

JMA

1005

September 17, 1981

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

Dear Mr. Auble:

Enclosed please find a fully signed copy of Modification No. 5 to the original Consortium Agreement between CCF and NASA of February 22, 1977. Dr. John F. McCarthy, Jr., as Center Director signed the modification on September 8, 1981, however the agreement is retroactively effective to January 1, 1981.

Thank you for your cooperation in getting the modification signed, so that the treatment of cancer patients using the NASA LeRC Cyclotron could continue.

Sincerely,



Edward A. Zak
Office of Chief Counsel

bcc:

1500/V. Hlavin

5500/H. Mark - w/enc.

0110/J. Burnett - w/enc.

1234/H. Monroe - w/enc.

✓ 1001/J. Earls - w/enc.

1005/Correspondence

1005/Consortium Agreement - Cleveland Clinic File

1005/ E. Zak

1005/EAZak:bm:9-17-81

MODIFICATION NO. 5 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, NASA has advised CCF that it will not be able to support the cyclotron operation; both as to its operating personnel staff and its continuing maintenance of the cyclotron facility, due to changing programmatic needs and the lack of available resources for this purpose within NASA, and

Whereas, the parties have consequently negotiated and agreed that effective January 1, 1981, CCF will assume operating control with respect to, and normal maintenance responsibilities arising out of its use of, said cyclotron facility, and

Whereas, the parties have negotiated an extension of up to five years in the term of this Agreement, upon the revised terms herein, for the period January 1, 1981 through December 31, 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 has been advised that their use of the cyclotron facility for the treatment of cancer patients has been approved and continued funding by the National Cancer Institute (NCI) of the National Institutes of Health (NIH)

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. In Article 13 of the Agreement, at the end thereof, on page 10 of the Agreement, delete the new last paragraph added by Modification No. 1 hereto and substitute the following therefor: "NASA agrees further to make up to 7,000 square feet of usable space in the basement of Bldg. 49 at NASA-LeRC available to CCF, with the exact amount of square footage to be determined yearly by the NASA-LeRC Chief of Industrial Programs, for up to 60 months after the date of Modification No. 5 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, in advance each quarter CCF shall pay NASA, on a monthly basis, the sum of \$.58/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 first day of actual CCF occupancy. In the event CCF ceases occupancy of all or some of these quarters prior to the end of the contemplated use period, the user charge of \$.58/sq.foot/month will be reduced proportionally, for the period of any one month not used by CCF. Said user charge of \$.58/sq.foot/month is subject to upward adjustment of 7% or more per year for every year, starting on January 1, 1982 and thereafter, with the exact rate of increase to be determined by the NASA-LeRC Chief of Industrial Programs each year based upon the cost increases being experienced by NASA during the prior year as well as based upon the National rate of

said rate. 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 Consortium Agreement; or (2) a determination by the appropriate NASA Administrator at NASA Headquarters, or the Director of the NASA Lewis Research Center, 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 NASA-LeRC, 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, with the first increment of the Agreement being October 1, 1976 thru March 31, 1978 and the second increment being April 1, 1978 thru March 31, 1979, and the third increment being April 1, 1979 thru March 31, 1980, and the fourth increment being April 1, 1980 thru June 30, 1980, and the fifth increment being July 1, 1980 thru December 31, 1980; provided however that the term hereof shall automatically continue from year to year for up to five (5) full years after December 31, 1980, i.e. until December 31, 1985, unless either party gives at least ninety (90) days advance written notice, i.e. no later than October 1, of each year, to the other of an intention not to continue the Agreement beyond its stated expiration date. The parties further agree that continuation

of suitable appropriations to support NASA's limited responsibilities for the upkeep and maintenance of the cyclotron facility; should such appropriations not be funded by the Congress in an amount deemed adequate by the Director of Lewis Research Center, this Agreement is then subject to: (1) its immediate unilateral termination by the Director of Lewis Research Center; or, (2) by the parties' mutual agreement to a renegotiation of all terms of this Agreement affected by the lack of available resources within NASA to support the cyclotron facility."

3. On page 2 of the Agreement, near the bottom thereof, in Article 3, delete the paragraph thereunder and substitute the following therefor:

"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 research in treatment of cancer patients and in radiology, in accordance with and subject to the terms and conditions of this Agreement. The cyclotron shall normally be available for use by CCF all 5 days of the work week (Federal holidays 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 the facility available on other days and times, based on medical need and upon reasonable advance notice from CCF. CCF shall have priority over all other uses or users of the cyclotron during all hours of every day beginning January 1, 1981, except that its usage may be preempted in case of local or national emergency, as determined by the Director of NASA-LeRC, or his designee."

4. On page 3 of the Agreement, delete Article 4 and substitute the following therefor:

"4. Duties of Cyclotron Operation

The CCF shall be solely responsible for producing a high-powered

both vertical and horizontal fashion at the treatment room (Room No. 1 of NASA-LeRC Building 49) on the Lewis Research Center premises. CCF shall also be responsible for operation, maintenance, and repair of the cyclotron facility, (including the special support facilities for patients to be maintained by CCF staff or CCF's contractors) arising in connection with CCF's use of the cyclotron facility, but shall not be responsible for maintenance and repair arising in connection with use by others, ordinary wear and tear, aging and/or obsolescence and any other cause beyond CCF's control. The cyclotron shall be used by CCF to do research in the treatment of cancer patients and in radiology."

5. Under Article 5, "CCF Patient Treatment Responsibilities and Indemnification," delete the first full sentence and substitute the following therefor:

"The CCF shall be solely responsible for monitoring the cyclotron beam current, alignment and focus, and for the generation of the neutron beam by stopping or passing the cyclotron beam to the target, and for the use and operation of the neutron beam from its point of reception in the treatment room."

6. Under Article 6, "Payments," delete paragraph "(C)" on page 5 thereunder, and substitute the following therefor:

"(C) For the year January 1, 1981 thru December 31, 1981 and years thereafter: All payments shall be made in advance for each quarter year. The CCF shall pay NASA at the rate of \$31.00 per hour, or proportionately for fractions of an hour, for beam time. The CCF shall also reimburse NASA for maintenance and repair materials and supplies and for maintenance personnel costs, including salary, fringe benefits, and applicable overhead expenses, for the services of NASA personnel as requested by CCF to perform maintenance, recurring and nonrecurring, on the cyclotron; provided that the maintenance effort performed shall

notify CCF when CCF requests for NASA-LeRC manpower will exceed the level deemed to be reasonably available by NASA. The beam time hourly charge shall be separately negotiated by the parties by December 1, of each year after April 1, 1980 and reflected in a subsequent bilateral modification of this Agreement."

7. In Article 13, CCF-Sponsored Facility Modifications, on page 9 of the Agreement, delete the third full sentence appearing on page 9 and substitute the following therefor: "Each quarter year, in advance, for these services, CCF agrees to pay to NASA a monthly charge of \$.58 per square foot, inside building dimensions, for the term January 1, 1981 thru December 31, 1981. Said user charge of \$.58 per square foot per month is subject to upward adjustment of 7% more per year for every year starting January 1, 1982 and thereafter, with the exact rate of increase to be determined by the NASA-LeRC Chief of Industrial Programs each year, based upon the cost increases being experienced by NASA during the prior year as well as based upon the National rate of inflation experienced during said prior year, starting on December 1, 1981, and on each December 1, thereafter."

8. Add the following new Article 16 following Article 15 on page 10 of the Agreement:

"16. Designation of Respective Points of Contact

The person holding the position of Chief of Industrial Programs, NASA Lewis Research Center, or his designee during his absence, shall be the prime point of contact for all correspondence and other contacts directed to NASA relative to the operation of the cyclotron facility under this Agreement. The similar point of contact for CCF shall be the person holding the position of Chairman, Department of Radiation."

9. Add the following new Article 17 following the new Article 16, also on page 10 of the Agreement:

The parties hereto recognize that as of January 1, 1981 there is a lack of available personnel and resources within NASA for the purposes of performing support services under this Agreement and that accordingly NASA shall in no event be obligated to provide any more than 26 man-weeks of reimbursable support services per year, all within the absolute discretion of the Director of NASA-LeRC or his designee; said NASA services shall be provided solely on a reimbursable basis, as mentioned elsewhere in this Agreement, to the quantity and extent deemed available by NASA, to perform those items of residual maintenance on the cyclotron facility which both parties mutually agree can be best and most efficiently performed by NASA personnel. The NASA-LeRC point of contact shall keep his counterpart at CCF advised reasonably well in advance of the point when 26 man-weeks level shall be exhausted."

10. Add the following as a new Article 18 following the new Article 17 on page 10 of the Agreement:

"18. Transition to CCF Operating Responsibility For The Cyclotron

The parties agree and recognize that CCF shall undertake a new, distinctive, and greater role in the operation of the NASA-LeRC cyclotron as of January 1, 1981 and accordingly no later than December 31, 1980 CCF shall complete a plan to assume its duties relating to the operation and maintenance as provided in Article 4 above. Such plan shall include all aspects of implementing CCF responsibilities for cyclotron operation and maintenance, including a plan for staffing the cyclotron operation, once direct NASA-LeRC operation thereof has ended on December 31, 1980. The CCF shall have all staff personnel who require training in cyclotron operations in its employ by January 1, 1981 and available for training by NASA-LeRC in cyclotron operation and maintenance by said date of January 1, 1981. The NASA-LeRC agrees to provide suit-

the accomplishment of such staff training, without direct charge to CCF, in order to accomplish a smooth transition to complete CCF operation on January 1, 1981."

11. Add the following as a new Article 19 following the above new Article 18:

"19. CCF Support of NASA-LeRC Projects and Programs on and After January 1, 1981

Since the parties recognize that CCF will be performing operation, repair and maintenance responsibilities as provided in Section 4 above now performed by NASA when CCF takes charge of operations and maintenance on the cyclotron on January 1, 1981, CCF hereby agrees to then make available, at times solely within CCF's discretion, its manpower at the LeRC Cyclotron and cyclotron beam-time to meet specific NASA-LeRC requirements for experiments or projects, which require the unique features of the Cyclotron. Such CCF manpower services shall be accounted for and returned to CCF by NASA on a "quid-pro-quo" basis; and use of the beam-time for NASA purposes shall result in a credit for such amount of beam-time thus used on the billings to CCF under this Agreement. The official log of beam-time consumed, which shall be maintained at the Cyclotron Facility by its operating personnel, shall reflect the use of the Cyclotron for this purpose by means of a signature block to be completed by the supervisory CCF staff person and then by the NASA person in charge of the program which uses the Cyclotron."

12. Add the following as a new Article 20 following the above new Article 19:

"20. Responsibility For Damage to NASA Property, Damage to Third Parties' Property, and Injury or Death to Third Persons

The CCF hereby agrees to indemnify and hold harmless, beginning on and after January 1, 1981 and until this Agreement is concluded, the United

of CCF's use and operation of the NASA-LeRC Cyclotron Facility, including the adjunct patient handling area and other associated NASA facilities and equipment. Such expenses, damages, claims and causes of action include, but are not necessarily limited to, damage to any and all Government-owned property being used under this Agreement, damage/injury to the personal property or person of any Government employee, and damage/injury to the personal property or person of any third party who might be damaged or injured solely through CCF operations on site of the NASA Lewis Research Center. However solely in regard to any claim by the Government for damage to the NASA LeRC Cyclotron Facility allegedly caused by CCF operations of said Cyclotron, it is mutually agreed that CCF shall only be responsible for damages to or loss of said Government-owned facility/property caused by the gross negligence, or willful or wanton misconduct of CCF employees. Damage to or loss of the NASA LeRC Cyclotron Facility caused through use by others, ordinary wear and tear, aging and/or obsolescence of said facility and any cause beyond CCF's control shall not be a responsibility of CCF under this Article 20, except as may otherwise be provided for under this Agreement.

To this end, CCF agrees to carry the following types and amounts of insurance, at its expense, naming the United States of America as an additional insured as an endorsement on each insurance policy so carried for this purpose:

- (A) Comprehensive general liability and property damage insurance, with a limit of not less than \$1,000,000.00 per incident.
- (B) Comprehensive motor vehicle liability insurance with limits of not less than \$500,000.00 for bodily injury or death, per person, \$1,000,000.00 overall per incident, and \$100,000.00 per incident

At all times during work under this Agreement, the CCF shall maintain with the NASA LeRC Office of Chief Counsel (Mail Stop 500-318 at Lewis Research Center) a current certificate of insurance, showing at least the insurance required above and providing for 30-day advance written notice to the NASA LeRC Office of Chief Counsel by the insurance agency or insurance company involved, prior to cancellation or material change in policy coverage in the above areas.

However, in lieu of having the above insurance through an insurance carrier, CCF may establish and maintain during the pendency of this Agreement a program of self-insurance, employing adequate financial reserves to protect NASA and CCF against loss from any claims arising out of and cognizable under this Article 20. Before execution of Modification No. 5 to the Agreement and upon each anniversary date of this Agreement thereafter while this Agreement is still in force and effect, the CCF shall provide to the NASA-LeRC Office of Chief Counsel (Mail Stop 500-318) appropriate affidavit(s) or bank statements relative to said self-insurance program and the amount of reserves maintained for said purpose."

13. Add the following as a new Article 21, following the new Article 20:

"21. Compliance With Prevailing NASA Health and Safety Procedures

The CCF agrees that it shall abide by and comply with all prevailing NASA-LeRC practices, procedures, and regulations concerning personal health and safety during the entire term of its use of the NASA-LeRC Cyclotron under this Agreement. The CCF also agrees to similarly comply with all applicable local, state, and Federal laws on health and safety."

14. Add the following as a new Article 22, following the new Article

The CCF agrees to allow other interested, responsible third parties to utilize the NASA facilities covered by this Agreement on an equitable, non-discriminatory basis during the term of this Agreement, for purposes deemed proper by the third-party user and by CCF, to the maximum extent then deemed available by CCF. All such requests shall first however be brought to the attention of the NASA-LeRC Chief of Industrial Programs, in writing, before CCF makes any decision on such third-party requests."

15. Add the following as a new Article 23, immediately following the new Article 22:

"23. NASA Consideration of CCF Request For Other Needed NASA Support Facilities and Services

The NASA-LeRC Chief of Industrial Programs agrees to consider all requests from CCF for providing additional NASA services or support facilities to CCF to facilitate the CCF research program being conducted under the scope of this Agreement (e.g. such as machine shop and laboratory facilities). To the extent deemed practicable and deemed consistent with other requirements of the NASA mission, NASA will attempt to give favorable consideration to such CCF requests; however the rates for reimbursement to NASA of the expense of providing additional services and support facilities, pursuant to this Article 23, will be separately determined by NASA and communicated to CCF at the time that any CCF request is approved for implementation by NASA."

16. Add the following as a new Article 24, immediately following new Article 23:

"24. Use and Maintenance Responsibilities for NASA-Owned Equipment

The CCF shall be entitled to use in the performance of this Agreement, two (2) categories of NASA-owned equipment, which is located in the general area of the LeRC Cyclotron Facility and which has generally

categories: (1) that equipment which is hard-wired or otherwise similarly permanently connected to the cyclotron or is equipment which is peculiar to work involving nuclear radiation; (2) that general purpose test equipment which has generally been used by NASA in direct support of the cyclotron operation.

It is agreed between the parties that CCF shall be assigned custody of and shall maintain and repair all such category (1) equipment, and at the conclusion of this Agreement shall return all such category (1) equipment back to NASA's control, reasonable wear and tear excepted, in the same condition as when first furnished to CCF. In regard however to category (2) equipment, NASA shall maintain custody of said equipment, except when in the physical custody of CCF personnel, and shall repair and maintain said equipment, to the extent deemed necessary by NASA.

The NASA equipment, referred to above, includes those items shown on the attached Exhibit "AA" (NASA computer run of 2-28-80), which is made a part of this Agreement, which have not been stricken out and thus deleted therefrom. The CCF shall maintain accountability for all NASA equipment under its control."

17. Add the following as a new Article 25 immediately following new Article 24, as above:

"25. Production of Radioisotopes in the Cyclotron Facility

The CCF agrees to fully cooperate, to the extent CCF determines to be feasible, with NASA and other Federal Agencies as well as with other third-party requestors (non-Federal Agencies) in the production of radioisotopes needed solely for medical research and medical treatment purposes, when such radioisotopes are not readily available in CCF's opinion from ordinary commercial sources. The rates of charges for the production of such radioisotopes for users outside of CCF shall be

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

This Modification No. 5 shall be effective this 1st day of January, 1981.

In witness thereof, the parties have caused this Modification No. 5 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

8/12/81
Date of Signing

9/8/81
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.

8/12/81 nrn b

STATE OF OHIO)
) SS:
COUNTY OF CUYAHOGA)

AFFIDAVIT

JOHN A. AUBLE, being first duly sworn, deposes and says as follows:

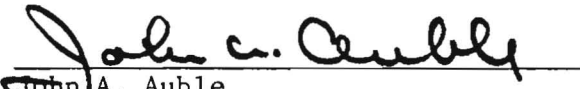
That he is Secretary of The Cleveland Clinic Foundation, and that effective August 15, 1975, The Cleveland Clinic Foundation became a self-insurer for its general liability exposure.

Affiant further states that in accord with the Department of Health and Human Services regulations, an irrevocable trust has been established with Society National Bank of Cleveland for the payment of claims and judgments for general liability claims against The Cleveland Clinic Foundation.

Affiant further states that corpus of such trust at the present time is in excess of \$5,000,000.00, and the use of the funds in such trust is restricted to the payment of general liability claims.

Affiant further states that in the event The Cleveland Clinic Foundation elects to terminate the self-insurance program, such will be replaced by commercial coverage and certificates evidencing such coverage will be forwarded to the National Aeronautics and Space Administration.

Further Affiant sayeth naught.


John A. Auble

SWORN TO BEFORE ME and subscribed in my presence this 12th day
of August, 1981.