FOIA Number: 2018-0756-F

FOIA MARKER

This is not a textual record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

Collection/Record Group: Clinton Presidential Records

Subgroup/Office of Origin: National AIDS Policy Office

Series/Staff Member: Kristine Gebbie

Subseries:

OA/ID Number: 3772

FolderID:

Folder Title:
Meeting with Project Inform 11/5/93

Stack:	Row:	Section:	Shelf:	Position:
S	66	5	5	3

PROJECT inform

Kristine Gebbie, National AIDS Policy Coordinator
Office of National AIDS Policy
750 17th St., NW, Suite 1060
Washington, DC 20503

Dear Ms. Gebbie:

Thank you for taking the time to meet with Ben Cheng and me on November 5 to discuss issues relevent to Project Inform and your office. We particulary appreciate the opportunity to talk with you personally, as we have received some mixed messages from other people in your office. We are aware that your time is in great demand, and acknowledge the priority you give to research issues and the Future Directions in AIDS Research process.

I look forward to seeing you this weekend at the upcoming FDAR meeting in Boston. As always, if there is anything we at Project Inform can do for you, don't hesitate to let us know.

Sincerely,

Dan Cusick

Dan Cusick
Public Policy Advocate

1965 MARKET STREET, SUITE 220
SAN FRANCISCO, CALIFORNIA 94103

ADMINISTRATIVE OFFICES
415·558·8669

FAX
415·558·0684

LOCAL HOTLINE
415·558·9051

CALIFORNIA HOTLINE
800·334·7422

NATIONAL HOTLINE
800·822·7422

PROJECT inform

1965 MARKET STREET, SUITE 220
SAN FRANCISCO, CALIFORNIA 94103

Kristine Gebbie, National AIDS Policy
Coordinator
Office of National AIDS Policy
750 17th St., NW, Suite 1060
Washington, DC 20503

MEETING INFORMATION FOR
KRISTINE M. GEBBIE

ONAPC STAFF CONTACT: Steve Lee / Ben Merrill

DATE/TIME EVENT: 11/5 c 9 – 9:30 (maybe 11/6 Baltimore think tank)

LOCATION: 750 G - KG's office

ORGANIZATION: Project INFORM

CONTACT: Ann Donelly 415 558. 8669

TOPIC: Immune Reconstruction Think Tank - FADR

FORMAT: meeting - 5 or 6 people

BACKGROUND: F/U on SF mtg. Cross-over from FDAR. ONDS research process, New Orleans presentation.

CONFLICTS:

DIRECTION TO STAFF

SCHEDULE ____ **SCHEDULE FOR OTHER TIME** ____ **REGRETS** ____

SEND SURROGATE (who?) _____

COMMENTS: _____

STAFF CHECKLIST: CONFIRMED___ **CALENDAR**___ **TRAVEL**___ **HOTEL**___

Project INFORM

1965 Market Street, Suite 220
San Francisco, CA 94103

FAX Transmittal Form

Date: 10/29/93

To: STEVE LEE Fax Number:

From:

Anne Donnelly
Public Policy Coordinator
Fax Number: (415)558-0684
Voice Phone: (415)558-8669

Total Pages: 9

Comments

PROJECT inform

10/28/93

Steve Lee
Chief Scheduler
Office of National AIDS Policy
750 17th Street, NW, Suite 1060
Washington, DC 20503

Dear Steve;

On behalf of Project Inform, I would like to request a meeting with Kristine Gebbie, National AIDS Policy Coordinator, on Friday, November 5, 1993 at 9:00 a.m. Members of our staff will be in the area for the Immune Restoration Think Tank sponsored by Project Inform. The IRTT meeting is scheduled for November 6 and 7 in Baltimore, MD. An invitation and agenda follow this letter.

Martin Delaney; Founding Director, Brenda Lein; Information and Advocacy Coordinator, Dan Cusick; Policy Advocate, Ben Cheng; Information Associate, and Joel Thomas, a member of our Board of Directors will be available for the Friday morning meeting with Ms. Gebbie. We would like to discuss the role of Ms. Gebbie in the Future Directions in AIDS Research process and some general but pressing issues in the AIDS research and treatment arena.

We greatly appreciate your consideration in arranging this meeting on such short notice and hope that Ms. Gebbie may be able to join us at the Immune Restoration Think Tank to experience first hand this innovative forum. We hope that the type of collaboration and team work exhibited at IRTT will become one model for addressing critical questions in AIDS research.

Again, our thanks,

Anne Donnelly
Public Policy Coordinator

1965 MARKET STREET, SUITE 220
SAN FRANCISCO, CALIFORNIA 94103
ADMINISTRATIVE OFFICES 415.558.8669
FAX 415.558.0684
LOCAL HOTLINE 415.558.9051
CALIFORNIA HOTLINE 800.334.7422
NATIONAL HOTLINE 800.822.7422

PROJECT IMMUNE RESTORATION

October 29, 1993

Kristine Gebbie
National AIDS Policy Coordinator
750 17th Street, NW, Suite 1060
Washington, DC. 20503

Dear Ms. Gebbie:

On behalf of Project Inform, I am writing you to invite you to attend our Immune Restoration Think Tank 3 to be held at the Harbor Court Hotel on the harbor in Baltimore, MD on November 5-7. Detailed logistics of the meeting are enclosed. We sincerely hope that you will be able to attend, as we feel your experienced input will be invaluable in helping us define and implement courses of action to address immune deficiency in late stage HIV disease. After the results of the very productive prior two meetings, we are excited to use this event to update you on the progress of the plans that grew out of these meetings and to refine and move forward the details of these plans.

The most recent versions of the 12 (Plan A) and 36 (Plan B) month approaches will be enclosed with the mailed copy of this letter. We will go over some of the exciting progress that has been made in each aspect of these plans at the November meeting. Especially intriguing will be results from cryopreservation studies from Drs. McCune and Dwyer, clinical results from cell transfer studies, both involving twins by Dr. Lane and complete and partial HLA matches by Dr. Waites and doctors at the Center for Special Immunology, plus progress on gene therapy protocols in combination with cell transfer by Dr. Gallo (in collaboration with Dr. Blaese at NIH). Based on this information, we will then break up into groups to brainstorm on how most expediently and effectively to move the plans forward. Remember the ultimate goal of both plans is the execution of clinical protocols designed to provide our "best shot" at augmenting or restoring immunity in late stage disease. Your input regarding these plans prior to the meeting, especially if you are aware of any progress in these areas, would allow us to be that much more effective at the meeting. We understand that you are very busy, but feel that this information would be extraordinarily valuable. Also, ideas logistics, location and the meeting agenda would be very welcome.

We do want to emphasize that the effectiveness of the meeting will be greatly enhanced if you are able to participate in the entire meeting. A tentative agenda is enclosed. We feel that every aspect of the agenda, from the cocktail party to the breakout sessions to Saturday evening dinner, is an important part of the "chemistry" which makes this meeting so unique and effective. While we will make exceptions for those who have unavoidable conflicts, we really hope you will come for the entire time. We are having the meeting near Washington, DC to reduce travel time for the many participants who live in the area, but be aware that full participation in all of the agenda is highly desirable.

A program of

Project Inform

1965 Market Street

Suite 220

San Francisco

California 94103

415.558.8669

415.558.0684 fax

We are developing our press strategy for the meeting much earlier this time, so there will be no disruption due to press activities. Those of you who will be requested to participate in the press conference at 3 PM Sunday afternoon will be contacted separately well in advance of the meeting. It is currently planned that there will be no press allowed at the meeting itself. You will be notified of any desired changes in this policy for your approval if they occur.

Again, we hope to see you in Baltimore. As always, we thank you for your invaluable research efforts, without which there would not exist the slim hope that keeps Project Immune Restoration and numerous other volunteer groups fighting this horrible disease.

Please don't hesitate to contact us if we can be of service of any kind.

Sincerely,

Brenda Lein

Brenda Lein

Enclosures

IMMUNE RESTORATION THINK TANK 3
Baltimore, Maryland, November 5-7, 1993

Attendees

Jay Berzofsky - National Cancer Institute
Sam Broder - National Cancer Institute
John Dwyer - Prince of Wales Hospital, Australia
Anthony Fauci - National Institutes of Allergies and Infectious Diseases
Robert Gallo - National Cancer Institute
Phil Greenberg - University of Washington
Mark Harrington - Treatment Action Group
Suzanne Ildstad - University of Pittsburgh
Peggy Johnston - National Institutes of Allergies and Infectious Diseases
Jonathan Kagan - National Institutes of Allergies and Infectious Diseases
Stella Knight - Clinical Research Center, Harrow, United Kingdom
Scott Koenig - MedImmune Inc.
Clifford Lane - National Institutes of Allergies and Infectious Diseases
Michael Lederman - Case Western Reserve University
Judy Lieberman - New England Medical Center
Mike McCune - SySteMix
Thomas Merigan - Stanford University School of Medicine
Dewey Moody - Applied Immune Sciences
Gary Nabel - Howard Hughes Medical Institute, University of Michigan
Yair Reisner - Weitzmann Institute of Science, Israel
Jonas Salk - Jonas Salk Institute
Rein Saral - Emory University School of Medicine
Nava Sarver - National Institutes of Allergies and Infectious Diseases
Steven Schnittman - National Institutes of Allergies and Infectious Diseases
Robert Schooley - University of Colorado
Gene Shearer - National Cancer Institute
Jay Siegel - Food and Drug Administration
Thomas Wagner - Ohio University
Bruce Walker - Massachusetts General Hospital
Ed Winger - ImmunoDiagnostic Laboratories, San Leandro, California
Robert Yarchoan - National Cancer Institute
John Zaia - City of Hope National Medical Center
Susan Zolla-Pazner - VA Medical Center, New York City

IMMUNE RESTORATION THINK TANK 3
Baltimore, Maryland, November 5-7, 1993

AGENDA

FRIDAY EVENING

Welcoming Reception Harbor Court Suite, Room 840	8:00-11:00 pm

SATURDAY

Wakeup Call	7:15 am
Breakfast Reception Room, 2nd floor	8:00-8:30 am
Morning meeting Whitehall Ballroom North, 2nd floor	8:30 am-12:00 pm
Welcome	8:30-9:00 am
Presentations of New Information	9:00-11:30 am
Break	10:15-10:30am
Orientation for Small Groups	11:30 am-12:00 pm
Lunch Reception Room, 2nd floor	12:00-1:15 pm
Small Groups (Development) Whitehall Ballroom North, 2nd floor Ravenhurst, 2nd floor Seton, 2nd floor Caucus, 2nd floor	1:15-4:15 pm
Break	4:15-4:30 pm
Large Group (Development) Whitehall Ballroom North, 2nd floor	4:30-6:00 pm

SATURDAY EVENING

Cocktails	7:00 pm
Dinner Westminster, Lobby level	7:30 pm
Dessert and after dinner drinks Harbor Court Suite, Room 840	9:30 pm

SUNDAY

Wakeup Call	7:15 am
Checkout	before 12:00 pm
Breakfast Westminster, Lobby level	8:00-8:30 am
Overview of Saturday Westminster, Lobby level	8:30-9:00 am
Small Groups -(Implementation) Westminster, Lobby level Guilford, Lobby level Board Room, Lobby level Regency, Lobby level	9:00-10:30 am
Break	10:30-11:00 am
Large Group -(Implementation)	11:00 am-12:00 pm
Lunch	12:00-1:00 pm
Large Group Roundtable Westminster, Lobby level	1:00-2:00 pm
Press Conference Harbor Court Suite, Room 840	3:00-5:00 pm

IMMUNE RESTORATION THINK TANK 3 LOGISTICS

Accommodations

All IRTT 3 activities will take place at the Harbor Court Hotel located on Baltimore's Inner Harbor at 550 Light Street, Baltimore, Maryland 21202-6099. 410-234-0550. Fax: 410-659-5925.

Think Tank schedule

Please arrive at the hotel Friday evening and join us at a welcoming reception from 8 to 11 pm.

Breakfast will be served at 8 am Saturday morning and the first session begins at 8:30 am. (You will all receive a 7:15 wake-up call.) The Saturday session will continue until 6 pm.

Dinner will be served at 7:30 pm Saturday evening.

Sunday events will begin again with breakfast at 8 am (and the 7:15 wake-up call) and last until 2 pm. Check out time is 12 noon so it will be necessary to check out before the meetings begin on Sunday. Luggage can be stored by the hotel during the session.

Travel

Please arrive Friday evening and schedule your return flight after 3 pm on Sunday so you can stay for the entire meeting. Please make all air travel arrangements with Marlene Binnion, our travel agent at Adelman Travel, 415-772-5342, fax: 415-772-5052. Whenever possible, book your flight through Baltimore-Washington International Airport. As always, it will help Project Inform if you can take advantage of 14-day advance tickets.

Ground transportation to the Harbor Court Hotel

Please schedule your own ground transportation to the hotel. Two limousine services provide transportation from Baltimore-Washington International Airport to the hotel:

- Carey Limousine Service, 410-837-1234, has service every half hour on the hour and half hour from 7 am to 11 pm. Tickets can be purchased at "Ground Transportation", airport lower level, near the US Air baggage claim. Cost is $8 one way or $12 round trip.
- Maryland Limousine Service, 410-850-4100. Call in advance (for gate pickup) or upon arrival for pickup in five to ten minutes. Cost is $25.

Save your shuttle receipts and we will reimburse you. If neither of these services are satisfactory for you, please let us know so that we can arrange alternate transportation. Transportation from other airports is possible, but logistically difficult. Contact us if this is required.

Logistics questions and special requests

Please contact Ben Collins at Project Inform, 415-558-8669.

As guests of Project Inform, you will be provided with air transportation, shuttle service, food and lodging and are welcome to bring a guest. Responsibility for car rental and incidentals will be yours.

PLEASE FILL OUT FOLLOWING QUESTIONNAIRE AND RETURN TO PI

IMMUNE RESTORATION THINK TANK - 3
Baltimore, Maryland, November 5-7, 1993

Ms. Gebble:

Please answer the following questions and mail or fax them back to: Ben Collins at Project Inform, 1965 Market Street, Suite 220, San Francisco, CA 94103. Fax: 415-558-0684.

- ❑ I will be attending IRTT - 3.
- ❑ I will not be attending IRTT - 3.

- ❑ I will be coming to the hotel by my own transport.
- ❑ I will use the shuttle service from Baltimore-Washington International.
- ❑ I will not be able to use the shuttle service from Baltimore-Washington International and will need alternate transportation to the hotel.

- ❑ I am bringing a guest.
- ❑ I am not bringing a guest.

- ❑ I will be attending the Saturday evening banquet.
  - ❑ 1 person
  - ❑ 2 person

What are your food restrictions or room requirements, if any?

_____

_____

_____

Comments?

_____

_____

_____

PROJECT inform

1965 Market Street, Suite 220, San Francisco, CA 94103
Phone: 415-558-8669, Fax: 415-558-0684

FAX COVER PAGE

To: **Kristine Gebbie**
Fax number: **202-632-1096**
From: Ben Collins
Date: 11.2.93
Subject: **IRTT**
Number of pages: **5**

THIS FAX INCLUDES:

- **IRTT AGENDA**
- **LIST OF PARTICIPANTS, OBSERVERS AND STAFF**
- **FINAL LOGISTICS NOTE**
- **MAP TO HARBOR COURT HOTEL**

GOVERNMENT EMPLOYEES PLEASE NOTE:

IF YOU ARE HAVING DIFFICULTY FIGURING OUT HOW TO STAY IN BALTIMORE DUE TO GOVERNMENT RESTRICTIONS OF ANY KIND PLEASE CALL BEN COLLINS AT 415-558-8669.

IMMUNE RESTORATION THINK TANK 3

BALTIMORE, MARYLAND
NOVEMBER 5 - 7, 1993

AGENDA

FRIDAY EVENING

Welcoming Reception	8:00-11:00 pm
Harbor Court Suite, Room 840	

SATURDAY

Wakeup call	7:15 am
Breakfast	8:00-8:30 am
Reception Room, 2nd floor	
Morning meeting	8:30-10:30 am
Whitehall Ballroom North, 2nd floor	
Welcome	8:30-9:15 am
Presentation of New Information	9:15-9:45 am
Orientation for small groups	9:45-10:15 am
Break	10:15-10:30 am
Small Groups (Development)	10:30 am-12:00 noon
Lunch	12:00-1:00 pm
Reception Room, 2nd floor	
Presentation of New Information	1:00-1:30 pm
Small Groups (Development)	1:30-4:15 pm
Break	4:15-4:30 pm
Large Group (Development)	4:30-6:00 pm
Whitehall Ballroom North, 2nd floor	

SATURDAY EVENING

Cocktails	7:00 pm
Dinner	7:30 pm
Westminster, Lobby level	
Dessert and after dinner drinks	9:30 pm
Harbor Court Suite, Room 840	

SUNDAY

Wakeup Call	7:15 am
Checkout	before 12:00 noon
Breakfast	8:00-8:30 pm
Overview and Reorientation	8:30-9:00 am
Westminster, Lobby level	
Small Groups (Implementation)	9:00-10:30 am
Break	10:30-10:45 am
Large Group (Implementation)	10:45 am-12:00 noon
Westminster, Lobby level	
Working Lunch	12:00-1:00 pm
Break out groups: funding, regulatory, Plan A, Plan B, other	
Westminster, Lobby level	
Large Group Roundtable	1:00-2:00 pm
Westminster, Lobby level	
Press Conference	3:00-5:00 pm
Harbor Court Suite, Room 840	

PROJECT IMMUNE RESTORATION

A program of

Project Inform

1965 Market Street

Suite 220

San Francisco

California 94103

(415) 558-0684

(415) 558-0685 fax

IRTT-3 List Of Attendees

Participants

Jay Berzofsky - National Cancer Institute
Sandy Bridges - National Institutes of Allergies and Infectious Diseases
Sam Broder - National Cancer Institute
John Dwyer - Prince of Wales Hospital, Australia
Anthony Fauci - National Institutes of Allergies and Infectious Diseases
Robert Gallo - National Cancer Institute
Phil Greenberg - University of Washington
Mark Harrington - Treatment Action Group
Suzanne Ildstad - University of Pittsburgh
Peggy Johnston - National Institutes of Allergies and Infectious Diseases
Jonathan Kagan - National Institutes of Allergies and Infectious Diseases
Stella Knight - Clinical Research Center, Harrow, United Kingdom
Scott Koenig - MedImmune Inc.
Clifford Lane - National Institutes of Allergies and Infectious Diseases
Michael Lederman - Case Western Reserve University
Judy Lieberman - New England Medical Center
Mike McCune - SySteMix
Thomas Merigan - Stanford University School of Medicine
Dewey Moody - Applied Immune Sciences
Gary Nabel - Howard Hughes Medical Institute, University of Michigan
Yair Reisner - Weitzmann Institute of Science, Israel
Jonas Salk - Jonas Salk Institute
Rein Saral - Emory University School of Medicine
Nava Sarver - National Institutes of Allergies and Infectious Diseases
Steven Schnittman - National Institutes of Allergies and Infectious Diseases
Robert Schooley - University of Colorado
Gene Shearer - National Cancer Institute
Jay Siegel - Food and Drug Administration
Thomas Wagner - Ohio University
Bruce Walker - Massachusetts General Hospital
Ed Winger - ImmunoDiagnostic Laboratories, San Leandro, California
Robert Yarchoan - National Cancer Institute
John Zaia - City of Hope National Medical Center
Susan Zolla-Pazner - VA Medical Center, New York City

Observers

Robert Darga - National Association of People with AIDS
Tom Dunlap - Design Industries Foundation for AIDS
Kristine Gebbie - Office of National AIDS Policy
David Gold - Gay Men's Health Crisis
James Hill, - National Institutes of Allergies and Infectious Diseases
Larry Kramer
Rosemary Kuropat - Design Industries Foundation for AIDS
Dagmar Oette - Hoechst-Roussel

Staff

Tom Beckman - Project Inform
G'dali Braverman - Project Inform
Ben Cheng - Project Inform
Ben Collins - Project Inform
Dan Cusick - Project Inform
Linda Dee - AIDS Action Baltimore
Martin Delaney - Project Inform
Brenda Lein - Project Inform
Rod O'Neal - Epic, Electronic Publishing and Integration Consultants
Joel Thomas - Project Infrom

IRTT Logistics

Please take the time to read this information. It will help us very much. Thank you.

Quite simply, if you are on the List of Attendees and we haven't heard from you already, we are assuming that you are coming to IRTT, staying in the hotel, attending the meetings, and having dinner on Saturday evening. Reservations and dinner have been set with that in mind. If you are not coming, if you are not planning to stay in the hotel, or if you are not planning to have dinner on Saturday please let us know immediately. The room situation is very tight and we would really appreciate knowing.

Government employees: Some of you have expressed concerns about billing, staying in Baltimore, etc.

- In response to requests, bills from Project Inform will be available in Baltimore if you need them. They will include: lodging for two nights at $78/night, food for 2 half days and one whole day totaling $68 and parking.
- For the process of the think tank it is important that you be able to attend the Friday evening Welcoming Reception, the meetings on Saturday, the dinner Saturday evening and the meetings on Sunday. If you need help with any of these billing procedures don't hesitate to call me.

Observers: Reservations have been made for you. We are asking you to be responsible for your rooms and your transportation. Meals will be provided by Project Inform. We appreciate your help in making the Think Tank possible.

Travel: If you have not yet made flight reservations, contact Adelman Travel at 800-659-5555.

Ground transportation from the airport to the hotel: As far as we know, all air travelers will be arriving at Baltimore-Washington International and coming to the hotel by rental car or shuttle. Two limousine services provide shuttles from BWI to the hotel:

- Carey Limousine Service, 410-837-1234, has service every half hour on the hour and half hour from 7 am to 11 pm. Tickets can be purchased at "Ground Transportation", airport lower level, near the US Air baggage claim. Cost is $8 one way or $12 round trip.
- Maryland Limousine Service, 410-850-4100. Call in advance (for gate pickup) or upon arrival for pickup in five to ten minutes. Cost is $25.

Save your shuttle receipts and Project Inform will reimburse you. If you need transportation other than these shuttles please let us know.

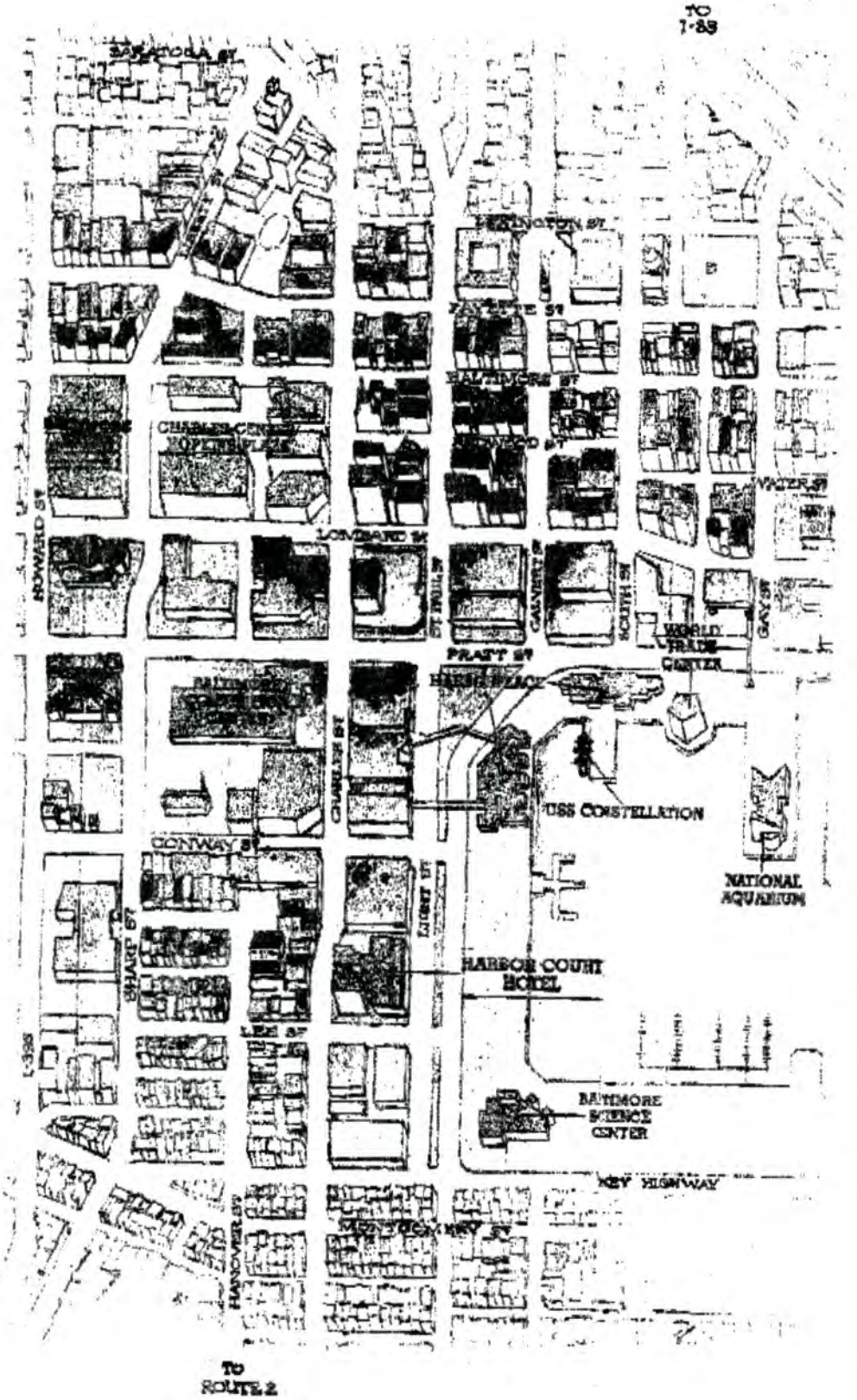
Map: See next page.

Welcoming Reception: Friday night please join the rest of the attendees in the Harbor Court Parlor, Room 840 for food and drinks from 8 to 11 pm.

Thank you very much. If you have questions, contact Ben Collins at 415-558-8669.

DIRECTIONS TO.....

HARBOR COURT HOTEL



FROM New York
Philadelphia

Take 95 South to

Fort McHenry Tunnel.

After exiting tunnel take 395 following signs reading

DOWNTOWN BALTIMORE-
INNER HARBOR.

As you come off 395 you will make a RIGHT turn onto CONWAY STREET... go to end, which is LIGHT STREET (you will be facing the Harbor).

Turn RIGHT...1½ blocks to HARBOR COURT HOTEL.

Make a right hand turn into our Courtyard.

****

FROM Washington

Take 95 NORTH to 395.

Follow signs reading
DOWNTOWN BALTIMORE-
INNER HARBOR.

As you come off 395 you will make a RIGHT turn onto CONWAY STREET... go to end (you will be facing the Harbor) which is LIGHT STREET.

Turn RIGHT...1½ blocks to HARBOR COURT HOTEL.

Make a right hand turn into our Courtyard.

VALET & SELF PARKING
AVAILABLE

Have a pleasant trip!!

PROJECT IMMUNE RESTORATION

October 29, 1993

A program of

Project Inform

1965 Market Street

Suite 220

San Francisco

California 94103

415.558.8669

415 558 0684 fax

Kristine Gebbie
National AIDS Policy Coordinator
750 17th Street, NW, Suite 1060
Washington, DC. 20503

Dear Ms. Gebbie:

On behalf of Project Inform, I am writing you to invite you to attend our Immune Restoration Think Tank 3 to be held at the Harbor Court Hotel on the harbor in Baltimore, MD on November 5-7. Detailed logistics of the meeting are enclosed. We sincerely hope that you will be able to attend, as we feel your experienced input will be invaluable in helping us define and implement courses of action to address immune deficiency in late stage HIV disease. After the results of the very productive prior two meetings, we are excited to use this event to update you on the progress of the plans that grew out of these meetings and to refine and move forward the details of these plans.

The most recent versions of the 12 (Plan A) and 36 (Plan B) month approaches will be enclosed with the mailed copy of this letter. We will go over some of the exciting progress that has been made in each aspect of these plans at the November meeting. Especially intriguing will be results from cryopreservation studies from Drs. McCune and Dwyer, clinical results from cell transfer studies, both involving twins by Dr. Lane and complete and partial HLA matches by Dr. Waites and doctors at the Center for Special Immunology, plus progress on gene therapy protocols in combination with cell transfer by Dr. Gallo (in collaboration with Dr. Blaese at NIH). Based on this information, we will then break up into groups to brainstorm on how most expediently and effectively to move the plans forward. Remember the ultimate goal of both plans is the execution of clinical protocols designed to provide our "best shot" at augmenting or restoring immunity in late stage disease. Your input regarding these plans prior to the meeting, especially if you are aware of any progress in these areas, would allow us to be that much more effective at the meeting. We understand that you are very busy, but feel that this information would be extraordinarily valuable. Also, ideas logistics, location and the meeting agenda would be very welcome.

We do want to emphasize that the effectiveness of the meeting will be greatly enhanced if you are able to participate in the entire meeting. A tentative agenda is enclosed. We feel that every aspect of the agenda, from the cocktail party to the breakout sessions to Saturday evening dinner, is an important part of the "chemistry" which makes this meeting so unique and effective. While we will make exceptions for those who have unavoidable conflicts, we really hope you will come for the entire time. We are having the meeting near Washington, DC to reduce travel time for the many participants who live in the area, but be aware that full participation in all of the agenda is highly desirable.

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Again, we hope to see you in Baltimore. As always, we thank you for your invaluable research efforts, without which there would not exist the slim hope that keeps Project Immune Restoration and numerous other volunteer groups fighting this horrible disease.

Please don't hesitate to contact us if we can be of service of any kind.

Sincerely,

Brenda Lein

Brenda Lein

Enclosures

IMMUNE RESTORATION THINK TANK 3
Baltimore, Maryland, November 5-7, 1993

Attendees

Jay Berzofsky - National Cancer Institute
Sam Broder - National Cancer Institute
John Dwyer - Prince of Wales Hospital, Australia
Anthony Fauci - National Institutes of Allergies and Infectious Diseases
Robert Gallo - National Cancer Institute
Phil Greenberg - University of Washington
Mark Harrington - Treatment Action Group
Suzanne Ildstad - University of Pittsburgh
Peggy Johnston - National Institutes of Allergies and Infectious Diseases
Jonathan Kagan - National Institutes of Allergies and Infectious Diseases
Stella Knight - Clinical Research Center, Harrow, United Kingdom
Scott Koenig - MedImmune Inc.
Clifford Lane - National Institutes of Allergies and Infectious Diseases
Michael Lederman - Case Western Reserve University
Judy Lieberman - New England Medical Center
Mike McCune - SySteMix
Thomas Merigan - Stanford University School of Medicine
Dewey Moody - Applied Immune Sciences
Gary Nabel - Howard Hughes Medical Institute, University of Michigan
Yair Reisner - Weitzmann Institute of Science, Israel
Jonas Salk - Jonas Salk Institute
Rein Saral - Emory University School of Medicine
Nava Sarver - National Institutes of Allergies and Infectious Diseases
Steven Schnittman - National Institutes of Allergies and Infectious Diseases
Robert Schooley - University of Colorado
Gene Shearer - National Cancer Institute
Jay Siegel - Food and Drug Administration
Thomas Wagner - Ohio University
Bruce Walker - Massachusetts General Hospital
Ed Winger - ImmunoDiagnostic Laboratories, San Leandro, California
Robert Yarchoan - National Cancer Institute
John Zaia - City of Hope National Medical Center
Susan Zolla-Pazner - VA Medical Center, New York City

IMMUNE RESTORATION THINK TANK 3
Baltimore, Maryland, November 5-7, 1993

AGENDA

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Breakfast Westminster, Lobby level	8:00-8:30 am
Overview of Saturday Westminster, Lobby level	8:30-9:00 am
Small Groups -(Implementation) Westminster, Lobby level Guilford, Lobby level Board Room, Lobby level Regency, Lobby level	9:00-10:30 am
Break	10:30-11:00 am
Large Group -(Implementation)	11:00 am-12:00 pm
Lunch	12:00-1:00 pm
Large Group Roundtable Westminster, Lobby level	1:00-2:00 pm
Press Conference Harbor Court Suite, Room 840	3:00-5:00 pm

IMMUNE RESTORATION THINK TANK 3 LOGISTICS

Accommodations

All IRTT 3 activities will take place at the Harbor Court Hotel located on Baltimore's Inner Harbor at 550 Light Street, Baltimore, Maryland 21202-6099. 410-234-0550. Fax: 410-659-5925.

Think Tank schedule

Please arrive at the hotel Friday evening and join us at a welcoming reception from 8 to 11 pm.
Breakfast will be served at 8 am Saturday morning and the first session begins at 8:30 am. (You will all receive a 7:15 wake-up call.) The Saturday session will continue until 6 pm.
Dinner will be served at 7:30 pm Saturday evening.
Sunday events will begin again with breakfast at 8 am (and the 7:15 wake-up call) and last until 2 pm. Check out time is 12 noon so it will be necessary to check out before the meetings begin on Sunday. Luggage can be stored by the hotel during the session.

Travel

Please arrive Friday evening and schedule your return flight after 3 pm on Sunday so you can stay for the entire meeting. Please make all air travel arrangements with Marlene Binnion, our travel agent at Adelman Travel, 415-772-5342, fax: 415-772-5052. Whenever possible, book your flight through Baltimore-Washington International Airport. As always, it will help Project Inform if you can take advantage of 14-day advance tickets.

Ground transportation to the Harbor Court Hotel

Please schedule your own ground transportation to the hotel. Two limousine services provide transportation from Baltimore-Washington International Airport to the hotel:

- Carey Limousine Service, 410-837-1234, has service every half hour on the hour and half hour from 7 am to 11 pm. Tickets can be purchased at "Ground Transportation", airport lower level, near the US Air baggage claim. Cost is $8 one way or $12 round trip.
- Maryland Limousine Service, 410-850-4100. Call in advance (for gate pickup) or upon arrival for pickup in five to ten minutes. Cost is $25.

Save your shuttle receipts and we will reimburse you. If neither of these services are satisfactory for you, please let us know so that we can arrange alternate transportation. Transportation from other airports is possible, but logistically difficult. Contact us if this is required.

Logistics questions and special requests

Please contact Ben Collins at Project Inform, 415-558-8669.

As guests of Project Inform, you will be provided with air transportation, shuttle service, food and lodging and are welcome to bring a guest. Responsibility for car rental and incidentals will be yours.

PLEASE FILL OUT FOLLOWING QUESTIONNAIRE AND RETURN TO PI

IMMUNE RESTORATION THINK TANK - 3
Baltimore, Maryland, November 5-7, 1993

Ms. Gebbie:

Please answer the following questions and mail or fax them back to: Ben Collins at Project Inform, 1965 Market Street, Suite 220, San Francisco, CA 94103. Fax: 415-558-0684.

- ❑ I will be attending IRTT - 3.
- ❑ I will not be attending IRTT - 3.

- ❑ I will be coming to the hotel by my own transport.
- ❑ I will use the shuttle service from Baltimore-Washington International.
- ❑ I will not be able to use the shuttle service from Baltimore-Washington International and will need alternate transportation to the hotel.

- ❑ I am bringing a guest.
- ❑ I am not bringing a guest.

- ❑ I will be attending the Saturday evening banquet.
  - ❑ 1 person
  - ❑ 2 person

What are your food restrictions or room requirements, if any?

_____

_____

_____

Comments?

_____

_____

_____

PROJECT inform

10/28/93

Steve Lee
Chief Scheduler
Office of National AIDS Policy
750 17th Street, NW, Suite 1060
Washington, DC 20503

Dear Steve;

On behalf of Project Inform, I would like to request a meeting with Kristine Gebbie, National AIDS Policy Coordinator, on Friday, November 5, 1993 at 9:00 a.m. Members of our staff will be in the area for the Immune Restoration Think Tank sponsored by Project Inform. The IRTT meeting is scheduled for November 6 and 7 in Baltimore, MD. An invitation and agenda follow this letter.

Martin Delaney; Founding Director, Brenda Lein; Information and Advocacy Coordinator, Dan Cusick; Policy Advocate, Ben Cheng; Information Associate, and Joel Thomas, a member of our Board of Directors will be available for the Friday morning meeting with Ms. Gebbie. We would like to discuss the role of Ms. Gebbie in the Future Directions in AIDS Research process and some general but pressing issues in the AIDS research and treatment arena.

We greatly appreciate your consideration in arranging this meeting on such short notice and hope that Ms. Gebbie may be able to join us at the Immune Restoration Think Tank to experience first hand this innovative forum. We hope that the type of collaboration and team work exhibited at IRTT will become one model for addressing critical questions in AIDS research.

Again, our thanks,

Anne Donnelly

Anne Donnelly
Public Policy Coordinator

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PROJECT IMMUNE RESTORATION

Immune Restoration Think Tank - 2
Plan A
In progress as of 4/21/93

Plan A (the 12 month plan) emphasizes the further development and optimization of approaches that are currently in or close to human trials. The plan calls for whatever is available after 12 months to be combined into a protocol to test the effect of multiple treatments being applied simultaneously.

Antivirals

The ultimate goal of this part of the plan would be to test not only nucleoside analogs and other reverse transcriptase inhibitors, but also tat and protease inhibitors in multiple combinations, to minimize further damage to and dysregulation of the immune system by replicating HIV. *In vitro* studies of combinations, including alpha interferon and monoclonal antibodies to HIV should be conducted, with the most promising of these progressing to Phase 1 trials. Endpoints for multiple combination antiviral protocols should include PCR, CD4 counts, and development of opportunistic infections. Whatever combination seems to offers the strongest antiviral effect while still being relatively safe should be used in the trial. This may include evaluating an individual's resistant phenotype.

- ❑ *In vitro* testing of combinations
  → Dave Fox and Don Angus to generate a matrix of what is currently being tested and by whom
  → what other combinations should be tested first, how and by whom?
  → how do we get owners of various products to cooperate quickly?
  → contact pharmaceutical consortium on antivirals
- ❑ Short (3-6 month) studies of best combinations, preferably before use in protocol
- ❑ Resistance testing
- ❑ ACTG 241 (AZT/ddI/Nevirapine) amended to include <50 CD4 arm

Autologous Cell Transfer

The goal of this part of the plan is to augment the immune system, particularly focusing on CD4 and CD8 cells, increasing number, life span and function. Encompassed in this approach is an intention to watch carefully for immune activation.

→ Have DAIDS call a meeting of current researchers in CD8 and CD4 expansion in the May time frame. This is languishing; Gallo to contact NCI participants to encourage participation; Jesse to explore video teleconferencing with Seattle
→ Desired attendees at cell expansion meeting
→ Dr. Judy Lieberman/New England Medical Center/PHA with IL-2 HIV specific cell expansion
→ Dr. Scott Koenig/Medimmune/anti-CD3 with allo feeders and IL-2
→ Dr. Kent Weinhold/Duke U./?
→ Dr. Tyler Curiel/U. of Colorado/?
→ Dr. Phil Greenberg/U. of Washington/?
→ Dr. Bruce Walker/Massachusetts General/?
→ Dr. Dewey Moody/AIS/PHA with IL-2
→ Dr. Rick Koup/Aaron Diamond/?

A program of

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→ Dr. Francis Gotch/Oxford/SIV?
→ Dr. Reinert Kurth/Paul Erlich Institute/SIV?
→ Dr. Steve Rosenberg/NCI/?
→ Yves Revere/Pasteur Institute/?
→ Seth Pincus/Rocky Mountain-NIAID/CD4 cell purging with rs-CD4 IgG

Autologous Transfer - CD4

- ❑ Study the optimization of CD4 expansion with respect to number, life span and function
  → what is being tested and by whom?
  → what approaches to expansion should be tested first, how and by whom?
  → how do we get owners of various products/technologies to cooperate quickly?
- ❑ Pilot Study
  → Is it possible to achieve 10^9 expansion?
  → Reinfuse with and without IL-2
- ❑ Study the potential of spleen harvesting to increase the number of cells available
- ❑ Test purging strategies for HIV infected cells, for example CD4 PE40 *in vitro*
- ❑ Cell marking may be necessary to determine where the cells go and how long they are viable. Joel Martinez is looking into the techniques and limitations of this technology

Obstacles: Regulatory concerns
Obstacles: GMP Requirement

Autologous Transfer - CD8

- ❑ *In vitro* optimization with various cytokines with respect to number and function (e.g. IL-4 vs IL-2 vs combo, PHA vs anti-CD3, etc.). Special attention needs to be put on measuring cell function and life span
  → what is being tested and by whom?
  → what other approaches to expansion should be tested first, how and by whom?
  → how do we get owners of various products to cooperate quickly?
- ❑ *In vivo* testing with and without IL-2
- ❑ Cell marking

Allogeneic Transfer

Soluble Factors

- ❑ Explore antiviral effect of supernatant from CD8 cells of asymptomatic seropositives. Jay Levy feels this approach won't work due to proteases freed on cell destruction but has not tried, says he needs industry support for scale-up of his purification process. He seems unwilling to discuss further details.
  → contact others?

Adoptive Transfer -Twins

- ❑ This is essentially the same as the autologous transfer of CD4 and CD8 except that this provides a source of uninfected CD4 and possibly other cells that have not had their function altered by HIV infection.

Obstacles: Money
Obstacles: Availability of twins

Partial HLA-Matched Transfer

- ❑ Explore literature
- ❑ Explore protocol at Center for Special Immunology in Miami which is currently underway
- ❑ Animal studies

- ❑ If the survey looks promising proceed as with autologous and adoptive transfer from twins studies.

Obstacles: Regulatory concerns
Obstacles: Ethical issues
Obstacles: Identifying animal model
Major Obstacle to All Cell Transfer Studies: Access to PegIL-2
→ contact Chiron

Active Immunization

This approach may act as an adjunct to any or all of the other strategies by providing an enhanced immune response especially prior to cell expansion. Any vaccine candidates, including the envelope vaccines, especially with novel adjuvants (e.g., Chiron), whole killed virus and core antigen approaches should be studied for their effect on anti-HIV antibodies and CTL activity.

→ what is being tested and by whom?
→ what vaccines should be tested first, how and by whom and in whom (<50 CD4)?
→ how do we get owners of various products to cooperate quickly?

Passive Immunity

The goal of this strategy is antibody replacement, both IgG specific and non-specific. This approach may include the use of monoclonal antibodies.

IVIG

- ❑ Analysis of bacterial profile (currently underway)

CMV

- ❑ Test levels of antibodies

Parallel Research into Basic Science Questions

- ❑ Explore stem cell and thymus transplant

- ❑ The following approaches were considered to *possibly* have a place in a Plan A:
  cyclosporine
  cytotoxin
  Insulin and human growth factors

→ what is being tested and by whom?

Standard Clinical Care

Maximizing non-toxic prophylaxis against a host of viral, bacterial, protozoan and fungal infections including the use of acyclovir, high CMV-antibody IVIG, anti-MAC, anti-PCP, and antifungal agents.

Patients should be receiving a minimum high level standard of care with doctor visits and blood work monitoring a least once per month

Patients should be maintaining minimum level or greater of basic nutrition. This program should emphasize the availability and absorption of nutrients, especially protein, carbohydrates, vitamins and minerals.

→ Develop a short, but comprehensive minimum protocol for nutrition. Possible sources, Larry Waites, Joan Priestley, Open Hand

Cytokine Balance

- ❑ Monitor anti-TNF, for example pentoxifyline results
- ❑ Plasma exchange to reduce the level of circulating immune complexes such as gp-120, free tat protein, etc.

→ contact Dobry Kiprov, others?

Antigen Presenting Cells

- ❑ Measure the effect of GM-CSF and M-CSF on antigen presenting cell function *in vivo*. Could be done through nested studies in existing trials of CSF's
  → contact PI's of existing studies.

Progenitor Cells

- ❑ Monitor the results of the Thymosin-α with IL-2 trial at Stanford. Gary Crawford to follow up this study and other thymic peptide studies. Jesse Dobson to follow up with Adria on THF. It is clear that THF only increases the number of mature thymocytes if sufficient immature thymocytes are present. Should we be testing this in combination with methods of generating precursor cells, such as ex-vivo expansion? Is this true of other thymic peptides?
  → Review thymosin-α, THF and TP-5 literature. Try to convince developers to do more basic science work to elucidate method of action.

PROJECT IMMUNE RESTORATION

Immune Restoration Think Tank - 2
Plan B
Working Plan

A program of

Project Inform

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415 558 0684 fax

Structural Issues

This strategic plan should take place in a multi-center setting.

- ❑ Coordination of this effort should include:
  - ⇨ Industry
  - ⇨ Academia
  - ⇨ Government
  - ⇨ Community
- ❑ A steering committee should be established to see this plan through to fruition
- ❑ A budget must be established
- ❑ Clinical, animal and laboratory facilities must be identified

This plan incorporates a three pronged approach to a three year targeted research effort aimed at restoring immune function in late stage HIV-disease. A clinical track, beginning immediately, represents one arm of this approach, a preclinical research track represents a second arm, and a pathogenesis research track represents the third arm would culminate in a clinical protocol in three years. This plan proceeds on the assumption that new technologies would be added to a foundation of aggressive nutritional maintenance, combination antiviral approaches and optimum OI prophylaxis. It also assumes that progress on antiviral approaches and the treatment and prevention of OIs will move forward on its own, in the next three years, and therefore does not address particulars on the further development of antiviral therapies and therapies for opportunistic infection prevention, treatment and maintenance.

The strategy on which this plan is formulated is the goal of reconstituting the immune system with progenitor cells. Therefore, further studies of the feasibility of autologous and allogeneic cell transfer/expansion, modified perhaps by gene therapy, is the centerpiece by which we proceed. Included in this effort is research into xenogeneic cell transfer. All of these technologies would of course be examined with and without conditioning regimens.

In addition to examining the feasibility of immune restoration through reconstitution with progenitor cells, this plan includes a salvage plan in the event research does not achieve our goal. The salvage protocol involves supporting and reconstituting the immune system with autologous cells which have been harvested and frozen, with and without immunization with antigens from HIV and opportunistic pathogens. By selecting a cohort now and cryopreserving cells with and without conditioning regimens, even if the following outlined path of research leads nowhere, we still have some of

the tools necessary to attempt an aggressive phase II protocol at the end of the given 36 month time frame.

The success of this plan will require that a highly rigid pace of research must be followed. In addition to strict time frames, the collective group participating in this effort must proceed with the notion that at determined time points, decisions must be made on the basis of existing data gathered at the completion of various components of research. These decision points are critical and there is no room for decisions which step backwards to repeat experiments. While a risk may have to be taken, proper quality controls should be implemented throughout this plan to minimize risk.

TRACK I - CLINICAL TRACK

Cells of volunteers in the cohort should be drawn and preserved, with and without immunization against HIV and opportunistic infections. The goal of this strategy is to support and reconstitute with autologous cells that have been harvested and frozen.

- ❑ Examine the feasibility of cell preservation
- ❑ Identify cohort (HIV+, CD4+ greater than or equal to 300 -perhaps less)
- ❑ Determine methods of intervention with and without immunization with HIV-antigen and other proteins (eg. HIV, CMV, Toxo, MAI, crypto, PCP)
- ❑ Begin collecting cells as soon as possible

TRACK II - PATHOGENESIS

Basic Research and Clinical Studies into the Basic Defects of the Immune Dysfunction in Late and Mid-Stage HIV

- ❑ Enabling studies
  - ⇨ Progenitor cell identification
  - ⇨ Animal models
  - ⇨ Vectors/Resistance
  - ⇨ Gene Therapy

Following the cohort selected in Track I, the following data would be gathered:

- ❑ Viral reservoir in patient's peripheral blood and tissue
  - ⇨ Infection of bone marrow and peripheral blood stem cells
  - ⇨ Turn over
- ❑ Virus strain/mutations
- ❑ Immune status at various stages
- ❑ Cytokine Profiles
  - ⇨ For example, determine if α interferon over-production is involved in immunosuppression in AIDS (is it possible to demonstrate and relieve immunosuppression?)
- ❑ Circulating stem cells

TRACK III - BASIC SCIENCE AND PRECLINICAL

Intensification of Research Efforts Into Thymus and Stem Cell Therapy

The goal of this strategy is to understand whether or not thymus transplants will work and if they have a role in immune restoration. Moreover, this strategy seeks to understand if the 'adult' environment provides all the necessary components for full immune reconstitution, and if not, what must be added. If thymus transplants prove to be useful, moving into the clinical setting with stem cell therapy at the earliest possible time is deemed critical to this plan. Outlined below are various studies and other recommendations to achieve this goal.

- ❑ Plan a workshop for people doing research in the field of Bone Marrow Transplant

- ❑ Examine Bone Marrow Transplant patients (both HIV+ and non-HIV infected) to determine what repertoire of reconstituted cells are thymic dependent versus independent, as well as the types of responses they elicit.
- ❑ Examine Bone Marrow Transplant patients at different ages
- ❑ What are the major issues?
  - ⇨ What is the cellular response for graft rejection?
  - ⇨ Age of donor and how this relates to growth
  - ⇨ How to get allogeneic and xenogeneic thymus tissue to engraft
  - ⇨ What kind of T-cells can develop as a result of allogeneic thymus transplant

- ❑ Conduct a study examining the T-cell repertoire of people with HIV/AIDS versus non-HIV infected individuals to determine what is present and what is not.
- ❑ Create a database on the state of the Thymus, in both humans and primates, at different stages of disease
- ❑ Examine autopsies to glean information on the state of the thymus at various stages of disease.
- ❑ Utilize non-invasive techniques to evaluate the state of the thymus
- ❑ Conduct studies on the thymus utilizing biopsy and examine trafficking using labeling techniques.
- ❑ Determine if there are waves in humans, as in mice, of sequential development of T-cells that have distinctive receptors, times of development, and distinctive final locations.

Evaluate the Potential of Utilizing Xenogeneic Thymus/Cell Transplant (e.g. pig)

- ⇨ What type of cells repopulate?
- ⇨ Establish an animal model
- ⇨ Efficacy determined by lack of toxicity and HIV challenge

Adoptive Autologous Immune Therapy

- ❑ Conduct studies on the direct *specificity, homing* and *lifespan* of transferred cells, including an analysis of the functional role of T-cell subsets and clones (including techniques mediated by gene therapy)
- ❑ Develop methods to prolong the lifespan of adoptively transferred cells *in vivo* without toxic side effects of injected cytokines (e.g. perhaps BCL2 in order to block apoptosis)
- ❑ Develop methods to get adoptively transferred cells to the sites of T-cell infection

Evaluate the Potential of Utilizing Allogeneic Immune Therapy With and Without Antiviral Approaches.

- ❑ Many of the research questions are similar to what is outlined in previous section on autologous immune therapy.

Gene Therapy in Stem Cells

- ❑ Determine which stem cells, and in what context, to target with gene therapy
- ❑ Determine the status of infection of stem cells and their subsets
- ❑ Vectors -establish vehicles which improve the efficiency of delivering genes to stem cells
- ❑ Regulation -determine the best way to express genes in the appropriate progeny
- ❑ Determine which genes, and in what combination, to utilize (eg. those that block viral replication or transcription, those that express T-cell receptor genes or immunoglobulins that will effect HIV infection or opportunistic infection).
- ❑ Determine if there are genes which interfere with the pathogenic effect of HIV infection
- ❑ Study the possibility of direct gene transfer *in vivo*

- ❑ Proceed on the basis of efficacy and lack of toxicity

Research Into The Basic Defects of The Immune System in Late and Mid-Stage HIV

The primary focus of this research is to understand the cytokine dysfunction in HIV and answer the questions of whether or not it is necessary to manipulate the cytokine milieu to optimize immune reconstitution, or manipulate the cytokine milieu to decrease the cytokine 'mischief' during reconstitution.

- ❑ Basic research into understanding and controlling cytokines in immunodeficiency in AIDS as part of the pathophysiology
  - ⇨ Utilize animal models to conduct systematic studies determining which cytokines are expressed in the disease process (e.g. IL-6, TNF)
  - ⇨ Determine if there is reason to associate cytokine expression with progression of disease
  - ⇨ Determine what removal of a particular cytokine's activity (by whatever means) has on progression of disease.
- ❑ Test Zagury's theory by determining if antibodies to CD4 crossreactive epitope recreates immunosuppression and cascade in chimps. Possible therapeutic evaluation (e.g. interference with molecular mimicry with antibodies)

Strategies for Diminishing Viral Load

- ❑ Continue ongoing efforts in evaluating combination antiviral approaches (apply post thymus transplant)
- ❑ Develop drugs to target different stages of viral replication
- ❑ Examine the potential of drugs which target specific cells (attack viral reservoirs, what reservoir purging strategies are possible?)
- ❑ Evaluate the use of antibodies/passive immune therapy with molecules with specificity for viral antigens (examine both passive and adoptive immunization with human monoclonal and polyclonals)
- ❑ Intensification of research into molecular strategies for diminishing viral load with molecules with nucleic acid sequence specificity
  - ⇨ Specific genetic molecules as drugs (eg. antisense)
  - ⇨ Gene therapy applies to T-cells and their subsets (eg. antisense, ribozymes, molecular decoys, transdominant mutants)
    - ⇨ Antisense -Toxicology, dosing, in vivo efficacy and distribution

Other

- ❑ What factors are present that 'protect' exposed, but uninfected people and clinically stable individuals?
- ❑ What containment strategies are available to prevent repopulation of graft with HIV-1?

Technology

- ❑ Intensification into research into the development of a technology for the fast and efficient typing of cells

MAJOR OBSTACLES

- ❑ **Funding**
- ❑ **Industrial role may have to be revisioned** as proprietary attitudes will hinder this effort
- ❑ **Conventional wisdom** may impede the ability to envision success of a new strategy

- ❑ **Competing priorities**, for both funding and public health needs must be considered
- ❑ **Scaling up** for this plan, including the availability of animal colonies, presents a major challenge
- ❑ **QC/QA and new assays**
- ❑ **GMP/Safety issues** must be considered in the balance of the potential life lost and the sense of urgency required to deal with the AIDS epidemic
- ❑ **Scientific culture** itself will present an obstacle
- ❑ **Need for a new infrastructure** to facilitate this type of targeted research effort
- ❑ **Training and recruiting** scientists, human resources, presents a challenge
- ❑ **Ethical issues** are of utmost importance to consider as this plan is aggressive and yet the possibility of failure must give us pause to consider what is being asked of study participants in the context of this strategy

PUBLIC POLICY RECOMMENDATION

Appoint an objective party whose responsibility it would be to transfer necessary proprietary information and technology to advance significantly the fight against AIDS

- ❑ This person(s) would by law have access to all research on AIDS, both public and private
- ❑ This person(s) must receive information only with extreme confidentiality provisions