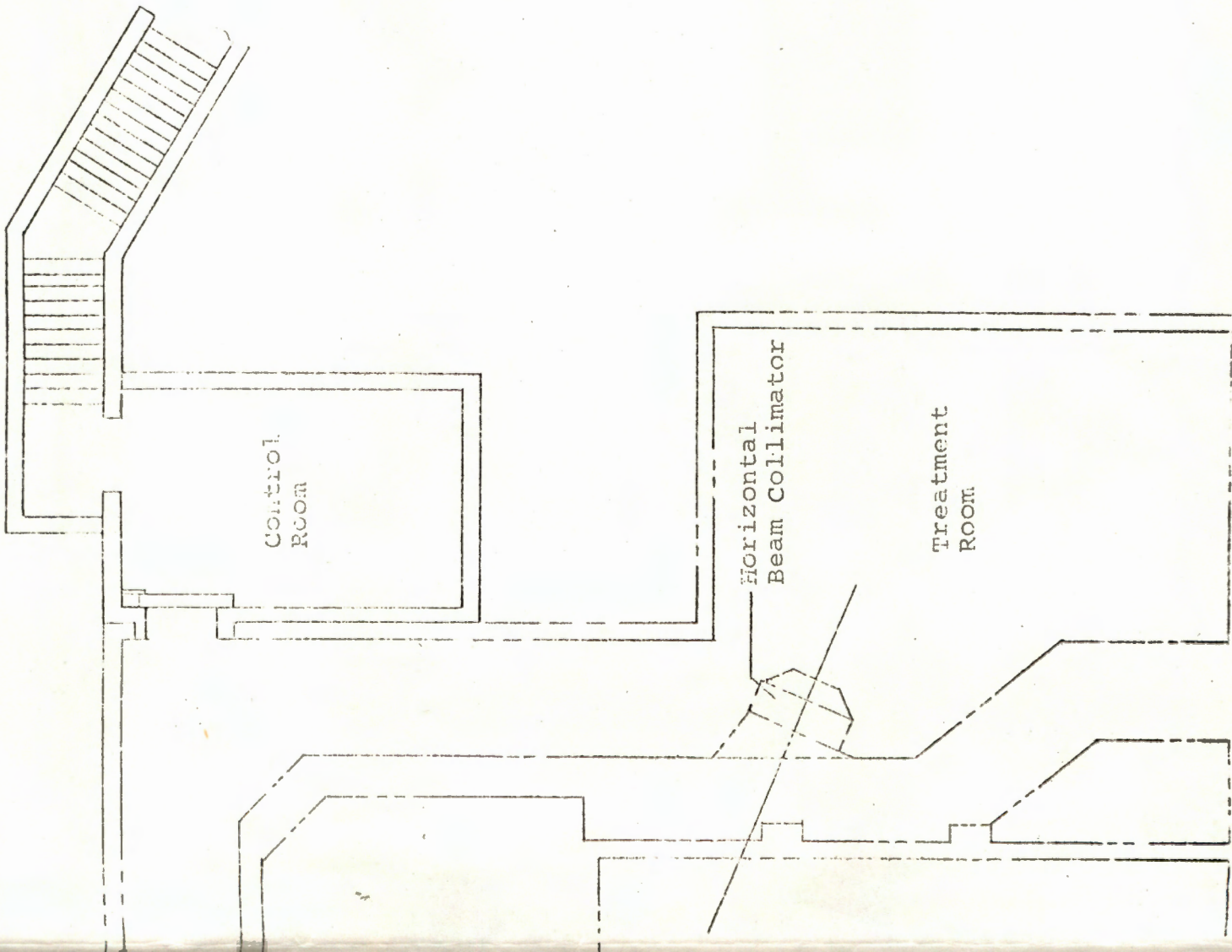
(a) This agreement and all subcontracts issued thereunder are subject to Section 305 of the National Aeronautics and Space Act of 1958 (42 U.S.C. 2457) relating to property rights in inventions. The term "invention" includes any invention, discovery, improvement or innovation. Any invention made in the performance of work under this agreement or any subcontract issued thereunder shall be presumed to have been made under the conditions of and subject to Section 305(a) of the Act and becomes the exclusive property of the United States subject, however, to the retention by CCF or its subcontractor of a royalty-free license to practice the invention pursuant to, and of the scope defined in, 14 C.F.R. 1245.204(a). This license may be revoked under the conditions set forth in 14 C.F.R. 1245.211(b) and (c). CCF or its applicable subcontractor may petition for waiver of title to the invention in accordance with the NASA Patent Waiver Regulations, 14 C.F.R. 1245, Subpart 1.

(b) CCF shall furnish to NASA a written report containing full and complete technical information concerning any invention made in the performance of any work under this agreement promptly upon the making of such invention and shall require all subcontractors to do so. Upon written request by NASA, CCF shall furnish additional information available to it and shall secure the execution of such documents as may be necessary to enable the Administrator, NASA, to file and prosecute patent applications on any such invention. Upon completion of the work under this agreement, CCF shall furnish to NASA a report as to whether or not any

EXHIBIT C

Page 1 of 2

Basement floor plan showing addition
of Control Room and Emergency Egress
Stairway (Building 49)



Elevation View showing addition of Magnet Building
and Vertical-Beam Installation

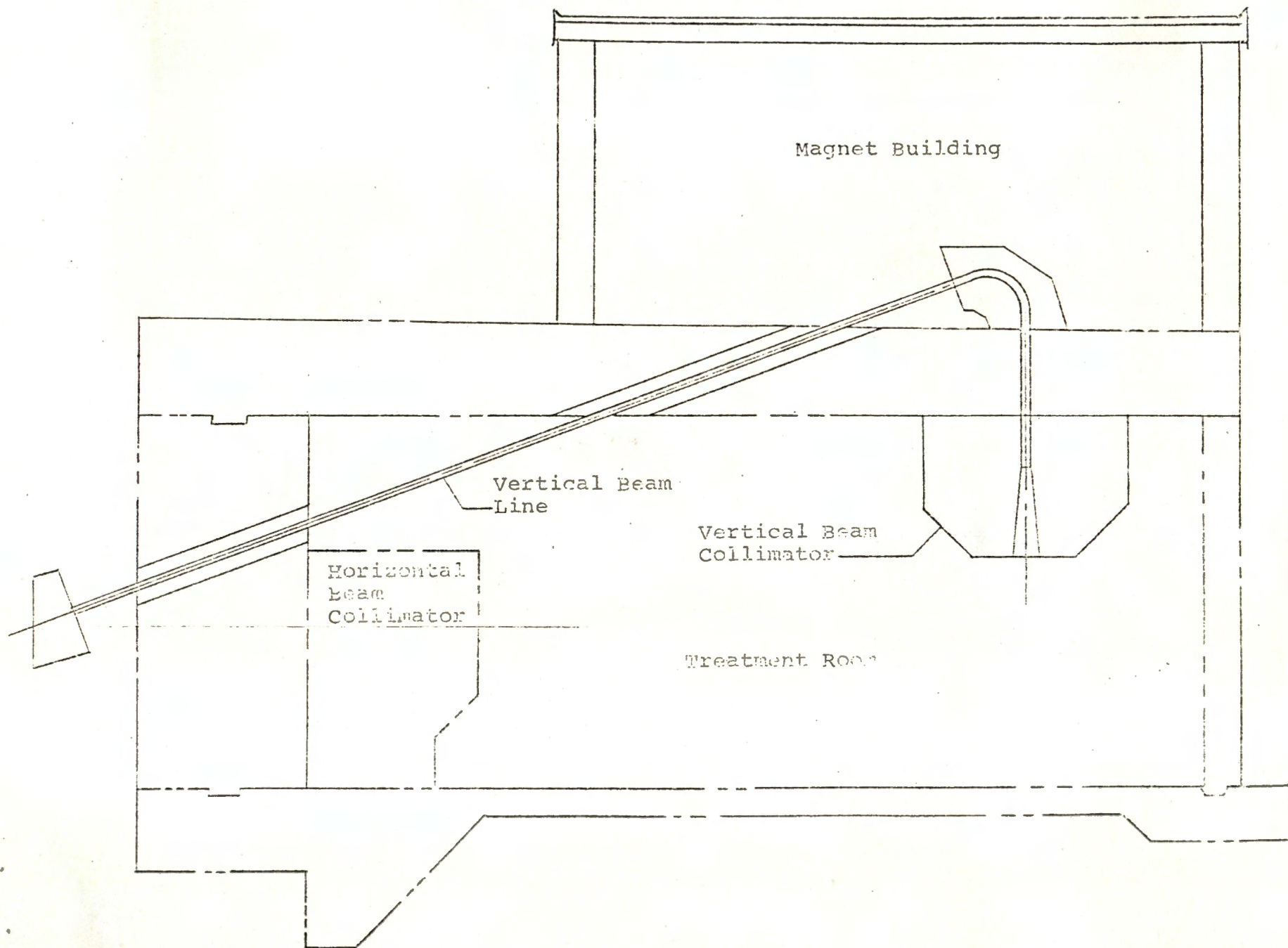
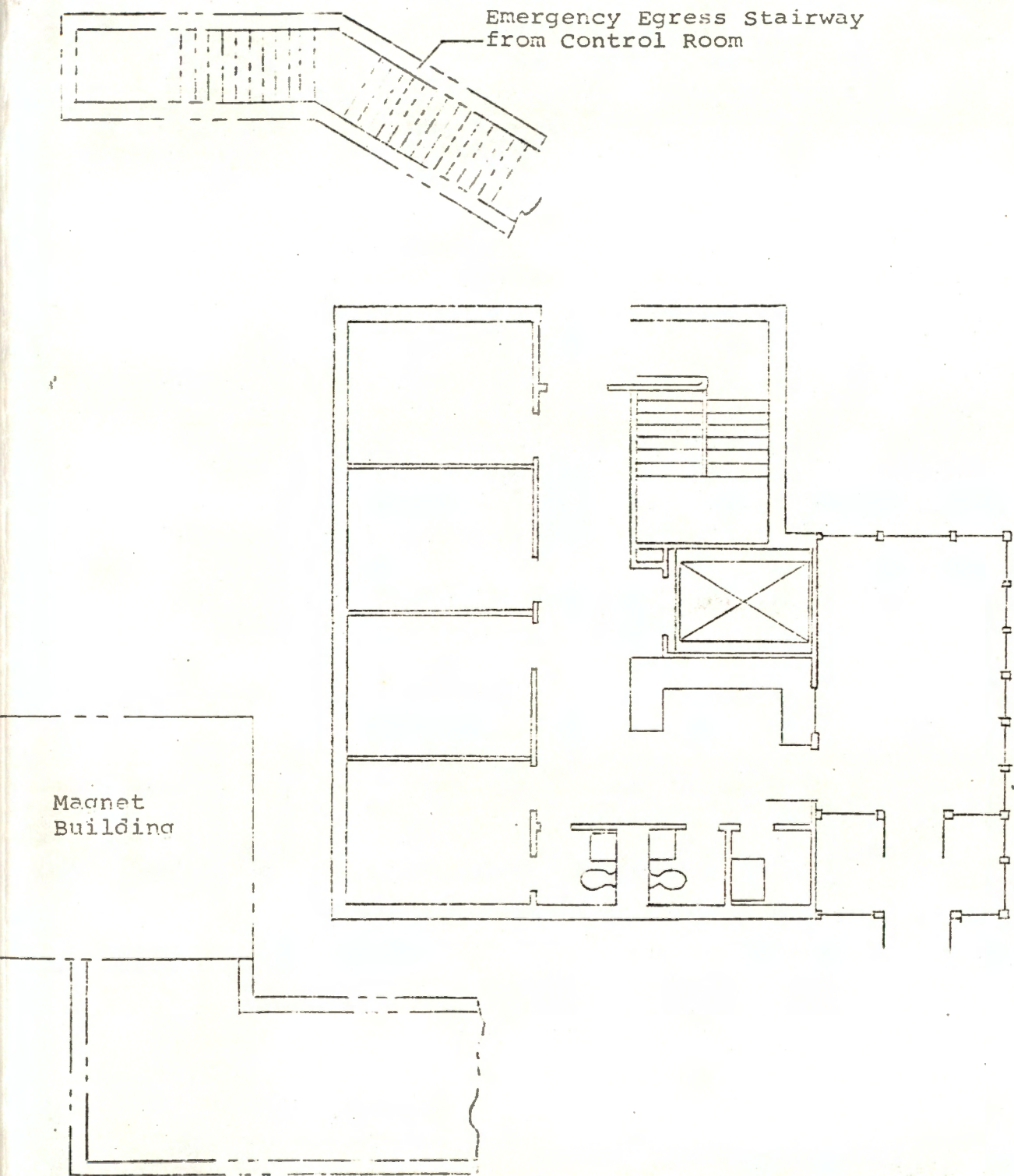


EXHIBIT D

Proposed First-Floor Plan View of
Patient Examining Facility



Clause No. EBADGES, PASSEMERGENCIES, ACCIDENTTRAFFIC PROCEDURES

A. All Contractor personnel having a need to enter areas of the Lewis Research Center or Plum Brook Station shall have an identification badge or pass. This badge or pass shall be obtained at the entrance of the Lewis Research Center or Plum Brook Station.

B. The Contractor's on-site supervisor shall comply with the Badge and Property Regulations (NASA C-421) a copy of which will be given to the Contractor's supervisors at the time of issuance of Badges or Passes. The Badge and Property Regulations are quoted below:

"1. Maintain weekly contact with the Badge Clerk at Visitor Control (FAX 2290) for work at the Lewis Research Center and (FAX 301) for work at Plum Brook Station.

- a. Verify at the beginning of each work week the presence and the job location of contractor employees at the Center.
- b. Report any changes in crew on duty.
- c. In the case of concurrent contracts, report any subsequent shift of contractor employees from one contract to another before the commencement of work.
- d. Report terminations of employment.
- e. Report lost badges.
- f. Provide liaison for the handling of Contractor's visitors.

2. Upon termination of duties, obtain the employee's badge and issue him a "Contractor's Employee Gate Pass" (C-421, copies of which will be furnished to the Contractor's on site supervisor). Return the badge to the Badge Clerk within 24 hours after departure of the employee.

3. If the employee is absent for any reason for more than 5 days, obtain his badge and return to the Badge Clerk. If the badge cannot be obtained, report to the Badge Clerk immediately. Upon his return to duty, and upon verification of new or continued assignment, his badge may be reissued by the Badge Clerk.

4. When an employee terminates his employment without surrendering his badge, report to the Badge Clerk immediately.

5. Final clearance of a Contractor upon completion of a contract will depend in part upon the accounting for all badges issued to employees during the performance of the contract. It should be recognized that security badges are Government property.

6. A Property Pass (C-702) is required for the removal of all contractor-owned property and equipment and must be presented to the gate guard upon exit. Lewis or Plum Brook inspection personnel will help Contractors obtain the proper pass authorization and will ensure that the Property Pass contains a complete description of the material/equipment being removed. Material relating to a specific contract or purchase order must be identified by insertion of the appropriate contract/purchase order number on the Pass by the Inspector."

C. The Contractor shall require its employees to comply with instructions on the use of employee badges. These instructions, a copy of which will be provided to each employee at the time of issuance of a badge or pass, are as follows:

1. The Contractor's badge which is being issued to you at this time is charged to you personally. You will be held responsible for the proper use of this badge and for its protection as property of the United States Government and within the protective jurisdiction of the Federal Bureau of Investigation.

2. The permitted area of access is the area or areas where you are actually working. If access to another area is desired, you are required to telephone the party you wish to contact and you may leave your assigned area by invitation only.

3. During normal working hours, 7:30 a.m. to 5:00 p.m. Monday through Friday, the guards at the gates will permit your entrance and departure. At any other time (other than normal hours), advance clearance is required, and may be obtained through the Lewis/Plum Brook inspection personnel who will then make the request to the Security Office. After-hour clearances as approved by the Security Office are certified to the guards as authority for admittance of a Contractor during off hours, including Saturdays, Sundays and holidays.

4. In cases of normal hour entrance wherein Contractor badge holders find it necessary to remain after 5:00 p.m., the procedure described in subparagraph three above shall be followed. Guards are under instructions to request all unauthorized Contractor personnel to leave the reservation.

5. Upon completion of your work assignment at this Center, you shall return this badge to your company supervisor and obtain a "Contractor's Employee Gate Pass" which you shall give to the gate guard upon your final departure. In the event your company supervisor is not on the site at the time of your termination, you are instructed to notify the guard at the gates that you have completed your assignment and are therefore surrendering your badge. Should you leave the Lewis Research Center or Plum Brook Station for a period of more than five days for any reason whatsoever, you are requested to surrender your badge in the same manner. Upon returning, your badge will be reissued by the guard upon verification of your current employment.

6. As a condition of entrance into the Security area of the Lewis Research Reservation, you waive any and all legal immunity possessed from the search of your person, luggage or vehicle, which may be instituted for the purpose of prevention of nonauthorized removal of Government property.

7. Your acceptance of the responsibilities and compliance with the foregoing requirements will facilitate your final clearance from the reservation with a minimum of inconvenience to you and your employer.

D. The Contractor shall comply with the following emergency, accident and traffic requirements:

1. The Contractor agrees to require that all his personnel shall comply with all "Posted" traffic signs, signals and instructions of personnel assigned for traffic control purposes. In addition the Motor Vehicle Laws for the State of Ohio shall apply.

2. Contractor personnel shall be informed that Emergency, Fire, Medical and Safety Security assistance can be requested by "Dialing 12" on the Center's FAX or FAX telephone systems. Emergencies are defined as incidents involving

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November 8, 1977

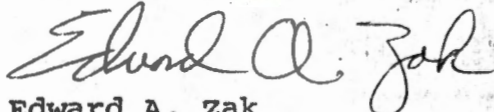
John A. Auble, Esq.
Secretary and General Counsel
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, OH 44106

Dear Mr. Auble:

Subject: CCF/NASA Consortium Agreement for the
Operation of the NASA-LeRC Cyclotron
in the Treatment of Cancer Patients

Enclosed please find a fully executed copy of Modification
No. 1 to subject agreement, as signed by Dr. Bernard
Lubarsky, Acting Center Director, on November 7, 1977.
Thank you for your cooperation in the prompt signing of
this modification.

Sincerely yours,



Edward A. Zak
Office of Chief Counsel

Enclosure

cc:
Norman Jeavons, Esq.
c/o Baker, Hostetler and Patterson

bcc:
0110/J. Burnett
6301/J. Blue
2501/M. Valerino
1210/M. Hoyman✓
1241/L. Zutz
1200/A.J. Hess
1005/E. A. Zak
1005/Correspondence
1005/Cooperative Cleveland Clinic Cyclotron Agreement File

1005:EAZak:jbc

THE CLEVELAND CLINIC FOUNDATION

JOHN A. AUBLE
Secretary and General Counsel

October 28, 1977

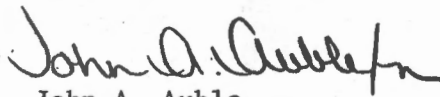
Edward A. Zak
Office of Chief Counsel
NASA - Lewis Research Center
21000 Brookpark Road
Cleveland, Ohio 44135

Re: Modification No. 1. to Consortium
Agreement between The Cleveland
Clinic Foundation and the
NASA-Lewis Research Center

Dear Mr. Zak:

Enclosed herewith please find original and three copies of
the above captioned modification agreement executed by
William S. Kiser, Vice President. Upon execution by the
NASA director, please return one copy of this agreement to
the undersigned.

Yours very truly,


John A. Auble

nrn

enclosures

*Rec'd
10/31/77
EGZ*

MODIFICATION NO. 1 TO
CONSORTIUM AGREEMENT BETWEEN
THE CLEVELAND CLINIC FOUNDATION
AND THE
NASA-LEWIS RESEARCH CENTER

NOW, WHEREAS, the Cleveland Clinic Foundation ("CCF") and the National Aeronautics and Space Administration, Lewis Research Center ("NASA") have entered into a consortium or cooperative agreement as of February 22, 1977 calling for CCF to utilize the NASA cyclotron for the treatment of cancer patients and related research, and

Whereas, CCF has requested NASA to temporarily provide additional space in the basement of NASA-LeRC Bldg. 49 for use as an interim patient handling facility, pending CCF construction of a new patient handling facility on the grounds of NASA-LeRC, for a period of not-to-exceed 6 months from the date of this modification No. 1, with a rate of reimbursement to NASA for such space and related services agreed upon in this same modification No. 1, and

Whereas, the space being granted herein in the basement of NASA-LeRC Bldg. 49 is not required for a current NASA program and the CCF's exercise of rights in respect to such space in the basement of Bldg. 49 will not interfere with NASA operations, and

Whereas, fair value in money, as required by NASA regulation NPD 8813.2 (6-1-64), will be received from CCF for the granting of the interest in real property herein described, and

Whereas, the parties have agreed to clarify their prior

Now, Therefore, the parties hereto agree that the consortium agreement between the parties of February 22, 1977 is amended solely in the following respects:

1. In Section 13 of the agreement, at the end thereof, on page 10 of the agreement, the following new paragraph is added:

"NASA agrees further to make up to 1000 square feet of usable space in the basement of Bldg. 49 at NASA-LeRC available to CCF, for up to 6 months after the date of modification No. 1 to this agreement, as an interim Patient Handling Facility to be used in the Cyclotron Cancer Therapy Program. Such space, as is delineated on the attached Exhibit "F" to this agreement, shall be provided on an 'as-is' basis, with CCF to bear the costs of any rehabilitation, modifications, or refurbishment thereof. Upon occupancy of such space by CCF, NASA will charge CCF and CCF shall pay NASA, on a monthly basis, the sum of \$.30/sq.foot/month for maintenance, security, utilities, inside telephone, and custodial services provided by NASA. The exact square footage shall be determined by representatives of each party and so certified in a written form no later than the 1st day of actual CCF occupancy. In the event CCF ceases occupancy of all or some of these quarters prior to the end of this 6-month period, the user charge of \$.30/sq.foot/month will be reduced proportionally, for that period of any

However, the above portion of this Consortium Agreement, relative to the use of space in Bldg. 49 basement, may be terminated, in whole or in part, without cost to the Government, if there has been:

(1) a failure to comply with any term or condition imposed by NASA upon CCF's usage of the space provided in the Bldg. 49 basement, as defined in this Mod. No. 1 to the consortium agreement,; or (2) a determination by the appropriate NASA Administrator at NASA Headquarters, or the Director of the field installation concerned, that the interests of the national space program, the national defense, or the public welfare require the termination of the interest granted; and a 30-day notice, in writing, to the CCF that such determination has been made. Written notice of such termination shall be given to the CCF by the appropriate Administrator at NASA Headquarters, or the Director of the field installation concerned, and the termination shall be effective as of the date specified by such notice."

2. On page 2 of the agreement, under Article 2 "Term of Agreement", delete the first paragraph thereunder and substitute the following therefor: "The term of this agreement shall commence October 1, 1976 and shall terminate March 31, 1980, with the first increment of the agreement being October 1, 1976 thru March 31, 1978 and the second increment

automatically continue from year to year after March 31, 1980 unless either party gives at least ninety (90) days advance written notice to the other of an intention not to continue the agreement beyond its stated expiration date."

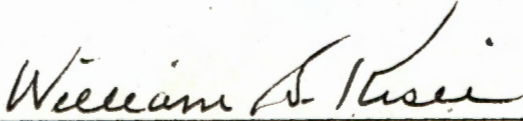
3. Except as noted above, all terms and conditions of the consortium agreement remain unchanged.

This Modification No. 1 shall be effective this 7th day of November, 1977, the date the modification was signed by the NASA-Lewis Research Center Director.

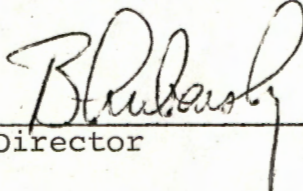
In witness whereof, the parties have caused this modification to their original agreement to be executed on the year and date indicated above.

THE CLEVELAND CLINIC FOUNDATION
9500 Euclid Avenue
Cleveland, Ohio 44106

NATIONAL AERONAUTICS AND SPACE
ADMINISTRATION
Lewis Research Center
21000 Brookpark Road
Cleveland, Ohio 44135

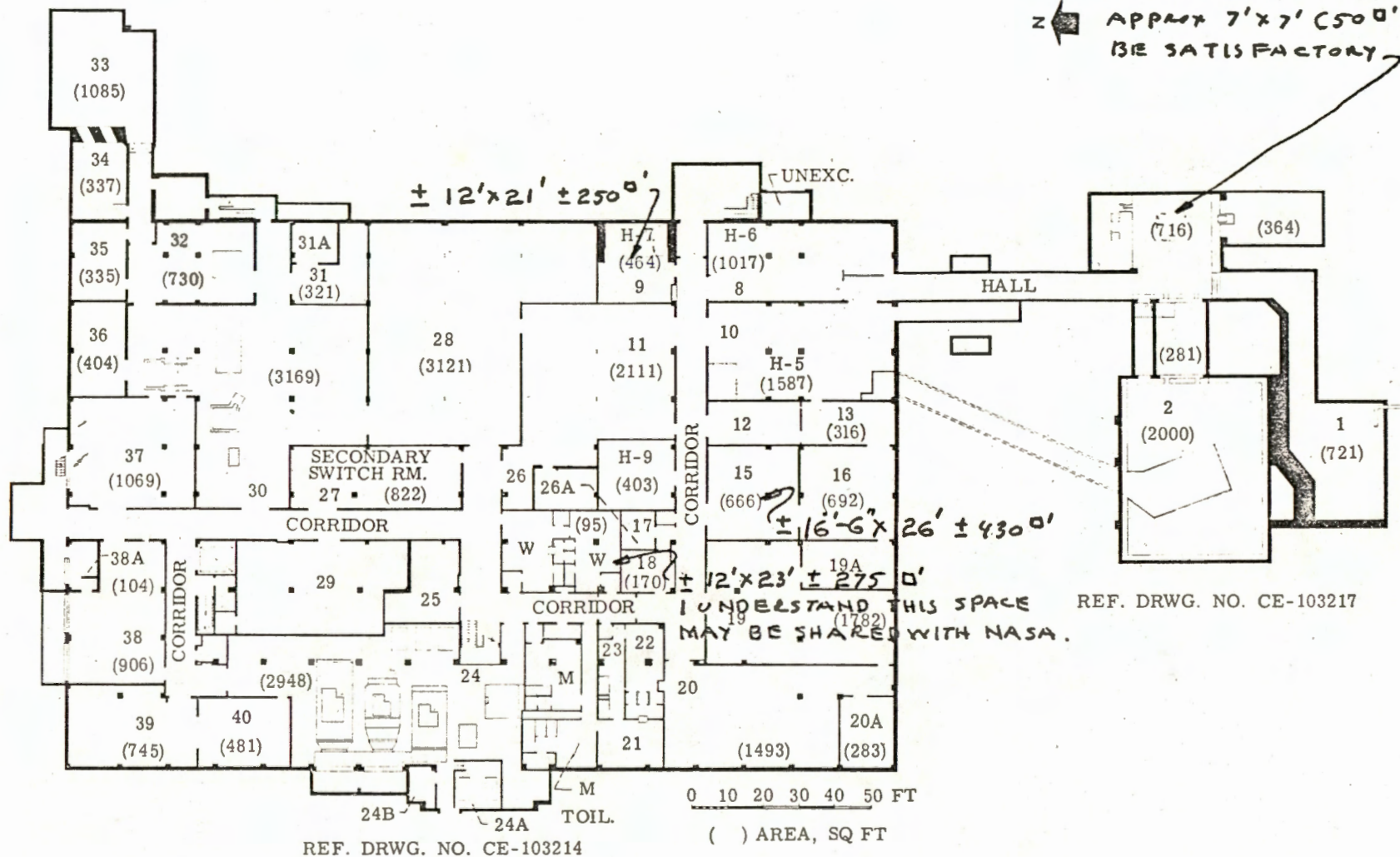


William S. Kiser
Vice President



Director

THE NEEDS OF THIS SPACE
HAVE NOT BEEN DEFINED YET.
IT IS ANTICIPATED A SPACE
APPROX 7'X 7' (500') WOULD
BE SATISFACTORY



BASEMENT FLOOR & SOUTH WING PLAN
MATERIAL AND STRESSES LABORATORY
STRUCTURE NO.

Exhibit "F"

1005

June 5, 1978

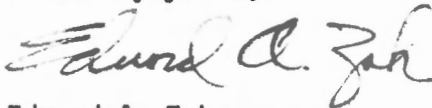
John A. Auble
Secretary and General Counsel
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, OH 44106

Dear Jack:

Enclosed please find a fully signed copy of Modification No. 2 to the original Consortium Agreement between CCF and NASA of February 22, 1977. Dr. Bernard Lubarsky as Center Deputy Director signed the modification on June 2, 1977.

Thank you for your cooperation in getting the agreement signed, so that the gamma radiation of cancer patients could begin in conjunction with your use of the NASA Cyclotron for these purposes.

Sincerely yours,



Edward A. Zak
Office of Chief Counsel

Enclosure

cc:

6301/J. Blue

0110/J. Burnett

2501/M. Valerino

1001/J. Earls

1005/Correspondence

1005/Consortium Agreement - Cleveland Clinic File

1005/E. A. Zak

1005:EAZak:jbc

MODIFICATION NO. 2 TO
CONSORTIUM AGREEMENT BETWEEN
THE CLEVELAND CLINIC FOUNDATION
AND THE
NASA-LEWIS RESEARCH CENTER

NOW WHEREAS, the Cleveland Clinic Foundation ("CCF") and the National Aeronautics and Space Administration, Lewis Research Center ("NASA") have entered into a consortium or cooperative agreement as of February 22, 1977 calling for CCF to utilize the NASA cyclotron for the treatment of cancer patients and related research, and

Whereas, CCF has requested NASA to allow CCF to install certain removable equipment in LeRC Bldg. 49, i.e. a Picker Teletherapy Unit with a Cobalt-60 source for gamma radiation treatments, in order to permit CCF to give cancer patients both neutron therapy treatments as well as gamma radiation treatments within a short interval of each other, which combined treatment offers greater prospects of success in the treatment of such cancer patients, and

Whereas, the space to be utilized for the installation of the gamma radiation unit in NASA-LeRC Bldg. 49 is not required for a current NASA program and the CCF's exercise of rights in respect to such space in Bldg. 49 will not interfere with NASA operations, and

Whereas, consequently, the scope of the current indemnification provision must be expanded to provide equivalent protection for the United States of America now that an additional patient treatment area, i.e. the gamma radiation unit, is to be added to the CCF patient treatment facility in Bldg. 49,

Now, Therefore, the parties hereto agree that the consortium agreement between the parties of February 22, 1977 is amended solely in the following respects:

1. In Section 5 of the agreement, on pages 4-5, delete the 2nd sentence thereunder and substitute the following sentence therefor:

unit mentioned later in this Agreement; CCF also agrees to indemnify and hold the United States of America and its officers, agents, and employees harmless from and against all claims, suits, expenses, damages, and liability arising as a result of the use, by CCF, its employees, patients, or other visitors to the CCF Cancer Treatment Center at LeRC, of the Cyclotron, other NASA facilities, or other CCF facilities and equipment, which are placed or installed at Lewis Research Center."

2. On page 8, in Section 13 of the Agreement, label the first full paragraph thereunder, which extends until the top of page 10, as paragraph "A" and insert the following immediately thereafter as new paragraph "B":

"B. CCF may also at its expense install a removable gamma radiation source in LeRC Bldg. 49, such as a Picker Teletherapy Unit, in the treatment area. Such radiation source shall be solely installed and operated by CCF personnel; such unit shall require no building modifications or additional shielding. Since a license is required from the U.S. Nuclear Regulatory Commission (NRC) for the operation of a radiation source that utilizes Cobalt-60, or other nuclear by-product material, CCF shall be required to obtain all necessary permits and licenses for said radiation source and CCF shall further assume sole responsibility for compliance with the terms of the NRC licenses and permits. CCF recognizes that both CCF and NASA have an interest in monitoring radiation safety in connection with said radiation source and that NASA has the responsibility for monitoring NASA employees and NASA visitors in the area of said radiation source. The CCF accordingly will keep the NASA-LeRC Environmental Health Office fully informed as to all aspects of radiation safety in connection with maintenance and operation of the radiation source. CCF also agrees that NASA Environmental Health Office has the right to terminate this operation involving the radiation source unit, if, in NASA's sole judgment, there is determined to be a health hazard to NASA personnel and/or visitors."

3. Except as noted above, all terms and conditions of the consortium agreement remain unchanged.

This Modification No. 2 shall be effective this 2nd day of June, 1978, the date the modification was signed by the NASA-Lewis Research Center Deputy Director.

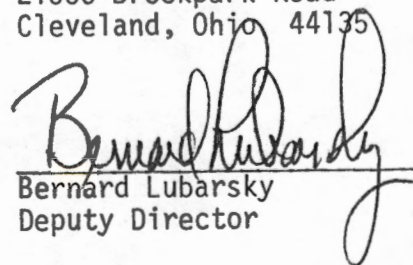
In witness whereof, the parties have caused this modification to their original agreement to be executed on the year and date indicated above.

THE CLEVELAND CLINIC FOUNDATION
9500 Euclid Avenue
Cleveland, Ohio 44106



William S. Kiser
Vice President

NATIONAL AERONAUTICS AND SPACE
ADMINISTRATION
Lewis Research Center
21000 Brookpark Road
Cleveland, Ohio 44135



Bernard Lubarsky
Deputy Director



NATIONAL AERONAUTICS AND SPACE ADMINISTRATION
LEWIS RESEARCH CENTER
CLEVELAND, OHIO 44135



REPLY TO
ATTN OF:

0100

May 19, 1977

MEMORANDUM

TO: AC/Associate Administrator for Center Operations
FROM: 0100/Director
SUBJECT: Use of Lewis cyclotron for cancer neutron therapy

Attached find copies of correspondence between The Cleveland Clinic
and The National Cancer Institute regarding extension of time on
the NCI Grant concerned with use of the Lewis cyclotron.

Bruce T. Lundin

Bruce T. Lundin

Attachment

cc:

J/Raymond A. Kline
AD/Alan M. Lovelace, Dr.
G/S. Neil Hosenball
B/William E. Lilly
AE/Edward P. Andrews
SB/David L. Winter, MD
G/Gerald J. Mossinghoff
BX/Robert H. Curtin
GK/Robert J. Wojtal
QG/Walton Jones, Dr.
BXB/John F. Ryan
YZ/Reuben P. Prichard
JI/James T. Richards, Jr.
RR/F. Carl Schwenk

Lewis Distribution:

cc:

0100/B. T. Lundin
0100/B. Lubarsky
0100/S. C. Himmel
0110/W. T. Olson
0110/J. E. Burnett
0112/P. E. Foster
1000/W. Dey, Jr.
1005/W. A. Brahms
1005/E. A. Zak
1200/V. Gordon
2501/M. F. Valerino
6000/D. J. Shramo
6300/W. E. Moeckel
6301/J. W. Blue
7000/J. F. Connors
8600/D. J. Keliher
8631/F. L. Kouba
0110:JEBurnett:rw 5-19-77
✓ 1210/J. W. Miser



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
BETHESDA, MARYLAND 20014

May 10, 1977

Our Reference: 1 P01 CA 19720-01

Dr. Antonio Antunez
The Cleveland Clinic
9500 Euclid Avenue
Cleveland, Ohio 44106

Dear Dr. Antunez:

The National Cancer Institute approves your request of April 18, 1977, and agrees to extend the end date of the 01 year of this grant to March 31, 1978. This extension is made with the understanding that no additional funds will be awarded due to the extension. As a result of this extension the end date of the grant is also extended (without additional funds) to March 31, 1980.

Sincerely,

Nathaniel E. Bowman
Grants Management Specialist
Division of Cancer Research
Resources and Centers
National Cancer Institute

cc: Mr. William H. True

CLEVELAND CLINIC

THE CLINIC CENTER • 9500 EUCLID AVENUE, CLEVELAND, OHIO 44195 • (216) 444-2200 • CABLE: CLEVELAND CL.

RESEARCH DIVISION

April 18, 1977

Mr. Leo F. Busher, Jr.
Grants Management Officer
Division of Cancer Research
Resources and Centers,
National Cancer Institute
National Institute of Health
Bethesda, Maryland 20014

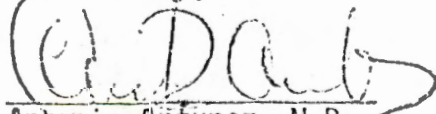
Re: CA 19720-01

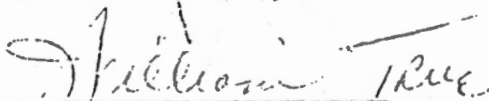
Dear Mr. Busher:

We wish to request an extension for the first year award for grant, CA 19720-01, Neutron Beam Radiotherapy, investigator - Dr. Antonio Antunez, for nine months from July 1, 1977 to March 31, 1978, without additional funding. As we discussed in the beginning of the award period, we have had some delays because of very bad construction weather. The construction is proceeding well and the consortium agreement has been executed and approved. We began expenditures from these funds about April 1, 1977.

Thank you for your support of this project. If you wish further information, please contact me at (216) 444-5840.

Yours truly,


Antonio Antunez, M.D.


William True
Research Administrator

me1

1005

July 2, 1980

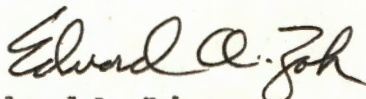
William S. Kiser, M.D.
Chairman, Board of Governors
Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, OH 44106

Dear Dr. Kiser:

Enclosed please find for your files a fully executed copy of Modification No. 4 to our Consortium Agreement for the operation of the NASA Cyclotron in the treatment of human cancer patients, to cover the six month period of July 1, 1980 thru December 31, 1980. Hence said modification extends the current agreement on exactly its current terms thru the end of this year.

Thank you for your cooperation in the prompt execution of this Modification No. 4.

Sincerely,



Edward A. Zak
Office of Chief Counsel

Enclosure

bcc:

0100/J. F. McCarthy, Jr.
0100/J. M. Klineberg
0100/S. Himmel
1000/E. A. Richley
0110/W. T. Olson
0110/J. E. Burnett
1005/E. A. Zak
5500/H. Mark
5533/J. W. Blue
7000/J. F. Connors
1234/C. Alexander
2103/M. F. Valerino
1005/Agreement-Consortium-Cleve. Clinic
1005/Correspondence

1005/EAZak:hmn:7-3-80

MODIFICATION NO. 4 TO
CONSORTIUM AGREEMENT BETWEEN
THE CLEVELAND CLINIC FOUNDATION
AND THE
NASA-LEWIS RESEARCH CENTER

NOW WHEREAS, the Cleveland Clinic Foundation ("CCF") and the National Aeronautics and Space Administration, Lewis Research Center ("NASA") have entered into a Consortium or Cooperative Agreement as of February 22, 1977 calling for CCF to utilize the NASA cyclotron for the treatment of cancer patients and related research, and

Whereas, the parties are in the process of negotiating an extension of up to 5 years in the term of this Agreement, upon certain proposed revised terms therein, for a period through 1985;

Whereas, the space being granted herein is not required for a current or contemplated NASA program and the CCF's exercise of rights in respect to such space will not interfere with NASA operations, and

Whereas, fair value in money, as required by NASA regulation NPD 8813.2 (6-1-64), will be received from CCF for the granting of the interest in real property herein described, and

Whereas, CCF however has not yet concluded the negotiation of the underlying grant for the treatment of cancer patients from the National Cancer Institute (NCI) of the National Institutes of Health (NIH), of the Department of Health, Education, and Welfare (HEW), and

Whereas, the parties hereto have therefore agreed to extend the current Agreement on its current terms for the period of July 1, 1980 through December 31, 1980,

Now Therefore, the parties hereto agree that the consortium agreement between the parties of February 22, 1977, as amended to date, is further amended solely in the following respects:

1. The parties agree that their Consortium Agreement, as previously amended through Modification No. 3, is hereby extended on exactly the same terms and conditions as are currently in effect for the 6-month period beginning July 1, 1980 and ending December 31, 1980.

2. Except as noted above, all terms and conditions of the Consortium Agreement remain unchanged.

This Modification No. 4 shall be effective on the 1st day of July, 1980.

In Witness Whereof, the parties have caused this Modification No. 4 to their original agreement to be executed on the dates indicated below.

THE CLEVELAND CLINIC FOUNDATION
9500 Euclid Avenue
Cleveland, Ohio 44106

by William S. Kiser
William S. Kiser, M.D.
Chairman
Board of Governors

6/20/80
Date of Signing

NATIONAL AERONAUTICS AND SPACE
ADMINISTRATION
Lewis Research Center
21000 Brookpark Road
Cleveland, Ohio 44135

by John F. McCarthy, Jr. for
Director

7/1/80
Date of Signing

This instrument was prepared by Edward A. Zak, Attorney at Law, representing the NASA-Lewis Research Center, 21000 Brookpark Road, Cleveland, Ohio 44135 and John Auble, representing the Cleveland Clinic Foundation, 9500 Euclid Avenue, Cleveland, Ohio 44106.

1005

April 2, 1980

William S. Kiser, M.D.
Chairman, Board of Governors
Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, OH 44106

Dear Dr. Kiser:

Enclosed please find for your files a fully executed copy of Modification No. 3 to our Consortium Agreement to cover the 91-day period of April 1, 1980 thru June 30, 1980. Said modification extends the current agreement on exactly its current terms thru June 30, 1980.

Thank you for your cooperation in the prompt execution of this Modification No. 3.

Sincerely,



Edward A. Zak
Office of Chief Counsel

Enclosure

bcc:

0100/J. F. McCarthy, Jr.
0100/J. M. Klineberg
0100/S. Himmel
1000/E. A. Richley
0110/W. T. Olson
0110/J. E. Burnett
1005/E. A. Zak
5500/ H. Mark
5533/J. W. Blue
7000/J. F. Connors
✓1005/Agreement-Consortium-Cleve. Clinic
1005/Correspondence

1005/EAZak:bmn:4-4-80

MODIFICATION NO. 3 TO
CONSORTIUM AGREEMENT BETWEEN
THE CLEVELAND CLINIC FOUNDATION
AND THE
NASA-LEWIS RESEARCH CENTER

NOW WHEREAS, the Cleveland Clinic Foundation ("CCF") and the National Aeronautics and Space Administration, Lewis Research Center ("NASA") have entered into a Consortium or Cooperative Agreement as of February 22, 1977 calling for CCF to utilize the NASA cyclotron for the treatment of cancer patients and related research, and

Whereas, the parties are in the process of negotiating an extension of up to 5 years in the term of this Agreement, upon certain proposed revised terms herein, for a period through 1985;

Whereas, the space being granted herein is not required for a current or contemplated NASA program and the CCF's exercise of rights in respect to such space will not interfere with NASA operations, and

Whereas, fair value in money, as required by NASA regulation NPD 8813.2 (6-1-64), will be received from CCF for the granting of the interest in real property herein described, and

Whereas, CCF however has not yet concluded the negotiation of the underlying grant for the treatment of cancer patients from the National Cancer Institute (NCI) of the National Institutes of Health (NIH), of the Department of Health, Education, and Welfare (HEW), and

Whereas, the parties hereto have therefore agreed to extend the current Agreement on its current terms for a period of 91 days, beyond April 1, 1980,

Now Therefore, the parties hereto agree that the consortium agreement

1. The parties agree that their Consortium Agreement, as previously amended through Modification No. 2, is hereby extended on exactly the same terms and conditions as are currently in effect for a 91 day period beginning April 1, 1980 and ending June 30, 1980.

2. Except as noted above, all terms and conditions of the Consortium Agreement remain unchanged.

This Modification No. 3 shall be effective this 1st day of April, 1980.

In witness thereof, the parties have caused this Modification No. 3 to their original agreement to be executed on the dates indicated below.

THE CLEVELAND CLINIC FOUNDATION
9500 Euclid Avenue
Cleveland, Ohio 44106

NATIONAL AERONAUTICS AND SPACE
ADMINISTRATION
Lewis Research Center
21000 Brookpark Road
Cleveland, Ohio 44135

by William S. Kiser
William S. Kiser, M.D.
Chairman
Board of Governors

by John F. McCarthy, Jr.
John F. McCarthy, Jr.
Director

March 31, 1980
Date of Signing

April 1, 1980
Date of Signing

This instrument was prepared by Edward A. Zak, Attorney at law, representing the NASA-Lewis Research Center, 21000 Brookpark Road, Cleveland, Ohio 44135 and John Auble, representing the Cleveland Clinic Foundation, 9500 Euclid Avenue, Cleveland, Ohio 44106.