DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health
National Cancer Institute

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Date June 27, 1984

From Associate Director, NCI

Subject Policy on Requests for the Distribution of NIH Cell Lines used in AIDS Research and Development

To Director, NIH
THRU: Director, NCI

I. POLICY ON REQUESTS FROM COMMERCIAL ORGANIZATIONS FOR THE DISRIBUTION OF CONTINUOUS HUMAN T CELL LINES PRODUCING HIGH TITER HTLV III

1. Commercial activities using the virus infected human continuous cell lines are circumscribed. The derivation, the infectious process, and the antibody testing procedures of these lines are protected by the language of the Patents, SN # E-316-84 and SN # E-317-84. Specific commercial usage of this cell line and virus has been granted to the organizations who applied for and received Government licenses to practice these inventions.

2. Cession of the infected cell lines described under the above patents to other commercial organizations must not compromise the effectiveness and the most rapid transition to practice by the present licensees.

3. If a commercial organization should wish to use, for research purposes only, the above cell lines, the viral information contained therein, and all derivative products, the infected cell line will be made available to them, if the organization agrees to the following provisos:

   a. The release granted by NCI and NIH shall be non-exclusive, so that the infected cell line could be made available to other commercial requestors for research purposes.

   b. Containment and safety precautions shall be followed (i.e., P_2 and P_3) as defined for various activities with this cell line and virus by the Director of Research Safety, NIH.

   c. The cell line or products derived from it shall not be transferred to parties outside the designated organization.

   d. Based on input from NIH legal experts, a confidential disclosure agreement should be signed by the organization so that the material received is held in confidence and is considered as government proprietary data.

*e. Should research on the cell line or its products lead to results which could have commercial applications other than those defined by the above patent applications, the Government shall be notified, and the content shall not be disclosed to third parties.

*f. It is projected that applied and developmental research could lead to valuable modifications of existing materials released, so that new commercial applications could result. If the modification represents an invention not implicit in the prior art disclosure of the above patent applications, and this is so ruled based on normal examination, commercialization may be possible.

4. Distribution of this cell line to scientists for non-commercial purposes follows standard NIH procedures and includes points 3-a, b, and c. Although point 3-d is not normally used, and although a number of non-profit organizations have received the infected cell line for research purposes already, all further transfer to non-profit organizations should also include a signed confidential disclosure agreement.

II. POLICY† ON REQUESTS FROM ORGANIZATIONS FOR THE DISPOSITION OF CONTINUOUS NON-INFECTED T CELL LINES CAPABLE OF LONG-TERM GROWTH OF HIGH TITER HTLV III

1. Release of this uninfected cell line by the Laboratory of Tumor Cell Biology (LTCB), NCI, for research by other BID's or HHS agencies, has taken place and will continue should the need arise.

2. Release of the uninfected cell line to non-profit concerns shall presently be at the discretion of Dr. Robert Gallo, LTCB, NCI, with a discussion of the resulting collaborative plan. The standard caveats of non-release to third parties for commercial purposes, and the prudent containment practices on infection shall be heeded as per the required confidential disclosure agreement.

3. Release of this cell line to the government licensees developing the blood antibody test for AIDS is granted for any purpose which has to do with the rapid realization of the test. Other lines of research with the cell line should be discussed relative to relevance and priority with NCI/NIH at this time.

*These two points were initially considered as useful. However, according to Randall/Riseberg, the inclusion of these two points may require Dr. Brandt's approval; they are within the purview of official policy because they fall within the area considered under collaborative research programs.

4. a. Because patent protection does exist on this cell line, and because a number of ongoing useful experiments are taking place within NCI which could lead to further patents by the Government, release of this cell line to non-licensee for-profit organizations shall not take place at this time.

   b. An additional reason is that a number of parallel uses of this cell line, which could readily lead to analogous AIDS blood tests, is obvious. It is considered prudent that the effectiveness and rapidity of the realization of the AIDS blood test by the existing licensees should not be compromised by additional competing technological thrusts.

†Because of the continuous nature of ongoing important findings on this cell line, the policy is for the present usage only, and may likely be liberalized within several months. At that time the cell line will be released with the confidential disclosure agreement.

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Attachment:

Nondisclosure Agreement