

HARVARD UNIVERSITY

GRAYS HALL 16

VICE PRESIDENT
FOR GOVERNMENT
AND COMMUNITY AFFAIRS

CAMBRIDGE, MASSACHUSETTS 02138

January 31, 1977

Mr. James L. Sullivan
City Manager
Cambridge City Hall
795 Mass Ave
Cambridge, MA 02139

Dear Mr. Sullivan:

With reference to your letter to Mr. Milne and myself dated January 17, 1977, requesting a written response from both Harvard and MIT to the Cambridge Experimentation Review Board's report dated January 5, 1977, we make the following comments:

1. The CERB report is a thorough piece of work and we agree with the intent of the report and agree in principal with its findings and recommendations.
2. (Points A & B of your letter) As you know, we are now and have been for some time doing a variety of so called Recombinant DNA experiments at the P1 and P2 levels of containment in our existing laboratory facilities. The University Committee on the Regulation of Hazardous Biological Agents has reviewed the experiments and the laboratory facilities and determined that both the work and the facilities comply with the requirements as are set forth in the NIH Guidelines for Recombinant DNA experimentation.

Memoranda of Understanding and Agreement have been submitted to NIH for all existing P1 and P2 experiments. As new experiments are proposed, they are reviewed by the Harvard Committee on the Regulation of Hazardous Biological Agents and, when approved, an appropriate Memoranda of Understanding will be issued.

Consistent with the information we shared with the City Council and the CERB around the first of November 1976, we are now in the process of constructing new containment laboratory space on the 4th floor of the existing Biological Laboratories building at 16 Divinity Avenue, Cambridge. Within approximately 1300 square feet of floor space we will construct five laboratories and service rooms. The estimated completion date for this project is June 1977. The entire space has been designed to meet or exceed the P3 requirements of the NIH Guidelines for Recombinant DNA.

The facility has been reviewed in detail by the University Committee on the Regulation of Hazardous Biological Agents and now has this Committee's agreement that the detailed design meets or exceeds all federal requirements for such a laboratory. The plans have the approval of the involved federal agencies and the Director of the NIH-NCI Office of Research Safety who has indicated that the facility will provide Harvard with an excellent facility for conducting research requiring P3 type containment. Proposals for P3 experiments will be reviewed by the University Committee on the Regulation of Hazardous Biological Agents and the appropriate government agencies and cannot proceed until they are approved.

3. (Point C of your letter) We agree with the intent of Section 3 of the CERB report and look forward to participating in the effort to have all Recombinant DNA work come under uniform federal guidelines and to be certain that appropriate monitoring systems are established and adhered to.

At this time, it is unclear to us as to what specific steps should be taken and by what parties. The steps we are and will be taking at Harvard which will, we hope, serve as examples for others who are or may be involved in Recombinant DNA research include:

- a. It has and will continue to be Harvard's policy to require compliance with the NIH Guidelines on all Recombinant DNA research.
- b. Requiring that all experiments involving the use of Recombinant DNA be reviewed and approved by the University Committee on the Regulation of Hazardous Biological Agents.
- c. Establishing a health monitoring system under the control of the University Health Services.

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- d. Maintaining an office of Biohazards Health & Safety within the Division of Environmental Health & Safety of the University Health Services.
- e. Appointing a faculty member as a Biohazards Safety Officer in each department where laboratory investigations involving possibly hazardous biological agents are underway or in prospect.
- f. Maintaining complete medical records, including frozen blood plasma samples, from all workers participating in Recombinant DNA research.

Sincerely,

A handwritten signature in cursive script, reading "Donald C. Moulton".

Donald C. Moulton



OFFICE OF
THE CHAIRMAN OF THE CORPORATION

CAMBRIDGE, MASSACHUSETTS 02139

3 February 1977

Mr. James L. Sullivan
City Manager
Cambridge City Hall
795 Massachusetts Avenue
Cambridge, Massachusetts 02139

Dear Mr. Sullivan:

I am writing in response to your letter to Mr. Donald C. Moulton, Assistant Vice President for Community Affairs, Harvard University, and to me requesting that we send you a written response to the report of the Cambridge Experimentation Review Board (CERB) and that we address in this response the following points:

- "A) What is the timetable for the preparedness of their respective labs which might be used for recombinant DNA experiments?
- B) Where is each institution respectively in the certification process with N. I. H. ?
- C) What steps are they respectively prepared to take in order to help the City implement Section III of the report?"

In regard to the report as a whole, I can only commend with the highest praise the care and thoroughness of the process that produced it. Over the years, I have seen many good citizen committees in action, but I have never observed one that dealt any more conscientiously or well with a more difficult subject. Surely the members of CERB who contributed so much to that process must have the gratitude and respect, which they truly deserve, of their fellow citizens.

That after much study the CERB was able to render a unanimous opinion must also be most gratifying. Those at M.I.T. who are involved in this research are naturally pleased that the Board recommended that recombinant DNA research be permitted in Cambridge and that the Acting Commissioner of Health and Hospitals has stated that in his professional opinion recombinant DNA research carried out under the recommendations of the CERB will pose no health hazard to the citizens of Cambridge.

Now, in regard to your specific questions, let me take them one by one.

- A) What is the timetable for the preparedness of their respective labs which might be used for recombinant DNA experiments?

M.I.T. has had laboratories being used for recombinant DNA experiments at the P-1 and P-2 levels of physical containment for approximately two years. Our Assessment of Biohazards Committee, which has been established in accordance with the N.I.H. Guidelines, has examined the laboratories where these experiments are being conducted from the standpoint of these national Guidelines and determined that the laboratories satisfy the P-1 and P-2 level requirements of the Guidelines. The Committee has also determined that the protocols for the various P-1 and P-2 experiments being conducted in these laboratories are within the Guidelines as promulgated by the N.I.H.

A self-contained laboratory in the M.I.T. Center for Cancer Research has been established for recombinant DNA research at the P-3 level of physical containment. This laboratory meets in every regard the requirements of the N.I.H. Guidelines for a P-3 facility and has been modified further to meet additional requirements recommended by the M.I.T. Biohazards Committee. The Procedures Manual for this facility has been prepared and reviewed by the M.I.T. Assessment of Biohazards Committee. This laboratory, which has been inspected by the Cambridge Laboratory Experimentation Review Board, the Acting Commissioner of Health and Hospitals of the City of Cambridge, the M.I.T. Environmental Medical Service, and the M.I.T. Biohazards Committee, is fully prepared and is ready for use for such P-3 experiments as may be approved.

B) Where is each institution respectively in the certification process with N. I. H. ?

As I have noted, P-1 and P-2 recombinant DNA experiments have been going on at M. I. T. for approximately two years with the support of N. I. H. We have submitted the required Memorandum of Understanding to N. I. H. for all existing P-1 and P-2 experiments. Proposals for several new P-1 and P-2 experiments have been submitted by M. I. T. after review by the M. I. T. Bio-hazards Committee, and they are currently being reviewed by the N. I. H. Office of Recombinant DNA Technology. With respect to recombinant DNA experiments requiring P-3 containment, a Memorandum of Understanding has been filed with N. I. H. for one experiment.

During the preparations for P-3 research at M. I. T. notices of all meetings, whether regular or special, of the M. I. T. Bio-hazards Committee were sent to the Acting Commissioner of Health and Hospitals, who was invited to attend all meetings of the Committee. Further, copies of all M. I. T. guidelines, including the M. I. T. "Procedures Manual" for recombinant DNA research at all levels, have been sent to the Acting Commissioner.

C) What steps are they respectively prepared to take in order to help the City implement Section III of the report?

With respect to Recommendation I of Section III, the stated purpose of the N. I. H. Guidelines has been to recommend safeguards for research on recombinant DNA molecules to the National Institutes of Health and to other institutions that support such research. The National Science Foundation, for example, is already requiring its grantees to follow the N. I. H. Guidelines. However, we believe that there is a need for further federal oversight in this area, and M. I. T. is looking forward to participating in further national discussions of safeguards in recombinant DNA research and the possible applications thereof. Until these and other issues relating to regulation have been further reviewed and clarified, it would be premature to comment on possible legislative steps. We do believe that further steps should be taken, however, and that these steps should move toward uniformity while taking into proper account the basic differences between fundamental research in universities and development and application by industry. We should be pleased to discuss these issues further with representatives of the City.

Mr. James L. Sullivan
3 February 1977
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With respect to Recommendation II, the N.I.H. Guidelines do, of course, require monitoring. Further, in response to suggestions for environmental monitoring, the guidelines now require the principal investigator to report a variety of categories of accidents to appropriate officials. The costs of this monitoring may be supported in different ways, and we are currently exploring various possibilities especially as they may be related to Federal grants and contracts.

With respect to Recommendation III that a Federal Register be established of all workers participating in recombinant DNA research for the purpose of long-term epidemiological studies, we believe that such a national register should be kept for persons participating in experimentation at the P-3 and P-4 levels. We will keep at M. I. T. our own institutional record of M. I. T. faculty, staff, and students involved in recombinant DNA experiments at these levels, and we will work to seek support for a central Registry. N.I.H. itself is currently investigating procedures for long-term surveillance of workers engaged in recombinant DNA research and we shall be pleased to cooperate with any procedures they may recommend at the local level.

In Recommendation IV of Section III, the CERB points out that it would be highly desirable that there be "a federal initiative to sponsor and fund research to determine the survival and escape of the host organism in human intestine under laboratory conditions." We agree with that recommendation, and we would be pleased to work with the City to encourage such an initiative. We plan at our own initiative to discuss these matters further with appropriate people in the Federal Research establishment.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Walter L. Milne".

Walter L. Milne
Assistant to the Chairman

WLM:pb



CITY OF CAMBRIDGE

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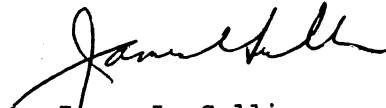
EXECUTIVE DEPARTMENT
JAMES L. SULLIVAN
City Manager

February 7, 1977

To the Honorable, the City Council:

In response to Council Order No. 7 of January 17, 1977,
enclosed please find copies of Harvard's and M.I.T.'s written
response to the Cambridge Laboratory Experimentation Review
Board's report of January 5, 1977.

Very truly yours,


James L. Sullivan
City Manager

JLS/mbf
Enc. 2

Agenda #8

S-80

Response to Council Order No. 7 of 1/17/77,
re: written response from Harvard and MIT
on the Cambridge Laboratory Experimentation
Review Board's report of 1/5/77.

In City Council,

Feb. 7, 1977

2/7/77

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