TRANSCRIPT OF 7-16-04 RTRC PLANNING MEETING

PLENARY SESSION: WELCOME AND OVERVIEW

NOTE: The following transcript captures most of the discussion among attendees at the RTRC planning meeting, held on July 16, 2004, in Bethesda, Maryland. Some questions and comments were not picked up because of low audio.

INTRODUCTION—STEVE STRAUS:

GOOD MORNING. MY NAME IS STEPHEN STRAUS. I AM VERY PLEASED THAT ALL OF YOU HAVE JOINED US TODAY. WE HAVE A VERY FULL DAY OF DISCUSSION ABOUT A VERY LARGE AND WE BELIEVE VERY IMPORTANT INITIATIVE WITHIN THE NIH ROADMAP.

TO PUT THIS INTO A LARGER CONTEXT, WE WILL BEGIN BY ASKING OUR COLLEAGUE, DR. DUSHANKA KLEINMAN, TO DISCUSS THE ROADMAP IN GENERAL. DUSHANKA IS THE DEPUTY DIRECTOR OF THE NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH. FOR ABOUT A YEAR, SHE HAS BEEN THE ASSISTANT DIRECTOR FOR COORDINATING THE NIH ROADMAP. IT IS ITS OWN IMPORTANT ENTERPRISE. I AM REALLY PLEASED YOU CAN JOIN US, DUSHANKA.

OVERVIEW OF THE NIH ROADMAP—DUSHANKA KLEINMAN:

THANK YOU AND GOOD MORNING. I AM GLAD TO BE HERE TO GIVE YOU AN OVERVIEW OF THE ROADMAP, SO THAT WHEN YOU DISCUSS THE REGIONAL TRANSLATION RESEARCH CENTER INITIATIVE (RTRC) YOU CAN PUT IT INTO CONTEXT OF THE ROADMAP.

ONE OF THE QUESTIONS OFTEN ASKED IS 'WHY WAS A ROADMAP NEEDED FOR NIH WHEN THERE ARE SO MANY GOOD THINGS HAPPENING IN EACH INSTITUTE AND CENTER'?

DR. ELIAS ZERHOUNI, IN HIS ROLE AS THE NEW NIH DIRECTOR, FELT WE NEEDED TO EXAMINE THE WHOLE ENVIRONMENT IN WHICH SCIENCE SITS AND TO LOOK WITHIN THE AGENCIES AT THE EMERGING SCIENCE AND CHALLENGE NEEDS. TOGETHER WITH THE IC DIRECTORS, HE FELT THAT IT WAS VERY IMPORTANT TO POSITION NIH IN A DIFFERENT WAY TO ADDRESS PUBLIC HEALTH CHALLENGES AND MOVE THINGS MORE RAPIDLY SO THE BENEFITS OF RESEARCH CAN GET IN THE HANDS OF HEALTH CARE PROVIDERS, THE PUBLIC, AND COMMUNITIES. MOST IMPORTANT, I THINK, WAS NOT ONLY A DESIRE TO MOVE TRANSLATION

FROM BENCH RESEARCH TO PATIENTS, BUT ALSO TO GET FEEDBACK BACK TO THE RESEARCH SPECTRUM. ***NEXT SLIDE.***

WHEN WE TOOK AN ENVIRONMENTAL SCAN, IT WAS CLEAR WHAT WE ARE FACING IN THE U.S. AND IN MANY OTHER COUNTRIES—A SHIFT FROM ACUTE DISEASES TO CHRONIC CONDITIONS THAT ARE BECOMING MUCH MORE COMPLEX WITH AN AGING POPULATION AND THE COMORBIDITIES ASSOCIATED WITH THIS HEALTH SITUATION AND OTHER COMPLEXITIES. THIS REALITY IS CREATING CHALLENGES.

HEALTH DISPARITIES HAVE COME TO THE FORE, NOT ONLY IN THE APPROACH WITHIN NIH WITH THE CREATION OF THE NATIONAL CENTER FOR MINORITY HEALTH AND HEALTH DISPARITIES. EACH IC IS ADDRESSING THIS ON ITS OWN OR HAS CREATED STRATEGIC PLANS TO ADDRESS THE DIFFERENCES BETWEEN THOSE WHO HAVE ACCESS TO CARE AND THOSE WHO DO NOT.

EMERGING DISEASES ARE SOMETHING THAT WE ALL KNOW WE'RE GOING TO CONTINUE TO LIVE WITH, BUT THE CHALLENGES OF ADDRESSING THEM MORE EFFECTIVELY ARE ALSO WITH US. AND FINALLY, WE MUST ADDRESS BIODEFENSE—WHICH WE ARE ADDRESSING ACROSS NIH AND ACROSS ALL THE AGENCIES, THROUGH THE LEADERSHIP OF THE NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES.

NIH'S OPPORTUNITIES AND CHALLENGES ARE TO EXAMINE HOW—WITH 27 ICs AND MULTIPLE OFFICES, EACH WITH ITS OWN MISSION AND DIRECTION—WE CAN PUT THIS ALL TOGETHER TO ADDRESS THE OPPORTUNITIES AND CHALLENGES BEFORE US AND MEET THE NEEDS OF PUBLIC HEALTH.

WITH THOSE QUESTIONS IN HAND, THE PROCESS IDENTIFIED WAS A LITTLE DIFFERENT THAN WHAT NIH HAS TRADITIONALLY DONE. TRADITIONALLY, WE HAVE FOCUSED ON DEVELOPING STRATEGIC PLANS FOR RESEARCH AND HAVE ASKED SCIENTISTS TO COME FORWARD AND PRESENT WHAT THEY THOUGHT WERE THE OPPORTUNITIES FOR FURTHER INVESTMENT IN RESEARCH QUESTIONS.

THE FOCUS HERE, HOWEVER, WAS TO BRING A DIFFERENT GROUP OF INDIVIDUALS TOGETHER—MULTIPLE GROUPS OF INDIVIDUALS, EXPERTS IN VARIOUS DISCIPLINES, AND HEALTH CARE PROVIDERS—AND ASK THEM THE SAME QUESTIONS: WHAT ARE THE OPPORTUNITIES AND CHALLENGES IN SCIENCE, WHAT ARE THE ROADBLOCKS TO ACHIEVING THOSE OPPORTUNITIES, AND WHAT CANNOT BE ACCOMPLISHED BY A SINGLE INSTITUTE OR CENTER, BUT IS THE RESPONSIBILITY OF NIH AS A WHOLE?

THE INPUT FROM THESE DIVERSE GROUPS RESULTED IN A SERIES OF INITIATIVES THAT THE IC DIRECTORS REVIEWED AND TO WHICH THEY APPLIED SEVERAL CRITERIA. THE CRITERIA ASKED WHETHER THE INITIATIVE ADDRESSES THE INTERESTS OF THE VARIOUS STAKEHOLDERS? IS IT TRANSFORMING? DOES IT ALLOW NIH TO ADDRESS SCIENCE IN A NOVEL WAY? IS IT AN INITIATIVE THAT WOULD ENHANCE EACH IC's ABILITY TO ACHIEVE ITS MISSION? IS IT SOMETHING THAT NIH IS UNIQUELY SUITED TO DO AND THAT NO OTHER ENTITY WITHIN THE FEDERAL GOVERNMENT OR PRIVATE SECTOR COULD ACHIEVE?

PEOPLE HAVE ASKED 'WHAT IS THE NIH ROADMAP'? IT IS HARD TO PUT YOUR ARMS AROUND IT. WE HAVE LOOKED AT IT AS BEING A FRAMEWORK OF NIH-SELECTED PRIORITIES THAT OPTIMIZE THE INSTITUTE'S ENTIRE RESEARCH PORTFOLIO. IT IS ALSO A SET OF INITIATIVES CENTRAL TO HOPEFULLY ENHANCING A SUCCESSFUL QUALITY OF LIFE. FINALLY, IT IS A VISION FOR A MORE EFFECTIVE, EFFICIENT, AND PRODUCTIVE WAY OF DOING BUSINESS AT THE AGENCY LEVEL.

THIS SCHEMA IS MEANT TO HIGHLIGHT WHERE THE ROADBLOCKS ARE. IT IS DESIGNED TO LOOK AT THIS MOVEMENT FROM BENCH TO THE PUBLIC AND BACK AND WHAT COULD BE DONE. OF THE 27-28 INITIATIVES SELECTED BY THE IC DIRECTORS, THREE THEMES EMERGED.

THE FIRST ONE, NEW PATHWAYS TO DISCOVERY, INCLUDES FIVE COMPONENTS. I WILL SUMMARIZE THIS THEME AND THEN HIGHLIGHT A FEW OF ITS INITIATIVES, WHICH ARE GEARED TOWARD DEVELOPING THE TOOLS, TECHNOLOGY, AND DATABASES THAT WOULD HELP THE DELIVERY AND CONDUCT OF BASIC SCIENCE. THEY ARE TO PROVIDE RESOURCES TO RESEARCHERS THAT NOT ONLY WILL HELP THEM BETTER UNDERSTAND BIOLOGY, BUT ALSO ALLOW THEM TO MORE EFFECTIVELY DEVELOP INTERVENTIONS. ***NEXT SLIDE.***

IF WE LOOK AT THE INITIATIVES UNDER THE MOLECULAR LIBRARIES AND IMAGING PROBES COMPONENT, WE CAN SEE THAT THE FOCUS IS TO DEVELOP TOOLS THAT WILL FACILITATE STUDIES OF BIOLOGY AND PATHOPHYSIOLOGY AND DEVELOP AND IDENTIFY THE VALIDATION OF NOVEL BIOLOGIC TARGETS FOR THERAPEUTICS DEVELOPMENT. HERE THE FOCUS IS ON ORPHAN DISEASES, AS WELL AS ON MARKERS THAT WILL ALLOW US TO LOOK AT THE PROGRESSION OF DISEASE AND DEVELOP POSSIBLE DIAGNOSTIC INTERVENTIONS.

THE NATIONAL CENTERS FOR BIOMEDICAL COMPUTING IS ANOTHER COMPONENT OF THIS THEME. IT EXEMPLIFIES THE MULTIDISCIPLINARY EFFORT NEEDED FOR THESE RESEARCH RESOURCES AND BRINGS TOGETHER COMPUTER SCIENTISTS AND EXPERIMENTAL AND CLINICAL

RESEARCHERS. THE FOCUS IS TO PROVIDE RESEARCH THAT WILL FACILITATE ANALYSIS AND MANAGEMENT OF VERY COMPLEX DATABASES. ONCE THE CENTERS ARE UP, IN ADDITION TO HAVING DRIVING BIOLOGIC PROJECTS THAT ARE WITHIN THE CONTEXT OF THE CENTERS' FOCUS, INVESTIGATORS WITH RO1s WILL BE ABLE TO USE AND APPLY THE CENTERS' RESOURCES TO PURSUE THEIR OWN WORK AND RESEARCH QUESTIONS.

RESEARCH TEAMS OF THE FUTURE, THE SECOND THEME, HAS THREE COMPONENTS. ONE FOCUSES ON INTERDISCIPLINARY RESEARCH, ANOTHER ON HIGH-RISK RESEARCH, AND THE THIRD ON PUBLIC/PRIVATE PARTNERSHIPS. UNDER THIS THEME, WE WILL EXPLORE THE AREA AND BUILD THE INFRASTRUCTURE FOR INTERDISCIPLINARY RESEARCH, PREPARING OUR WORKFORCE TO CONDUCT INTERDISCIPLINARY RESEARCH AND EXPLORING HIGH-RISK STRATEGIES. THESE ARE HIGH RISK IN THAT WE WILL BE INVESTING IN INVESTIGATORS TO SUPPORT THEIR CREATIVE IDEAS AND LOOKING AT OPENING THE DOOR TO PUBLIC/PRIVATE PARTNERSHIPS.

IN UNDERTAKING OUR INTERDISCIPLINARY RESEARCH COMPONENT, IT WAS IMPORTANT FOR US TO FIRST DISTINGUISH MULTIDISCIPLINARY RESEARCH FROM INTERDISCIPLINARY RESEARCH. MULTIDISCIPLINARY RESEARCH INVOLVES COLLABORATIONS AMONG PEOPLE FROM DIFFERENT DISCCIPLINES. INTERDISCIPLINARY RESEARCH INVOLVES THE CREATION OF NEW FIELDS THROUGH THE MERGER OF EXPERTISE FROM OTHER RELATED FIELDS. BIOCHEMISTRY IS AN EXAMPLE OF INTERDISCIPLINARY RESEARCH, EVOLVING FROM THE FIELDS OF BIOLOGY AND CHEMISTRY.

THE NIH DIRECTOR'S PIONEER AWARD IS ONE OF THE FLAGSHIPS OF THE HIGH-RISK INITIATIVE CATEGORY. IT IS INTENDED TO SUPPORT INDIVIDUALS WITH UNTESTED BUT EXTREMELY CREATIVE IDEAS WITH HIGH POTENTIAL. IT IS AN INVESTMENT THAT HAS HIGH RISK BUT ALSO HIGH SUCCESS. IT IS A NEW PROCESS BEING UNDERTAKEN AT NIH AND WE HAVE GOTTEN A WONDERFUL RESPONSE OF NOMINATIONS FROM INVESTIGATORS WHO HAVE SUBMITTED THEIR APPLICATIONS. THAT REVIEW IS ONGOING. WE WILL BE PROVIDING AWARDS TO A SELECT NUMBER OF INVESTIGATORS FOR UP TO 5 YEARS TO PURSUE THEIR IDEAS. WE ARE LEARNING THROUGH THIS PROCESS ABOUT THE INVESTMENT IN THIS TYPE OF WONDERFUL INITIATIVE.

THE THIRD THEME IS RE-ENGINEERING THE CLINICAL RESEARCH ENTERPRISE. IT IS KEY TO THE WHOLE ROADMAP AND INVOLVES MOVING THINGS FROM BASIC RESEARCH THROUGH THE CLINICAL AREA. IT HIGHLIGHTS ALL ASPECTS, FROM POLICY TO RESEARCH TRAINING AND INFRASTRUCTURE DEVELOPMENT.

PEOPLE ASK HOW MUCH IS NIH INVESTING? THIS SLIDE SHOWS THAT OVER THE 6-YEAR PERIOD, UNDER 1 PERCENT OF THE NIH BUDGET IS PROJECTED IN ANY 1 YEAR. THIS SLIDE SHOWS HOW IT IS DISTRIBUTED ACROSS THE AREAS. AN IMPORTANT PART OF THE FUNDING IS THAT IT REPRESENTS THE BUDGET CONTRIBUTION FROM THE ICs, WHICH POOLED THEIR RESOURCES. THE RESOURCES ARE COMPLEMENTED BY MONIES FROM THE DIRECTOR'S DISCRETIONARY FUND. THIS IS JUST A PICTORIAL GRAPH OF WHAT WE REQUESTED FOR FY 2005 AND HOW IT LOOKS IN RELATION TO NIH OVERALL.

ANOTHER FREQUENT QUESTION IS 'HOW DOES THE NIH ROADMAP BENEFIT RESEARCH FUNDED BY INDIVIDUAL ICs.' THIS GOES BACK TO THE BASIC PRINCIPLES AND THE CRITERIA FOR WHICH THESE INITIATIVES WERE SELECTED. THE HOPE IS THAT THE INITIATIVES WILL SPEED THE REMOVAL OF MAJOR ROADBLOCKS COMMON TO ALL DISEASES. THE INITIATIVES ARE OPEN TO INVESTIGATORS FROM ALL FIELDS, BECAUSE IN ESSENCE THEY ARE ADDRESSING SOME VERY GENERIC ISSUES RELATED TO SCIENCE OVERALL. AS WE TEST THEM, YOU WILL HAVE TO BRING YOUR RESEARCH QUESTION AND USE IT AS A PILOT OR FEASIBILITY STUDY. SO, IT IS A COMMON POOL OF RESOURCES.

SOME OF THE CROSS-CUTTING ISSUES THAT WILL PERSIST THROUGHOUT THE LIFE OF THE ROADMAP ARE CLEARLY COMMUNICATING TO YOU, TO THOSE NOT PRESENT TODAY, AT NIH, AND TO ALL OF THE PUBLIC HEALTH SERVICE AGENCIES THAT WE ARE LOOKING AT COLLABORATIONS BETWEEN THE PUBLIC HEALTH SERVICE AGENCIES AND BEYOND THE DEPARTMENT OF HEALTH AND HUMAN SERVICES WITHIN THE FEDERAL SECTOR. BUT EVALUATION IS KEY, AND WE ARE WORKING VERY HARD NOT ONLY TO FACILITATE EVALUATION OF AN INDIVIDUAL INITIATIVE, BUT ALSO TO DEVELOP A PROSPECT OF EVALUATION OF THE OVERALL ROADMAP. IS IT ACHIEVING WHAT IT WAS INTENDED TO DO?

FINALLY, CONGRESS HAS GIVEN US A NEW AUTHORITY CALLED THE FLEXIBLE RESEARCH AUTHORITY. THIS ALLOWS US TO PILOT WITHIN THE ROADMAP THE ABILITY TO DO PEER REVIEW A LITTLE DIFFERENTLY AND TO USE TRANSACTIONS BEYOND GRANT, CONTRACTS, AND COOPERATIVE AGREEMENTS. WE ARE PILOTING THE AUTHORITY THROUGH THE NANOMEDICINE INITIATIVE, WHICH HAS NOW HAD ITS SOLICITATION OUT FOR CONCEPT DEVELOPMENT PAPERS THAT WILL THEN EVOLVE INTO NANOMEDICINE DEVELOPMENTAL CENTERS.

THE LAST COUPLE OF ***SLIDES*** ARE OFF THE WEB. THEY SHOW THE BREADTH OF THE SOLICITATIONS THAT HAVE BEEN PUT OUT IN 2004. THERE ARE AROUND 23 SOLICITATIONS, 19 OF WHICH ARE OPEN FOR COMPETITION. I AM ESTIMATING FOR 2005 THAT WE WILL HAVE APPROXIMATELY THE SAME AMOUNT. WE HAVE JUST GONE THROUGH AN

EXERCISE TO IDENTIFY WHAT THE 2005 SOLICITATIONS WILL BE. SOME WILL BE REISSUANCES OF ONES THAT ARE ALREADY OUT THERE AND ARE ALREADY IDENTIFIED IN THE RFAs.

WE'RE UPDATING THE WEB, AND WITHIN THE NEXT MONTH WE WILL HAVE A LISTING OF COMING ATTRACTIONS, SO TO SPEAK. IF YOU GO TO NIHROADMAP.GOV, ALL THIS IS THERE. THIS IS THE LAST SLIDE, IN WHICH WE RE-EMPHASIZE THE GOALS OF THE ROADMAP IN ACCELERATING BASIC RESEARCH DISCOVERIES AND SPEEDING THEIR TRANSLATION AND, ULTIMATELY, DOING GOOD BY DOING WELL.

THAT IS THE END AND I'M OPEN FOR QUESTIONS. I KNOW THERE WILL BE QUESTIONS AT THE END OF THE PRESENTATIONS THIS MORNING SO I WILL BE GLAD TO STAY AND ANSWER THOSE THEN. THANK YOU.

RE-ENGINEERING THE CLINICAL RESEARCH ENTERPRISE—STEVE STRAUS:

DUSHANKA HAS GIVEN US THE OVERARCHING STRATEGY, HISTORY, AND GOALS OF THE ROADMAP. WE'RE GOING TO DRILL DOWN progressively IN THESE FIRST FOUR TALKS. I WILL SPEAK ABOUT THE CLINICAL RE-ENGINEERING PART. THEN MEMBERS OF THE WORKING GROUP, WHO HAVE SPENT MUCH TIME IN THE PAST YEAR WORKING ON THE DRAFT MATERIALS YOU HAVE SEEN, WILL WORK WITH US THROUGHOUT THE DAY. WE WILL HEAR HOW THIS MAY RELATE TO OTHER NIH-WIDE RESOURCES FOR TRANSLATIONAL RESEARCH THAT EXISTS TODAY AND THEN A DRAFT VISION FOR THESE RTRCs.

AFTER THESE FOUR TALKS, EACH SPEAKER WILL COME TO THE FRONT AND TAKE YOUR QUESTIONS BEFORE WE GET DOWN TO THE SERIOUS WORK OF THE DAY. LET ME MOVE US TO THE NEXT STEP FROM THIS ROADMAP OVERVIEW TO DISCUSS IN DETAIL THE RE-ENGINEERING THE CLINICAL RESEARCH ENTERPRISE THEME.

DUSHANKA INDICATED THAT 23 INITIATIVES ARE ALREADY ON THE STREET, WITH MORE COMING, INCLUDING THIS ONE. NIH TEAMS—IMPLEMENTATION GROUPS—ARE MANAGING THESE. SOME OF OUR MOST OUTSTANDING INTRAMURAL AND EXTRAMURAL PEOPLE ARE RUNNING THESE IMPLEMENTATION GROUPS. YOU WILL SEE ONE IMPLEMENTATION GROUP—THE RE-ENGINNERING THE CLINICAL RESEARCH ENTERPRISE—IN THE UPPER LEFT CORNER OF THIS SLIDE. STEVE KATZ, DIRECTOR THE NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES, AND I CO-CHAIR THIS GROUP. THERE ARE SEVERAL WORKING GROUPS UNDER THAT.

DUSHANKA POINTED OUT A PROBLEM THAT IS NOW VERY FAMILIAR TO MANY OF YOU: IF WE ARE GOING TO IMPROVE THE HEALTH OF OUR PEOPLE, WE HAVE TO HAVE WAYS OF UNDERSTANDING THEIR DISEASES AND PREVENTING AND INTERVENING AGAINST THOSE DISEASES USING NEW TECHNOLOGIES, TOOLS, AND STRATEGIES. THE ROADMAP IS POISED TO INCREASE THE PIPELINE OF OPPORTUNITIES AT THE BENCH, FACILITATE THE TRANSITION FROM BENCH TO BEDSIDE, AND CREATE NEW WAYS OF ACCELERATING THE TRANSLATION OF RESEARCH DISCOVERIES FROM CLINICS INTO LARGER PRACTICE ENVIRONMENTS. ***NEXT SLIDE.***

THIS IS THE SLIDE DUSHANKA SHOWED ABOUT CLINICAL RE-ENGINEERING. I'M GOING TO TALK ABOUT ALL OF THOSE NOW. ***NEXT SLIDE PLEASE.***

ONE OF THE THINGS I WANTED TO POINT OUT IN THE BUDGET SLIDE DUSHANKA SHOWED YOU IS THAT THERE ARE SUBSTANTIAL INVESTMENTS IN ALL AREAS. BUT THE MOST RAPIDLY GROWING PART OF THIS PIE IS IN CLINICAL RESEARCH. THE INITIATIVE WE'RE TALKING ABOUT TODAY IS THE LARGEST OF THOSE. IT ENVISIONS A LARGE COMMITMENT FOR NIH, WHICH WILL INCREASE ABOUT SIX-FOLD OVER THE FIRST 5 YEARS. ***NEXT SLIDE.***

IN DISCUSSING RE-ENGINEERING THE CLINICAL RESEARCH ENTERPRISE, WE TALKED ABOUT PROVIDING NEW TOOLS AND TECHNOLOGIES AND IMPROVED RESEARCH TEAMS TO DO THE WORK. EVENTUALLY, HOWEVER, WE BEGIN WITH CLINICAL PROBLEMS ADDRESSED IN TERMS OF TRANSLATING OPPORTUNITIES FROM THE BENCH TO BEDSIDE AND USING THE BENCH TO UNDERSTAND WHAT TROUBLES OUR PATIENTS.

SO WE BEGAN WITH TWO LARGE TIERS OF INITIATIVES FOR TRANSLATION RESEARCH THAT ARE SOMEWHAT RELATED. THESE SETS OF INITIATIVES SHARE THE GOAL OF SEEKING TO STIMULATE RESEARCH AT THE BENCH-TO-BESIDE INTERFACE AND TO IMPLEMENT MECHANISMS TO PREPARE NOVEL PRODUCTS OF PRE-CLINICAL AND CLINICAL STUDIES. THERE ARE ROBUST MECHANISMS EXIST THROUGH THE BIOTECH AND DRUG COMPANIES, BUT MANY SUCH OPPORTUNITIES ARE NOT SUPPORTED.

THIS WOULD BE A COMPLEMENTARY STRATEGY TO ENSURE ADEQUATE SUPPORT FOR REGULATORY OVERSIGHT, DATA MANAGEMENT, AND SPECIMEN ANALYSIS. THIS IS A HUGE OBSTACLE FOR US. TO INCREASE THE SENSITIVITY AND IMPACT OF EARLY-PHASE CLINICAL STUDIES, TO INVEST SUFFICIENTLY IN A MODEST AMOUNT OF PROGRAMS, TO FACILITATE RESEARCH IN MANY INSTITUTIONS RATHER THAN CREATING IN A COOKIE-CUTTER FASHION INCREASINGLY MORE SIMILAR

RESOURCES AT ALL POSSIBLE INSTITUTIONS. WE ARE LOOKING FOR ECONOMIES OF SCALE. ***NEXT SLIDE.***

OF THE TWO PARTS OF THE TRANSLATIONAL RESEARCH SERVICES, THE FIRST IS WHAT WE CALL TRANSLATIONAL RESEARCH CORE SERVICES. MY COLLEAGUE JOSIE BRIGGS FROM THE DIABETES DIGESTIVE AND KIDNEY INSTITUTE CHAIRS THIS ACTIVITY. LIKE MANY OF THE ROADMAP INITIATIVES, INCLUDING THIS ONE TODAY, IT GREW OUT OF EXTENSIVE CONSULTATION WITH LEADERS IN ACADEMIA AND INDUSTRY.

WE HAVE ALREADY FINISHED DESIGNING AND PREPARING FOR A PILOT INITIATIVE FOR FY 2005. ALL THOSE RESOURCES HAVE BEEN ASSEMBLED, AND THE STRATEGY IS IN PLACE. THIS IS MODELED ON A PROGRAM THAT NCI HAS HAD FOR MANY YEARS, KNOWN AS THE RAID PROGRAM, WHICH PROVIDES INVESTIGATORS, PRIMARILY THUS FAR IN THE CANCER COMMUNITY, ACCESS TO IMPRESSIVE CONTRACT FACILITIES FOR KEY SERVICES. HERE THERE WILL BE A PILOT PROGRAM THAT WILL SUPPORT EARLY PRECLINICAL DEVELOPMENT OF SMALL MOLECULES FOR THERAPEUTIC APPLICATIONS.

WE HOPE IN TIME TO ALSO BE ABLE TO SCALE UP TO MAKE BIOLOGICALS AND NOT JUST SMALL MOLECULES. JUST AS DRUG COMPANIES AND BIOTECH COMPANIES DO THIS DAILY, WE NEED TO LEARN FOR OUR PROCESSES THE DECISION MAKING TO DETERMINE WHAT IS A WORTHY PROJECT, WHAT ARE THE PROCESS CONTROLS, AND WHAT IS THE REGULATORY OVERSIGHT TO HELP LEAD A PRODUCT TO BE READY FOR AN IND.

THERE IS A UNIQUE FUNDING PARADIGM HERE. ALL THE REST OF THE ROADMAP FUNDS, AS YOU HEARD FROM DUSHANKA, ARE MONIES THAT HAVE BEEN JOINTLY POOLED BY THE ICs BECAUSE THESE PROJECTS HAVE SOME SHARED ISSUES AND DISCIPLINE-SPECIFIC THERAPEUTIC OR PREVENTIVE TARGETS. WE ARE USING THE POOLED MONEY AS AN INCENTIVE TO CREATE THE INFRASTRUCTURE. THE ROADMAP WILL BE FUNDING 20-25 PERCENT OF THE COST OF THIS AND THEN SPONSORING ICs WILL COVER THE REST.

TODAY WE WILL TALK ABOUT OPTIONS FOR RTRCs. WE VIEW THESE AS COMPLEMENTING BUT NOT DUPLICATING OR MERELY GROWING FURTHER NCRR, GCRC PROGRAMS, AND OTHER SIMILAR CORE SERVICES, OF WHICH THERE ARE MANY FUNDED BY MANY OF THE ICs. THE PURPOSE IS TO SUPPORT PHASE I STUDIES IN PART OF PRODUCTS MADE BY THE CORE SERVICES PROGRAMS, SO THAT THERE IS AN ENVIRONMENT FOR THAT HANDOFF WHEN NEEDED, BUT TO A GREATER EXTENT TO PURSUE ANY OTHER TRANSLATIONAL RESEARCH IDEAS AS WELL AS EARLY-

PHASE STUDIES OF THE PRODUCTS PEOPLE CAN GET THROUGH OTHER MECHANISMS.

YOU WILL HEAR FURTHER ABOUT A SERIES OF OPTIONS. WE HAVE PUT ON THE TABLE WHAT WE HAVE HEARD FROM THE COMMUNITY, AND WE WANT TO HEAR FROM YOU IN GREATER DEPTH WHAT KINDS OF REGULATORY, STATISTICAL, BIOETHICS, AND DATA MANAGEMENT SUPPORT ARE NEEDED TO FACILITATE TRANSLATIONAL RESEARCH, AND WHETHER IT WOULD BE HELPFUL TO STIMULATE IT WITH SOME NOVEL BENCH-TO-BEDSIDE AWARD PROGRAMS, MANAGED THROUGH THE REGIONAL CENTERS WITH FUNDS FROM SMALL PILOT PROJECTS. WE ALSO WANT TO DISCUSS WHETHER THERE ARE IMPORTANT OPPORTUNITIES FOR SPECIAL TRAINING PROGRAMS FOR TRANSLATIONAL RESEARCH FELLOWS AS WELL AS HAVING A SUBSET OF THESE RTRCs TO PROVIDE VERY ROBUST, EXPENSIVE CORE SERVICES, SO AS NOT TO DUPLICATE SUCH SERVICES IN EVERY INSTITUTION FOR PHARMACOLOGY, IMMUNOLOGY, GENETICS, MICROARRAY, BIOINFORMATICS, AND OTHER HIGHLY TECHNICAL SERVICES.

TODAY WE'RE TALKING ABOUT THE CENTERS. OUR HOPE IS THAT WE WILL CALL FOR PLANNING GRANTS OR FUNDING IN FY 2005 AND CENTERS IN FY 2006 AND BEYOND. THESE TRANSLATIONAL RESEARCH CENTERS AND THE CORE RESOURCES ARE TWO OF THE PIVOTAL PARTS, BUT THERE ARE OTHER PARTS TO THE RE-ENGINEERING ENTERPRISE. ALREADY UNDERWAY IS A SMALL PROGRAM KNOWN AS DYNAMIC ASSESSMENT FOR PATIENT-REPORTED CHRONIC DISEASE OUTCOMES.

THE BACKGROUND TO THIS IS THAT ASSESSMENT OF CHRONIC DISEASES RELIES HEAVILY ON SUBJECTIVE REPORTS OF SYMPTOMS AND HEALTH-RELATED QUALITY-OF-LIFE ITEMS. WE HAVE A MÉLANGE OF APPROACHES TO ASSESS QUALITY OF LIFE AND PATIENT SYMPTOMS, AND THERE ARE BETTER TECHNOLOGIES THAT NOBODY IS GOING TO DEVELOP FOR THIS IMPORTANT AREA IF WE DO NOT DO IT. WE HAVE CREATED THE PROMISED PROGRAM PATIENT-REPORTED OUTCOMES MEASUREMENT AND INFORMATION SYSTEMS AND WILL FUND A COOPERATIVE NETWORK OF INVESTIGATORS CHARGED TO DEVELOP AND IMPLEMENT A PUBLICLY AVAILABLE SYSTEM OF A LARGE ITEM BANK IN NEW TECHNOLOGIES USING COMPUTERS RATHER THAN SIMPLE READING SKILLS. ***NEXT SLIDE.***

NIH FUNDS MANY RESEARCH NETWORKS. ONE OF THE PROBLEMS IS THAT THESE ARE ALL-PURPOSE BUILT NETWORKS. WHEN THE PURPOSE IS OVER, THE NETWORKS ARE DISASSEMBLED. THE NETWORKS ARE EXTREMELY PAROCHIAL. IF YOU'RE STUDYING ALZHEIMER'S DISEASES YOU HAVE AN OLDER POPULATION, AND YOU'RE NOT TAKING THE OPPORTUNITY TO LOOK AT COEXISTING HEALTH CONDITIONS IN THOSE PATIENTS.

HOW DO YOU BEGIN TO THINK ABOUT INTEGRATING THESE CLINICAL RESEARCH NETWORKS? THE GOAL OF THIS INITIATIVE IS TO LINK EXISTING NETWORKS SO THAT CLINICAL STUDIES AND CLINICAL TRIALS CAN BE CONDUCTED MORE EFFECTIVELY AND TO HELP CREATE COMMUNITIES OF RESEARCH AS PARTNERSHIPS BETWEEN INVESTIGATORS, PRACTITIONERS, AND PATIENTS. ***NEXT SLIDE.***

THIS IS THE TYPICAL INDUSTRY-FUNDED OR NIH-FUNDED NETWORK. THERE IS A CENTRAL SITE AND A SERIES OF COOPERATING SITES AROUND A SET OF QUESTIONS. ***NEXT SLIDE*.**

IN THE ALZHEIMER'S MODEL THAT I MENTIONED, WHAT IF THERE WERE OTHER NETWORKS INTERESTED IN GERIATRIC HEALTH CONDITIONS? HOW WOULD YOU GET THESE NETWORKS TO SHARE DATA SO THAT THEY CAN COMMUNICATE AND SYNERGIZE THEIR RESEARCH PRODUCTIVITY? ***NEXT SLIDE***.

A CALL IS ON THE STREETS FOR APPLICATIONS TO HELP US BEGIN TO CREATE AN INTEROPERABLE NETWORK OF NETWORKS. THIS IS NOT TO BUILD A NETWORK, BUT TO STUDY HOW NETWORKS COULD INTERACT. THE FIRST PART IS CALLED THE NATIONAL ELECTRONIC CLINICAL TRIALS AND RESEARCH NETWORK. THIS SEEKS TO DEVELOP COMMON DATA STANDARDS, INFORMATICS, AND SOFTWARE APPLICATION TOOLS FOR PROTOCOLS SO THAT THE SITES IN THE DIFFERENT NETWORKS USE THE SAME LANGUAGE IN THE SAME KINDS OF INFORMATICS PLATFORMSAND CAN SPEAK TO EACH OTHER. ***NEXT SLIDE.***

THE PROCESS OF ENHANCING TRANSLATIONAL RESEARCH, TOOLS FOR DEALING WITH PATIENTS, AND COORDINATING NETWORKS REALLY SPEAKS TO NIH's ACKNOWLEDGEMENT THAT CLINICAL RESEARCH IS NO LONGER A HOBBY, BUT A FORMIDABLE DISCIPLINE. EVERYBODY IN THE DISCIPLINE SHARES A COMMON CORE KNOWLEDGE, AND THEN THERE ARE SPECIAL SETS OF KNOWLEDGE AND EXPERTISE THAT WE NEED TO LEARN. DUSHANKA TALKED ABOUT TRAINING FOR MULTIDISCIPLINARY RESEARCH. THERE ARE RELATED TRAINING NEEDS FOR THIS NEW DISCIPLINE. ***NEXT SLIDE***.

NIH ALREADY FUNDS A LARGE RANGE OF PROGRAMS FOR TRAINING AND CAREER DEVELOPMENT FROM COLLEGE THROUGH TO SENIOR ACADEMIC POSITIONS. THERE ARE NEW PROGRAMS WITHIN THE PAST FEW YEARS, SUCH AS THE LOAN REPAYMENT PROGRAM, THAT WE ARE ACTIVELY FUNDING. SOME NEW ROADMAP-SPECIFIC INITIATIVES HELP PROMOTE THIS DISCIPLINE. ***NEXT SLIDE.***

THE FIRST IS THE TRANS-NIH MULTIDISCIPLINARY K12 CAREER DEVELOPMENT PROGRAM. THIS IS TO PROMOTE DEVELOPMENT OF

INVESTIGATORS FROM A VARIETY OF DISCIPLINES AND TRAIN THEM IN MULTIDISCIPLINARY TEAM SETTINGS, RECOGNIZING THAT IT TAKES A LONG TIME TO BECOME A CLINICAL INVESTIGATOR. THIS INVOLVES UP TO 5 YEARS OF TRAINING. THERE ALSO ARE CORE DIDACTIC COURSES AND PROJECT-SPECIFIC TRAINING. THERE ARE FUNDS FOR THE MENTORS AND THE CURRICULUM AND TO SUPPORT TUITION FOR ANNUAL MEETINGS. THIS SOLVES WHAT WE HAVE LEARNED OVER THE PAST FEW YEARS ARE THE PROBLEMS WITH OTHER TRAINING AND CAREER DEVELOPMENT MECHANISMS. ***NEXT SLIDE***.

THERE'S ALSO A GRAND VISION. YOU SHOULD APPRECIATE THE ROADMAP AS A WHOLE, AS A GRAND VISION, AND LONG TERM TO SEE IF SOME OF THESE ARE POSSIBLE. ONE OF THE IDEAS WE HAVE BEEN ADVISED TO UNDERTAKE IS TO TRY TO CREATE THE NATIONAL CLINICAL RESEARCH ASSOCIATES PROGRAM. IT IS VERY AMBITIOUS TO CREATE THE FIRST LARGE NATIONAL GROUP OF TRAINED AND CERTIFIED PRACTITIONERS IN THE COMMUNITY WHO CAN ENROLL THEIR OWN PATIENTS. RIGHT NOW, THERE ARE CLINICAL RESEARCH ORGANIZATIONS THAT USE PHYSICIANS IN PRACTICE SETTINGS. AND A FEW NIH NETWORKS USE PHYSICIANS IN PRACTICE AS WELL. BUT HOW ARE YOU SURE THAT THEY ARE WELL-TRAINED FOR THAT WORK AND THAT IT IS A LEGITIMATE INTELLECTUAL PARTNERSHIP? THIS PROVIDES A VEHICLE TO ACCELERATE TRANSLATIONAL RESEARCH RESULTS INTO PRACTICE.

OUR FIRST STEP IN DECIDING IF THIS IS FEASIBLE IS TO ASK ‘WHAT ARE THE BARRIERS’? WE CAN THINK OF ECONOMIC BARRIERS AND INCENTIVES, BUT THE QUESTION IS HOW DO YOU GET AROUND IT? WHAT IS THE TRAINING USED FOR PHYSICIANS IN THE COMMUNITY TODAY, AND WHAT ADDITIONAL TRAINING MIGHT BE NEEDED? WHAT ARE THE CORE COMPETENCIES NEEDED TO CERTIFY THESE INDIVIDUALS TO PARTICIPATE SO THAT THEY ALL REACH A HIGH BAR? NOT THAT THEY'RE GOING TO BE PRINCIPAL INVESTIGATORS, BUT THEY WOULD BE VERY GOOD SITE INVESTIGATORS. ***NEXT SLIDE***.

WHEN YOU TALK ABOUT CLINICAL RESEARCH, YOU DEAL WITH AN ABSOLUTELY UNIMAGINABLY COMPLICATED NEST OF REGULATIONS AND THIS SLIDE CAPTURES IT THE BEST. BY THE WAY, ALL SLIDES FROM TODAY WILL BE POSTED ON OUR WEBSITE, SO YOU WILL HAVE ACCESS TO THESE. BUT THE ISSUE IS, HOW COULD WE AT NIH HELP TAKE A LEADERSHIP ROLE IN HELPING INVESTIGATORS NAVIGATE THESE MULTIPLE REGULATORY REQUIREMENTS? ***NEXT SLIDE.***

WE HAVE BEGUN A PROGRAM TO TAKE A LEADERSHIP ROLE TO HELP HARMONIZE FEDERAL REGULATORY REQUIREMENTS FOR CLINICAL RESEARCH. THIS IS TO AGREE UPON AND CLARIFY WHAT AN ADVERSE EVENT IS AND HOW IT IS TO BE REPORTED, TO WHOM, AND IN WHAT

CONTEXT; HUMAN SUBJECTS PROTECTION ISSUES; AND THE GROUND RULES FOR IRB DSNB REACTIONS. AUDITING AND MONITORING ARE DONE BY SEVERAL DIFFERENT GROUPS WITH DIFFERENT APPROACHES. HOW DO WE HARMONIZE ALL THE POTENTIAL CONFLICTING ISSUES OF RESEARCH INTEGRITY AND CONFLICT OF INTEREST; WHICH IS AS LARGE FOR US AS IT HAS EVER BEEN; THE PRIVACY AND HIPAA ISSUES; INVESTIGATOR REGISTRATION AND FINANCIAL DISCLOSURES, AND THE LIKE.

TO DO THIS, WE HAVE CREATED A CLINICAL RESEARCH POLICY AND ANALYSIS COORDINATION INITIATIVE, ALREADY UNDERWAY AND WORKING VERY HARD WITH OUR HHS AGENCY PARTNERS AND OTHER GROUPS TO TRY TO PROMOTE CLEAR, EFFECTIVE, AND COORDINATED POLICIES. WE ARE ESTABLISHING A FORMAL NIH PROGRAM TO WORK IN CONCERT WITH THE AGENCIES TO CONSULT WITH THE DIVERSE STAKEHOLDERS AND DEVELOP THE TOOLS WE NEED TO TRY TO DO THIS. THIS IS A LONG-TERM, VERY HARD GOAL, BUT WE ARE AT LEAST WORKING ON IT.

LET'S COME BACK TO THE FIRST PART—THE RTRCs. WE HAVE BEEN WORKING ON THIS IDEA FOR OVER A YEAR. MONEY HAS BEEN ALLOCATED FOR THIS MEETING, FOR THE PLANNING GRANTS AS PROMISED, AND FOR THE CENTERS. WE HAVE CONVENED TODAY TO HEAR FROM YOU ABOUT OUR EARLIEST IDEAS. AS I SAID, WE'RE GOING TO FUND PLANNING GRANTS AND THE FIRST ROUND OF NEW CENTERS. ***NEXT SLIDE.***

WE WILL HEAR NEXT FROM ANTHONY HAYWARD, DIRECTOR OF NCRR's GCRC PROGRAM AND A LEADER OF OUR WORKING GROUP. HE WILL TALK ABOUT OTHER EXISTING RESOURCES IN TRANSLATIONAL RESEARCH AND HOW THOSE MAY RELATE TO WHAT WE ARE PROPOSING TODAY. WE WILL COME BACK FOR QUESTIONS FOR ALL OF US AT THE END OF THE TALK.

GCRCs AND OTHER NIH TRANSLATIONAL RESEARCH PROGRAMS—ANTHONY HAYWARD:

THANK YOU, STEVE. I'LL PURSUE YOUR DRILLING DOWN ANALOGY TO SAY THAT WHAT YOU HAVE HEARD SO FAR IS INFORMATION THAT CAME TO YOU. INCREASINGLY, YOU WILL HEAR QUESTIONS FROM US THAT WE HOPE WILL PROMPT RESPONSES FROM YOU.

CLEARLY, TRANSLATIONAL RESEARCH, ***NEXT SLIDE PLEASE***, IS NOT NEW. IT HAS GONE ON FOR MANY YEARS AND HAS USED A RANGE OF RESOURCES. I HAVE LISTED HERE IN TERMS OF INFRASTRUCTURE—AT THE TOP—THE GCRCs BECAUSE I KNOW A GREAT DEAL ABOUT THEM AND

ACKNOWLEDGE ALSO THE WIDE RANGE OF SINGLE-DISCIPLINE RESEARCH CENTERS THAT EXIST.

I SHOULD REMIND YOU THAT MOST OF YOU WHO ARE HERE TODAY WERE INVITED BECAUSE YOU ARE OUTSTANDING TRANSLATIONAL CLINICAL RESEARCHERS, SO YOU KNOW ALL ABOUT THIS. IF I WERE TO CHOOSE AN EXAMPLE, ALTHOUGH UNFORTUNATELY HE IS ON JURY DUTY TODAY, I WOULD CITE BOB DESNICK, WHOSE WORK I KNOW. USING THE RESOURCES OF THE GCRC, HE CREATED PEG CONJUGATED ENZYMES AND TRANSLATED THAT FROM A BENCH INTO A PATIENT AND INTO A SUCCESSFUL PHARMACEUTICAL. IF YOU WERE TO ASK HIM ABOUT DOING THAT, HE WOULD SAY THE DIFFICULTIES WERE ENORMOUS AND HE COULD HAVE DONE A GREAT DEAL BETTER AND MORE EASILY HAD THE RIGHT RESOURCES BEEN AVAILABLE.

THE QUESTION WE FACE TODAY IS 'WHAT ADDITIONAL RESOURCES WOULD BEST HELP IN THE PRESENT ENVIRONMENT?' CLEARLY THEY'VE CHANGED SINCE THE DAYS IN WHICH BOB, FOR INSTANCE, WAS DEVELOPING PEG CONJUGATED ADA. WE HAVE MANY ADDITIONAL DEMANDS TO MEET AND IN MANY WAYS THE PLAYERS THEMSELVES HAVE CHANGED.

I WILL BRIEFLY PRESENT THE ITEMS WE HAVE TO PLAY WITH AND THAT WE CAN THINK ABOUT USING TO CREATE RTRCs THAT CLEARLY HAVE TO BE MORE THAN GCRCs, THAT HAVE TO BE MORE THAN OUR EXISTING SINGLE-DISCIPLINE RESEARCH CENTERS.

WE NEED TO THINK NOT ONLY ABOUT THE INFRASTRUCTURE WE HAVE AND WHETHER WE CAN USE THIS INFRASTRUCTURE TO FACILITATE CREATING RTRCs. OR, FOR INSTANCE, IF YOU WERE TO DECIDE TO GO IN A DIFFERENT DIRECTION FROM OUR PRELIMINARY DOCUMENTS, IF THESE ARE THINGS THAT REALLY SHOULD BE CREATED DE NOVO AND SHOULD HAVE NO ASSOCIATION WITH SOME OF THESE EXISTING THINGS.

IN THINKING ABOUT WHO WE ARE SUPPORTING OR WHOSE FACILITIES, WE NEED TO CONSIDER BOTH THE BENCH AND CLINICAL SCIENTISTS. I EMPHASIZE THAT THE GCRC OFTEN FOCUSES ON THE CLINICAL END OF THE EQUATION. BUT IN THINKING ABOUT TRANSLATIONAL RESEARCH, WE ALSO NEED TO ENCOMPASS THE NEEDS OF THE BENCH AND BASIC SCIENTISTS DOING THE UNDERLYING RESEARCH. WHAT SORT OF RESOURCES DO THEY NEED?

I HAVE LISTED TWO HERE, AND CLEARLY THEIR NUMBERS WOULD BE LEGION. WHAT SORTS OF ANIMAL RESOURCES ARE NEEDED? ARE THESE PRIMATES, MICE, SPECIALLY CONSTRUCTED ANIMALS? WHAT SORT OF RESOURCES DO THE DIFFERENT DISCIPLINES REQUIRE? WHERE WE HAVE

VERY EXPENSIVE RESOURCES, LIKE THE CREATION OF TRANSGENIC ANIMALS, THESE NEED TO BE SHARED. WE HAVE SEEN THIS HAPPEN FREQUENTLY THROUGH OUR GCRC PROGRAM, WHERE WE HAVE INCREASINGLY RELIED ON CORES AT ONE GCRC THAT OFFERS SPECIALIZED SERVICES TO MAKE THOSE SERVICES AVAILABLE TO THE 80-CENTER NETWORK ACROSS THE COUNTRY.

REGARDING SPECIALIZED SERVICES, WE ALSO HAVE INVITED RESEARCH NURSES TO THIS MEETING. RESEARCH NURSING IS AN ESSENTIAL COMPONENT OF THE RESEARCH TEAM, AS INDEED ARE RESEARCH PHARMACISTS AND RESEARCH DIETICIANS. THE RANGE OF TRANSLATIONAL RESEARCH CONSISTS NOT ONLY OF EVALUATING NEW MEDICATIONS, BUT EVALUATING NEW TREATMENTS AND NEW PREVENTIVE MEASURES.

MY INTENT IN MY PRESENTATION WAS TO SURVEY WHAT NIH HAS IN THE WAY OF CLINICAL RESEARCH CENTERS. I WAS DAUNTED WHEN I REALIZED THAT NIH FUNDS MORE THAN 1,000-1,200 CENTERS NATIONWIDE. WE HAVE INVITED REPRESENTATIVES OF INDIVIDUAL ICs TO THIS MEETING SO THAT THEY CAN SPEAK FOR WHAT THEIR ICs DO FOR THEMSELVES. IT WOULD NOT BE RIGHT FOR ME TO TRY TO TELL YOU WHAT THE RESOURCES AND STRENGTHS OF THE NATIONAL CANCER CENTERS ARE, NOR THE ENORMOUS RANGE OF CENTERS RUN BY NIDDK, THE RENAL DIABETES RESEARCH, DIABETES EDUCATION, AND MANY OTHER ONES. I HAVE LISTED SEVERAL OF THEM HERE.

AS WE THINK ABOUT DEVELOPING RTRCs, IF WE DECIDE TO DRAW ON EXISTING INFRASTRUCTURE, THE RANGE IS IMMENSE. I'M NOT SAYING THAT YOU WOULD NECESSARILY THINK THE SPECIFIC COMBINATION BE DEDICATED, BUT IN A REGIONAL CONTEXT I AM SURE THAT THERE WILL BE STRENGTH IN SOME AREAS THAT COULD BE EXPLOITED.

MY OWN TOPIC FOCUSES ON THE 80 GCRCs. THEIR AIM, WHEN CREATED, WAS TO PROMOTE TRANSLATIONAL RESEARCH AND SPECIFICALLY TO CREATE ECONOMIES OF SCALE, BECAUSE REALLY EXPENSIVE RESOURCES COULD BE SHARED BETWEEN MULTIPLE GROUPS. I WILL TRY TO SHOW YOU THE SORTS OF INFRASTRUCTURE THAT THEY PROVIDE SO THAT YOU UNDERSTAND HOW CENTERS LIKE THIS CAN BE USED.

I DON’T THINK WE SHOULD THINK OF THIS EXCLUSIVELY AS AN EXTRAMURAL ACTIVITY. THE NIH CLINICAL CENTER ITSELF HAS BEEN REBUILT AND WILL BE OPENING THE END OF THIS YEAR. IT HAS OUTSTANDING CLINICAL FACILITIES, SOME THAT ENABLE REALLY ADVANCED SURGERY TO BE DONE. THIS IS SOMETHING THE GCRCs ARE RARELY ABLE TO DO BECAUSE OF THE ADVANCED LIFE SUPPORT THAT CAN BE REQUIRED AFTER PARTICULARLY CHALLENGING SURGERY. ONE

OF THE THINGS WE WILL BE THINKING IN TERMS OF ARE THE COMPONENTS THAT CAN BE PUT TOGETHER AND THE NETWORKS THAT CAN BE BUILT. HOW CAN THE NIH CLINICAL CENTER BE JOINED INTO THIS? CAN I HAVE THE ***NEXT SLIDE***?

I'M SHOWING YOU THIS SLIDE TO HELP YOU IN YOUR BREAKOUT DISCUSSIONS TO THINK WHAT AN RTRC WOULD NEED—IF IT WERE NOT TO USE GCRC INFRASTRUCTURE RESOURCES BUT WERE TO DEVELOP ITS OWN INFRASTRUCTURE AND RESOURCES. I CAN TELL YOU FROM EXPERIENCE THAT THE AVERAGE GCRC SPENDS ABOUT $3-4 MILLION A YEAR. IT SPENDS ABOUT A QUARTER OF THAT ON NURSING SUPPORT. WHERE WE ARE DOING TRANSLATIONAL RESEARCH WILL OFTEN NEED TRAINED NURSES TO MAKE THE SCIENTIFIC OBSERVATIONS. WE NEED NURSES WHO WOULD SAY THAT I HAVE THIS TIME DEDICATED TO GETTING THIS BLOOD SAMPLE NOW, THIS CSF SAMPLE NOW, OR TO GIVE THIS CHEMOTHERAPY DRUG NOW—THINGS THAT YOU CANNOT ASK AN RN ON A FLOATING POOL TO UNDERTAKE.

ABOUT 20 PERCENT OF THE FUNDS ARE ACTUALLY SPENT ON PROVIDING INPATIENT RESOURCES.

THE NEXT SECTION IS ADMINISTRATION. THIS DESCRIBES THE NEED FOR LEAD SCIENTIFIC STAFF TO CHECK THE QUALITY OF THE SCIENCE BEING DONE AND ENSURE THAT THE MOST IMPORTANT PROJECTS ARE PURSUED.

THE NEXT ONE THERE IS THE LABORATORY. THE CORES LABORATORIES ARE OFTEN NEEDED FOR VERY SOPHISTICATED MEASUREMENTS, BE THEY MRS, MASS SPEC, PET. THESE ARE SOPHISTICATED TOOLS THAT REQUIRE A SUBSTANTIAL AMOUNT OF FUNDING. I DRAW YOUR ATTENTION TO THE NEXT ONE, WHICH IS OUTPATIENT RESOURCE COSTING, WHICH COSTS ABOUT 10 PERCENT OF WHAT A CENTER NEEDS.

THE 7 PERCENT IN THE ORANGE/RED COLOR IS FOR RESEARCH SUBJECT ADVOCATES. THESE ARE EMPLOYED BY GCRCs TO FACILITATE THE INVESTIGATOR'S ABILITY TO KEEP UP WITH THEIR CONSENT FORMS AND HUMAN SUBJECT REQUIREMENTS. THEY DO NOT FUNCTION AS IRB ENFORCEMENT OFFICERS, BUT THEY'RE THERE TO FACILITATE THE SAFETY OF THE SUBJECTS AND TO HELP THE INVESTIGATORS ENSURE THAT SAFETY IS MET. THERE ARE OTHER MINOR THINGS—BIONUTRITION, BIOINFORMATICS, AND BIOSTATISTICS. BY VIRTUE OF THE COST WE PUT INTO THESE, WE HAVE INVITED HERE TODAY BIOSTATISTICIANS AND BIOINFORMATICS PEOPLE, BECAUSE WE THINK THEY ARE ESSENTIAL COMPONENTS OF THE RESEARCH TEAMS THAT WILL MAKE UP RTRCs.

WE SAMPLED A LOT OF PEOPLE TO ASK THEM WHAT ARE THEY NOT GETTING THAT THEY NEED. I HAVE LISTED SOME OF THESE HERE, WHICH

YOU SAW IN EARLIER ROADMAP DESCRIPTIONS. INVESTIGATORS SAY THEY NEED HELP FORMATTING THEIR DOCUMENTS FOR THE 16 DIFFERENT REGULATORY COMMITTEES THAT WILL PORE OVER THEM. YOU CAN SAY ASK WHY THEY DON'T HAVE THE SAME FORMAT. I'M NOT IN A POSITION TO ANSWER THAT.

CLEARLY INVESTIGATORS NEED HELP. WE ARE ALL AWARE THAT IF WE COULD ENROLL 60 PATIENTS IN A STUDY TOMORROW, WE CAN HAVE THE RESULTS IN 3 MONTHS' TIME. SOMETHING LIKE THE CYSTIC FIBROSIS RESEARCH NETWORK HAS SHOWN US HOW EFFECTIVE THIS SORT OF THING CAN BE. THE RARE DISEASE RESEARCH NETWORK RUN BY THE OFFICE OF THE DIRECTOR IS TELLING US HOW EFFECTIVE THAT CAN BE. IS THIS SOMETHING THAT RTRCs CAN PROMOTE? BIOINFORMATIC SUPPORT, THE REST DOWN THERE YOU CAN SEE. THESE ARE QUESTIONS THAT I AM ASKING OR POSING TO YOU AS THINGS THAT MIGHT BE NEEDED OR THAT WE HEAR ARE NEEDED BY PEOPLE WHO PURSUE TRANSLATIONAL RESEARCH. I THINK I HAVE ONE MORE ***SLIDE***.

I HAVE LISTED THIS ONE AS SPECULATION BECAUSE I DON'T WANT TO PLEAD GUILTY OF SOME OF THE THINGS AT THE BOTTOM. WHEN WE THINK OF TRANSLATIONAL RESEARCH, VERY OFTEN MULTIPLE INSTITUTIONS COULD BE BROUGHT TOGETHER TO PURSUE A COMMON GOAL MORE EFFICIENTLY.

THERE ARE MANY CENTERS ALSO, FOR INSTANCE, THAT DO NOT HAVE CLINICAL RESEARCH CENTERS BUT HAVE A SPECIALIZED RESEARCH CENTER. HOW COULD WE ORGANIZE OUR DECK OF PLAYING CARDS MORE EFFICIENTLY TO ALLOW TRANSLATIONAL RESEARCH TO WORK BETTER? THIS IS TRUE WHERE WE'RE DEALING WITH SCARCE AND EXPENSIVE RESOURCES. I AM CONCERNED FROM MY PERSPECTIVE THAT THE RESOURCE DISTRIBUTION THAT WE HAVE IS INEFFICIENT. IF WE COULD MOVE OUR CHESS PIECES AROUND WE COULD. BUT WHEN YOU'RE DEALING WITH SOMETHING LIKE A PET SCANNER, YOU CANNOT PUT IT ON THE BACK OF THE TRUCK AND DRIVE IT TO THE NEXT CENTER. ACTUALLY, IT IS THE CYCLOTRON THAT IS HARD TO MOVE.

THE LINE AT THE BOTTOM IS PARTICULARLY DEAR TO MY HEART. WE KNOW THAT WE RELY ULTIMATELY ON NIH RO1 FUNDING TO FUND MAJOR RESEARCH ACTIVITIES. THAT CAN BE SLOW TO OBTAIN, AND GETTING IT IS ENORMOUSLY FACILITATED BY HAVING GOOD PRELIMINARY DATA.

THERE ARE A FEW AVENUE OUTCOMES FOR INVESTIGATORS ASIDE FOR PIONEER AWARDS FOR DOING HIGH-RISK RESEARCH TO GET PRELIMINARY DATA TO ALLOW IMPORTANT ADVANCES TO PROCEED

RAPIDLY. WHAT PROPORTION OF AN RTRC's RESOURCES SHOULD GO TOWARD THIS SORT OF ACTIVITY?

AFTER THESE RATHER WILD SPECULATIONS, I'M GOING TO HAND OVER TO DR. STEVEN ZALCMAN, WHO HAS BEEN A KEY FIGURE IN THIS AND WHO HAS AUTHORED MUCH OF THE INTERIM DOCUMENTS THAT ARE ON THE WEB. WE HAVE DONE SOME OF IT TOGETHER, BUT I WILL GIVE MOST OF THE CREDIT TO HIM TO TAKE US ON AND FOCUS DOWN TO THE NEXT LEVEL OF OUR MORE SPECIFIC THOUGHTS ABOUT THE CENTERS. THANK YOU.

RTRCs: A WORK IN PROGRESS—STEVE ZALCMAN:

GOOD MORNING, I AM STEVE ZALCMAN FROM THE NATIONAL INSTITUTE OF MENTAL HEALTH. I WOULD LIKE TO ADD MY WELCOME TO THAT OF DUSHANKA, STEVE, AND ANTHONY TO ALL OF YOU COMING HERE TODAY. WE REGARD THE RTRC INITIATIVE AS AN IMPORTANT INITIATIVE, AND WE ARE VERY GRATEFUL FOR ALL OF YOU GOING THROUGH THE TIME, TROUBLE, AND EFFORT TO COME HERE TODAY SO THAT WE MAY BENEFIT FROM YOUR WISDOM AND COUNCIL.

THE MAJOR GOALS OF THIS INITIATIVE ARE LISTED HERE. BUT BEFORE GOING THROUGH THOSE, JUST A SMALL BIT OF HISTORY. AS INDICATED BY STEVE STRAUS, THIS IDEA GREW INITIALLY OUT OF A MEETING THAT WE HELD IN MAY 2003 IN WHICH REPRESENTATIVES OF 19 OF THE 27 NIH IC MET WITH CONSULTANTS REPRESENTING BOTH ACADEMIC HEALTH CENTERS, INDUSTRY, AND THE NOT-FOR-PROFIT SECTOR AND CAME UP WITH A NUMBER OF INITIATIVES, INCLUDING THIS ONE.

YOU HAVE HEARD ALREADY FROM DUSHANKA ABOUT THE ROADMAP IN GENERAL AND FROM STEVE STRAUS ABOUT THE SPECIFIC AREAS THAT ARE IN PART THE RE-ENGINEERING OF THE CLINICAL RESEARCH ENTERPRISE. AND ANTHONY HAS DONE A WONDERFUL JOB OF PREVIEWING, OVERVIEWING THE LARGE INFRASTRUCTURE SUPPORT CURRENTLY ACROSS ALL OF NIH TO SUPPORT TRANSLATIONAL RESEARCH.

OPERATIONALLY, WE ARE DEFINING TRANSLATIONAL RESEARCH AS RESEARCH AT THE INTERFACE BETWEEN THE BENCH AND BEDSIDE. THE DEFINITION REQUIRES A BI-DIRECTIONAL INFORMATION FLOW BETWEEN THE TWO DISCIPLINES AND, THEREFORE, INTIMATE WORKING RELATIONSHIPS BETWEEN BASIC AND CLINICAL SCIENTISTS.

IT IS OUR ADDITIONAL BELIEF THAT IT IS ONLY THROUGH SUCH INVESTIGATION THAT WE CAN FULLY LEVERAGE AND ADVANCE

KNOWLEDGE ABOUT THE ETIOLOGY, PATHOPHYSIOLOGY, PATHOGENESIS, DIAGNOSIS, TREATMENT, AND ULTIMATELY PREVENTION AND CURE OF DISEASES. IN THE NEXT FEW MINUTES, I WILL OVERVIEW THE STATE OF OUR VISION FOR THESE CENTERS, AS INDICATED IN THE INTERIM REPORT THAT WE POSTED ON THE WEB. ANTHONY WAS KIND ENOUGH TO GIVE ME MOST OF THE CREDIT FOR THIS, ALTHOUGH HE WROTE ALMOST EVERY WORD AND I EDITED IN TWO OR THREE COMMENTS. I WILL USE THIS OVERVIEW JUST AS A POINT OF DEPARTURE FOR TODAY'S ACTIVITIES—MAINLY OUR HEARING FROM YOU HOW WE CAN IMPROVE AND REFINE THIS CONCEPT. ***NEXT SLIDE PLEASE***.

IN OUR CONSULTATIONS WITHIN NIH AND WITH OUTSIDE CONSULTANTS, IT WAS THE BROADLY HELD VIEW THAT DESPITE THE VERY EXTENSIVE EXISTING INFRASTRUCTURE SUPPORT FOR TRANSLATIONAL RESEARCH OFFERED BY NIH, THAT TO MAKE MAXIMAL AND OPTIMAL PROGRESS, TO MOVE IDEAS FROM THE BENCH TO THE CLINICAL ARENA, AND TO THE STAGE OF A FIRST IN HUMAN TRIALS OF DRUGS AND BIOLOGICALS, WE NEEDED ADDITIONAL SUPPORT. THIS IS THE NOTION WE HAVE COME UP WITH. IT IS FELT THAT IT CAN PROVIDE ADDITIONAL COLLABORATIONS, INCREASE THE PATIENT INVOLVEMENT IN THESE SORTS OF STUDIES, ACHIEVE ECONOMIES OF SCALE, AND FACILITATE ON REGIONAL AND NATIONAL SCALES THE SORT OF COLLABORATIONS THAT CURRENTLY SIMPLY ARE NOT FEASIBLE. ***NEXT SLIDE.***

THE CURRENT NOTION, AS PREVIEWED IN STEVE STRAUS' PRESENTATION, IS FOR TWO TYPES OF CENTERS: A LARGER NUMBER, MAYBE 16-24 CENTERS, THAT WOULD PROVIDE A BROAD MENU OF CLINICAL RESEARCH SERVICES WITHIN A SPECIFIED REGION, AND A SMALLER NUMBER, MAYBE OPTIMALLY 4-8 CENTERS, THAT WOULD IN ADDITION TO PROVIDING THESE SAME SERVICES WOULD PROVIDE ROBUST CORE LABORATORY TECHNOLOGIES THAT ARE TOO EXPENSIVE TO PROVIDE AT EACH CENTER. ***NEXT SLIDE.***

THE NEXT TWO SLIDES ARE TENTATIVE LISTS OF THE SORT OF SERVICES THAT MIGHT BE PROVIDED. AS YOU LOOK AT THESE, I WOULD ENCOURAGE YOU TO NOTE IF THERE ARE ITEMS WHOSE VALUE YOU QUESTION OR, MORE LIKELY, IF THERE ARE OMISSIONS WE WERE NOT CLEVER ENOUGH TO INCLUDE. TWO OF THE BREAKOUT GROUPS THAT WILL CONVENE LATER THIS MORNING WILL BE DEVOTED TO SPECIFICALLY IMPROVING, EDITING, AND MAKING THESE SERVICES MORE IN LINE WITH YOUR ADVICE. OUR CURRENT VISION IS TO HAVE ALL THE CENTERS PROVIDE THINGS RANGING FROM PILOT PROJECTS TO RECRUITMENT CORES, WITH SPECIFIC EMPHASIS ON INCREASING MINORITY PATIENT PARTICIPATION IN CLINICAL RESEARCH, AND ASSISTANCE WITH THE VARIOUS REGULATORY DEMANDS, DATA,

STATISTICAL INFORMATICS SUPPORT, SUPPORT FOR SPECIALIZED STAFF OF THE SORT THAT DR. HAYWARD MENTIONED, ETC.

THE ***NEXT SLIDE*** SHOWS THE MORE EXTENSIVE NATIONAL-SCOPE CORE LABORATORY FACILITIES THAT WE IMAGINE BEING PROVIDED ON, IF NOT A NATIONAL LEVEL, AT LEAST ON A SUPER-REGIONAL LEVEL. THE GOAL WOULD BE TO ACHIEVE COST EFFICIENCIES, AS IT WOULD NOT BE PRACTICAL TO HAVE THESE AT EACH ONE OF THE CENTERS. ***NEXT SLIDE.***

ONE OF THE GOALS FOR ALL THE ROADMAP INITIATIVES IS TO TRY TO MAKE THEM MAXIMALLY INTERACTIVE—NOT ONLY WITH ONE ANOTHER, BUT WITH OTHER NIH ACTIVITIES. THIS IS A SELECT LIST OF ACTIVITIES WITHIN THE ROADMAP, INDICATED IN BRACKETS, AND OTHER NIH-SUPPORTED ACTIVITIES WE EASILY SEE THE RTRC INTERACTING WITH. DR. STRAUS MENTIONED BOTH IN THE NECTAR AND THE CORE RESOURCES PROGRAM, BUT THERE ARE OBVIOUS FORMS OF INTERACTIONS WITH THE CLINICAL RE-ENGINEERING TRAINING EFFORTS, OTHER EXISTING CENTERS OF THE SORT THAT ANTHONY HAS JUST HIGHLIGHTED, AND LASTLY THE NIH CLINICAL CENTER, WHICH IN MANY WAYS MIGHT BE THOUGHT OF AS THE ULTIMATE IN NATIONAL-SERVING RTRCs. IT IS OUR JUDGMENT THAT THE POTENTIAL INTERACTIONS ARE SO RICH THAT ONE OF THE BREAKOUT GROUPS WILL BE DEVOTED TO POSSIBLE INTRAMURAL-EXTRAMURAL INTERACTIONS. ***NEXT SLIDE.***

ON THE BASIS OF TODAY'S MEETING AND THE ADVICE WE GET FROM YOU, WE WILL REFINE THIS VISION AND USE IT TO HELP US IN PUTTING OUT IN EARLY 2005 A REQUEST FOR 1-2 YEAR PLANNING GRANTS, WITH THE INTENT TO FUND UP TO 30 OF THESE. THEN, BEGINNING IN 2006, SERIALLY ISSUE RFAs THAT WILL RESULT IN FUNDING OF BOTH REGIONAL AND NATIONAL-SCALE RTRCs. ***NEXT SLIDE.***

MOST OF TODAY IS DEVOTED TO OUR LISTENING TO YOU. THIS IS THE VISION AS IT CURRENTLY EXISTS. WHAT WE REALLY WANT TO HEAR IS YOUR VISION. HOW WE CAN REFINE THE CURRENT CONCEPT INTO SOMETHING BETTER? IN AN EFFORT TO HELP WITH THIS, WE HAVE A FEW QUESTIONS TO FRAME THE DISCUSSIONS. I'M SURE WE HAVE LEFT OUT SOME, BUT YOU WILL HELP PROVIDE THOSE.

ANTHONY NOTED THE RICH NATURE OF CURRENT RESOURCES AND TO WHAT EXTENT SOME OF THESE WORK TOGETHER TO SPEED TRANSLATIONAL RESEARCH. IF THAT IS THOUGHT TO BE A GOOD IDEA, HOW WOULD SUCH RESOURCES CHOOSE TO PARTNER? A FEW EXAMPLES AND SUGGESTIONS OF THOSE DECISION TREES ARE PROVIDED HERE. WHAT COMBINATIONS OF THESE WOULD MAKE MORE SENSE?

THE NEXT QUESTION FOCUSES ON THE TOPIC OF ONE OF THE BREAKOUT GROUPS—NAMELY, HOW THE RTRCs MIGHT INTERACT WITH THE EXTRAMURAL WORLD. THE ***NEXT SLIDE*** PLEASE.

WE ARE CALLING THESE 'REGIONAL CENTERS,' AND I'M SURE THERE WILL BE DISCUSSION ABOUT WHAT A REGION IS. OUR ANSWER TO YOU PROBABLY WILL BE IT IS WHATEVER YOU TELL US IT COULD AND SHOULD BE IN A PARTICULAR CASE. BUT IT SUGGESTS MULTIPLE INSTITUTIONS COMING TOGETHER TO CONSTITUTE SUCH A CENTER AND RAISES A QUESTION OF WHETHER THE GOVERNANCE SHOULD BE LOCATED AT ONE CENTER OR DISTRIBUTED ACROSS PARTICIPATING INSTITUTIONS? IN FACT, THE FOURTH BREAKOUT SESSION WILL FOCUS ON GOVERNANCE ISSUES. IF THERE ARE CENTERS, HOW DO YOU MAXIMALLY FOSTER INTERACTIONS AND PRODUCTIVITY?

THE NEXT QUESTION FOCUSES ON THE TOPIC FOR TWO OF THE BREAKOUT SESSIONS: WHAT IS THE OPTIMUM MENU OF SERVICES AND CORES TO BE PROVIDED? MOST OF THIS FOCUSES ON WHAT CAN NIH DO FOR THE RESEARCH COMMUNITY. THE NEXT QUESTION TURNS IT AROUND AND SAYS: WHAT LEVEL OF COMMITMENT IS REASONABLE TO EXPECT OF PARTICIPATING INSTITUTIONS AND REGIONS. ***NEXT SLIDE.***

BUT COMING BACK TO 'WE ARE THE GOVERNMENT AND WE ARE HERE TO HELP YOU,' WHAT ELSE MIGHT NIH DO TO HELP FURTHER ENCOURAGE AND FACILITATE THIS SORT OF MULTIDISCIPLINARY, MULTI-INSTITUTIONAL EFFORT TO FULLY LEVERAGE THE CENTERS?

LASTLY, WHAT WILL MAKE THIS INITIATIVE UNIQUE AND SET IT APART FROM ALL OF THE RESOURES THAT ANTHONY HAS JUST DESCRIBED AND JUSTIFY OUR GOING DOWN THIS NEW ROAD? THIS IS OUR VISION, BUT WE ARE PRIMARILY INTERESTED IN YOUR VISION, WHICH IS WHAT THE REST OF THE TODAY WILL BE ABOUT.

CHARGE TO ATTENDEES—STEVE STRAUS:

BEFORE WE GET ON TO THAT AND BEFORE YOU SEGREGATE YOURSELVES INTO THE WORKING GROUPS, WE HAVE ALLOWED SOME TIME FOR QUESTIONS ABOUT THIS GENERAL VISION. DUSHANKA, ANTHONY, AND STEVE ARE HERE WITH ME, AND WE HAVE INVITED DAN KASTER TO JOIN US. HE IS ONE OF THE EXCEPTIONAL TRANSLATIONAL INVESTIGATORS IN THE NIH CLINICAL CENTER WITHIN THE ARTHRITIS INSTITUTE WHO HAS TAKEN A LEADERSHIP ROLE IN THINKING ABOUT IMPROVING PROSPECTS FOR CLINICAL AND TRANSLATIONAL RESEARCH IN THE CLINICAL CENTER AND ITS INTERACTIONS EXTRAMURALLY. WE ARE HERE IF THERE ARE GENERAL QUESTIONS OR COMMENTS THAT YOU WOULD LIKE TO RAISE.

HARRY. WHY DON'T YOU STAND UP AND SAY WHO YOU ARE SO PEOPLE CAN SEE HERE WHO THEIR COMPANIONS ARE.

[LOW AUDIO] AUDIENCE MEMBER

STEVE STRAUS: DUSHANKA, DO YOU WANT TO COMMENT ON SOME OF THE PUBLIC/PRIVATE PARTNERSHIP ISSUES YOU RAISED? DO YOU WANT TO COME UP HERE? IN FACT, EVERYBODY COULD, AND WE CAN TAKE TURNS AT THE MICROPHONE. AS I SAID, THIS PART OF THE ROADMAP IS AT ITS INFANCY AND IS MORE FOCUSED INTERNALLY TO NIH AT THIS POINT. YOUR DISCUSSION ABOUT THE OPPORTUNITIES FOR OUR RELATIONSHIP IN THE BREADTH OF THE ROADMAP IS VERY WELCOME.

THE CONCEPT PUT FORWARD BY THE RTRC WORKING GROUP FOR PUBLIC/PRIVATE PARTNERSHIPS WAS TO HAVE A SERIES OF MEETINGS THAT WOULD BE WITH INDUSTRY AND NONPROFIT ORGANIZATIONS. WE NEED TO SEE WHAT IS NEEDED NOT ONLY IN CLINICAL AND TRANSLATIONAL RESEARCH, BUT ALSO IN AREAS OF TRAINING AND POLICY.

[LOW AUDIO] AUDIENCE MEMBER

STEVE STRAUS: WE HAVE HAD PRELIMINARY TALKS WITH PEOPLE FROM SEVERAL CONSORTIA, INDIVIDUALS, BIOTECH GROUPS, AND COMPANIES ABOUT POSSIBLE MODELS—SOME OF WHOM WERE INVITED HERE TODAY. THEY HAVE PRESENTED A VARIETY OF MODELS, AND WE WOULD LIKE YOUR HELP IN THINKING ABOUT HOW YOU WOULD STITCH THOSE TOGETHER TO BE SURE THERE IS A VEHICLE FOR SERVING THE NEEDS OF THE RESEARCH COMMUNITY AS OUR PRIMARY GOAL AND IF THERE ARE WAYS TO LEVERAGE OTHER RESOURCES IN THE PRIVATE SECTOR, CORPORATE OR OTHERWISE. OTHER COMMENTS OR QUESTIONS?

ANTHONY HAYWARD: I WOULD LIKE TO ADD A THOUGHT. WE AT NIH HAVE TO BEAR IN MIND THAT THE PATIENT WITH ASTHMA DOES NOT CARE IF THE THERAPEUTIC ADVANCE CAME FROM A UNIVERSITY LABORATORY OR FROM THE PHARMACEUTICAL COMPANY. THUS, GCRCs HAVE A MECHANISM, A SO-CALLED D-PROTOCOL MECHANISM, WHEREBY THE ACTUAL COST OF CONDUCTING THE RESEARCH—THE PHARMACEUTICAL COMPANY RESEARCH ON THE GCRC—IS SIMPLY REIMBURSED AT COST, BEING THAT IT WOULD BE A PARTNERSHIP. I THINK THE MOST SUCCESSFUL EXAMPLE OF THIS IS WITH THE CYSTIC FIBROSIS THERAPEUTIC NETWORK, WHERE THEY HAVE INTERACTIONS WITH A LARGE NUMBER OF BIOTECH PARTNERS.

STEVE STRAUS: THERE WAS A QUESTION OR COMMENT BACK HERE. YES? YOU ARE?

[LOW AUDIO] AUDIENCE MEMBER

STEVE STRAUS: I THINK WE SHOULD DISCUSS THIS IN THE BREAKOUT GROUPS FURTHER UNDER THE GOVERNANCE ISSUES AND THE CORE SERVICES. YES?

[LOW AUDIO] AUDIENCE MEMBER

STEVE STRAUS: THE QUESTION IS 'WHERE DO THE GCRCs FIT IN.' THEY FIT IN THE SAME WAY ALL THE OTHER INSTITUTE-FUNDED PROGRAMS DO. THIS IS NOT A MATTER OF BUILDING UP GCRCs. THEY DO HAVE RELATED GOALS—JUST AS THE GOALS OF GCRCs OVERLAP GREATLY WITH THE GOALS OF MANY OF THE OTHER INSTITUTE-FUNDED CENTERS. BUT I THINK WE SHOULD START WITH A CLEAN BLACKBOARD AND NOT FIGURE OUT HOW TO AUGMENT AN EXISTING PROGRAM BUT TO LEVERAGE THEM WHERE POSSIBLE. YES?

[LOW AUDIO] AUDIENCE MEMBER

ROCKEFELLER UNIVERSITY. HE SAID.

[LOW AUDIO] AUDIENCE MEMBER

STEVE STRAUS: NO, I THINK THE GCRCs CAN COMPETE TO BE PART OF THESE, BUT THERE ARE HUNDREDS OF CENTERS AROUND THE COUNTRY VERY INTERESTED IN RESEARCH. THE GCRC IS INVESTED IN ABOUT 80 OF THEM. I THINK WE HAVE THE OPPORTUNITY TO DISTRIBUTE THE IMPROVED ABILITY TO DO TRANSLATIONAL RESEARCH FAR MORE WIDELY, AND THE SERVICE TO BE PROVIDED OVERLAPS SOMEWHAT BUT THEY'RE NOT THE SAME. WE HAVE TO MOVE BEYOND THAT. YES, ON THE AISLE IN THE BACK?

[LOW AUDIO] AUDIENCE MEMBER

STEVE STRAUS: THAT IS A VERY GOOD QUESTION. I WOULD WELCOME ADDITIONAL THOUGHTS ABOUT THAT AND WE WILL TALK MORE ABOUT IT DURING THE DAY. WE VIEW IT NOT AS A PLACE NECESSARILY WHERE THE RESEARCH IS DONE. IT IS NOT A SITE FOR PATIENTS TO COME TO A CLINIC, BUT TO PROVIDE SERVICES AND RESOURCES TO INDIVIDUALS SO THAT THEY CAN BE MORE EFFECTIVE IN THEIR RESEARCH AND THE PATIENT INTERACTIONS THAT THEY HAVE. DOES THAT ANSWER YOUR QUESTION? IN PART?

[LOW AUDIO] AUDIENCE MEMBER
[LAUGHTER]

[LOW AUDIO] AUDIENCE MEMBER

YES.
[LOW AUDIO] AUDIENCE MEMBER

YES, CORRECT. YES. I'M SORRY. TED.

[LOW AUDIO] AUDIENCE MEMBER

STEVE STRAUS: WE ARE NOT TALKING ABOUT THE SECOND KIND OF TRANSLATION. THAT WILL BE ADDRESSED THROUGH OTHER ROADMAP INITIATIVES, PARTICULARLY THE NETWORKING ISSUES, THE TRAINING PRACTITIONERS IN THE COMMUNITY. WHEN WE CALLED FOR INDIVIDUALS WHO WOULD BE INTERESTED IN COMING TO THIS MEETING, AND WE HADA HUGE NUMBER OF PEOPLE APPLY, THERE WAS SOME CONFUSION ABOUT THAT. PERHAPS WE HAVE NOT MADE OURSELVES CLEAR ENOUGH, BECAUSE THE WORD TRANSLATION MEANS DIFFERENT THINGS TO DIFFERENT PEOPLE. WE ARE TALKING ABOUT THE FIRST TRANSLATIONAL BLOCK HERE. YES?

[LOW AUDIO] AUDIENCE MEMBER

STEVE STRAUS: AGAIN, THIS IS AN IMPORTANT ISSUE FOR DISCUSSION. I WOULD WELCOME MY COLLEAGUES' INPUT AS WELL. I THINK THERE ARE MANY INSTITUTIONS IN THE COUNTRY RICH IN RESOURCES THAT SERVE THEIR OWN COMMUNITIES, AND THERE IS SOME INSTITUTIONAL MONEY THAT PAYS TO CREATE THAT. BUT THE LIGHTS ARE KEPT ON AND THOSE MACHINES KEEP HUMMING AND THEIR OPERATORS ARE THERE BECAUSE THEY GET NIH OR OTHER PRIVATE SECTOR FUNDING FOR ALL OF THEIR DAILY WORK.

WE DO NOT BELIEVE THAT THE MONEY THAT CREATES THE RTRCs WILL COVER ALL THE OPERATIONAL COSTS. BUT IT WILL CREATE THE INFRASTRUCTURE SO THAT THEY ARE THERE, SO THAT THERE IS AN ENVIRONMEN IN WHICH WORK CAN BE DONE THAT WOULD HELP SECURE THE ADDITIONAL FUNDING FOR ALL OF THE EXPERIMENTS. IN THE SAME WAY, WE'RE NOT PAYING THE PATIENT COSTS IN THE RTRCs. THOSE OTHER RESEARCH COSTS HAVE TO BE BORN IN OTHER WAYS. WOULD YOU ADD TO THAT IN ANY WAY?

YES? PAUL.

[LOW AUDIO] AUDIENCE MEMBER

STEVE STRAUS: YES, THAT WOULD BE PART OF THIS.

[LOW AUDIO] AUDIENCE MEMBER
[LAUGHTER]
[LOW AUDIO] AUDIENCE MEMBER

STEVE STRAUS: LAWYERS WILL HAVE TO BE INVOLVED. SORRY GUYS.

[LAUGHTER]
[LOW AUDIO]

STEVE STRAUS: PAUL, YOU RAISED SOME VERY GOOD POINTS. THERE ARE ISSUES OF INTELLECTUAL PROPERTY. THE LAWYERS WILL BE MOST INTERESTED IN ONE OF THE ITEMS WE POSTED HERE ABOUT THE CONCEPT OF CENTRAL IRBs. THIS IS AN EXPERIMENT THAT IS GOING ON. THE NCI IS RUNNING SUCH EXPERIMENTS, AND THERE ARE OTHERS GOING ON. WE ALL REALIZE THAT IF WE ARE PARTICIPANTS—AS I HAVE BEEN IN MANY YEARS IN MULTICENTER STUDIES OF 60 SITES, 120 SITES—YOU NEED 120 DIFFERENT IRBs TO NAVIGATE THE CONSENT DOCUMENT.

IT IS AN EXPONENTIAL DILEMMA, AND WE THINK THAT IS ONE POSSIBILITY. WE WANT TO HEAR FROM YOU IF IT IS PRACTICAL. WE THINK THERE ARE TREMENDOUS EFFICIENCIES, BUT THERE ARE OBSTACLES TO MAKING THIS HAPPEN. WE WOULD LIKE YOUR ADVICE ON HOW TO GET BEYOND IT. SOME OTHER COMMENTS OR QUESTIONS? YES, ON THE AISLE.

[LOW AUDIO] AUDIENCE MEMBER

RTRC WG MEMBER: AS DUSHANKA'S SLIDE SHOWS, THE ENTIRE ROADMAP, OF WHICH THIS IS A SMALL PART, IS LESS THAN 1 PERCENT OF THE NIH BUDGET. THE OTHER 99+ PERCENT IS LARGELY DEVOTED TO THE SUPPORT OF THAT HYPOTHESIS-DRIVEN RESEARCH. PRESUMABLY IN THE EVALUATION OF APPLICATIONS FOR THESE INFRASTRUCTURE CENTERS, HOW INDIVIDUAL APPLICANTS MAKE THE CASE FOR THE BENEFIT AND NECESSITY FOR THIS SET OF INFRASTRUCTURES TO SERVE THEIR REGION, AND SPECIFIED INVESTIGATORS IN THE REGION, WILL FOLD INTO THAT VERY IMPORTANT ISSUE.

STEVE STRAUS: THERE IS A MERIT-BASED PROCESS HERE. THE FACT IS, MOST OF THE MONIES TO SUPPORT THE RESEARCH DONE IN SOME OF THESE CORES WILL BE THROUGH OTHER NIH FUNDING. THEY WILL HAVE TO APPLY, TO HAVE HYPOTHESES. THIS IS PART OF THE GOVERNANCE DISCUSSIONS. YOU WILL TALK ABOUT HOW TO PRIORITIZE WITHIN YOUR REGION AMONG POTENTIAL PROJECTS AND APPLICANTS FOR PRIORITIES TO USE THE RESOURCES AND TO HELP BUILD THEM, AND THIS IS NOT ABOUT KEEPING MACHINES RUNNING. THIS IS ABOUT DOING THE BEST SCIENCE. WE ARE ACTUALLY TRYING AT NIH, RATHER THAN MAKING

EVERY MINUTE DECISION FOR YOU ABOUT WHAT YOUR PRIORITIES SHOULD BE, TO PUT MORE RESOURCES IN YOUR OWN HANDS TO LET YOU GOVERN THE USE AND DISTRIBUTION OF THESE EQUITABLY AND IN THE PURSUIT OF BEST SCIENCE. YES? DAN?

DAN KASTNER: THERE IS ONE OTHER POINT WE HAVE TALKED ABOUT AND THAT IS AT LEAST SOME OF THE MONIES COULD BE EARMARKED FOR SMALL PILOT KINDS OF STUDIES, BENCH-TO-BEDSIDE KINDS OF GRANT APPLICATIONS, SO THAT PEOPLE WITHIN THE GEOGRAPHIC OR CONCEPTUAL REGION OF THE RTRC COULD APPLY FOR IT. OBVIOUSLY, THAT IS SOMETHING THAT YOU GUYS NEED TO DECIDE IN TERMS OF HOW LARGE A COMPONENT OF THE OVERALL PIE THAT MIGHT BE.

ANTHONY HAYWARD: WE HAVE PILOTED THAT ALREADY FOR THE LAST 6 YEARS AT THE NIH CLINICAL CENTER. IT HAS BEEN VERY SUCCESSFUL.

[LOW AUDIO] AUDIENCE MEMBER

RTRC WG MEMBER: CLINICAL INVESTIGATORS THAT DO TRANSLATIONAL RESEARCH NEED LABORATORY SUPPORT TO MAKE THEIR CLINICAL OBSERVATIONS. THIS IS NOT ABOUT SUPPORTING BENCH SCIENTISTS PER SE, TO DO THEIR CLASSICAL BENCH WORK. THIS IS ABOUT SUPPORTING INTERACTIONS BETWEEN THE CLINICAL RESEARCHERS AND THE BENCH RESEARCHERS AS PART OF A COLLABORATION. THIS IS NOT TO CREATE NEW MOUSE MODELS TO EXPLORE BASIC THINGS THAT ARE NOT CLOSELY TIED TO A CLINICAL QUESTION.

RTRC WG MEMBER: I WAS GOING TO ADD A RESPONSE TO TED'S QUESTION. IT IS NOT THAT WE DON'T FORESEE EXTENSIVE CLINICAL AND HUMAN ACTIVITY AT RTRCs. THE POINT WAS THAT WE DON'T SEE PROOF HAS BEEN MADE IN MANY OF THE CENTERS WHO WILL BE RESPONSIBLE FOR THE EXTRAPOLATION OF__ . IN ROUTINE CLINICAL PRACTICE, IT IS NOT THEIR RESPONSIBILITY TO MAKE SURE THAT EVERY PRIMARY CARE PHYSICIAN HAS __. THAT IS PART OF THE TRANSLATIONAL BLOCK. WHAT WE WANT TO FOCUS ON IS GETTING IDEAS, CONCEPTS, NOT ONLY FOR TREATMENTS, BUT ALSO FOR DIAGNOSES OFF OF THE LAB BENCH AND INTO PROOF OF CONCEPT IN A CLINICAL ENVIRONMENT.

RTRC WG MEMBER: ONE OTHER POINT I THINK NEEDS EMPHASIS IS THAT THE BENCH AND BEDSIDE DIALECTIC IS A TWO-WAY STREET AND THAT WE ARE REALLY THINKING ABOUT NOT JUST BENCH-TO- BEDSIDE BUT ALSO BEDSIDE-TO-BENCH. CERTAINLY THE KIND OF INFRASTRUCTURE WE'RE INTERESTED IN CREATING IS ONE IN WHICH THERE CAN BE A TWO-WAY STREET, A COMMUNICATION BETWEEN BENCH SCIENTISTS AND CLINICIANS. THE INTRAMURAL PROGRAM OF THE NIH HAS A LOT OF INFRASTRUCTURE IN PLACE FOR DOING THAT KIND OF THING. IT MIGHT

BE THAT CERTAIN COLLABORATIONS INVOLVING THE INTRAMURAL PROGRAM COULD HELP FACILITATE THAT, BUT CERTAINLY THERE WOULD BE THE THOUGHT THAT THESE KINDS OF THINGS COULD BE DONE AT THE RTRCs.

STEVEN STRAUS: NEW HANDS, YES.

[LOW AUDIO] AUDIENCE MEMBER

STEVE STRAUS: THE ISSUE HAS TO DO WITH THE PLANNING GRANT PROCESS. WE VIEWED THE $100,000 AS A VEHICLE TO BRING TOGETHER THE RELEVANT PEOPLE AND EXPERTISE WITHIN A REGION, A GEOGRAPHIC OR THEMATIC REGION, WHO COULD COME TOGETHER TO DESIGN A COMPETITIVE RTRC. IT IS GOING TO INVOLVE SOME STAFFING, MEETINGS, TRAVEL, PHONE CALLS, TELECONFERENCES, OR HOWEVER YOU NEED TO SPEND IT. WE WILL ARTICULATE WHAT WILL BE COVERED BY THAT IN THE RFA.

THE SECOND PART HAD TO DO WITH HOW THEY WOULD BE EVALUATED. WE INTEND TO PUT TOGETHER A SPECIAL STUDY SECTION AND THIS IS CHALLENGING BECAUSE, AS IN OTHER LARGE AREAS, JUST ABOUT EVERYBODY WHO WOULD BE REALLY GOOD AT THIS IN THE COUNTRY IS PROBABLY A PARTY TO AN APPLICATION. SO WE ARE GOING TO HAVE TO FIGURE THAT OUT, WHICHH WE ARE ACTIVELY ATTEMPTING TO DO.

WOULD ANY OF YOU ADD TO THIS? HOW DO YOU COMPETE YOUR GCRCs? WE DO IT AS A TWO-LEVEL PROCESS ACTUALLY WITH BOTH A SITE VISIT AND A PARENT COMMITTEE BUT IT IS DONE BY A PROCESS OF PEER REVIEW.

NEW HANDS, YES IN THE BACK. YES, JERRY?

[LOW AUDIO] AUDIENCE MEMBER

STEVE STRAUS: IT IS MORE THE LATTER JERRY. THIS IS NOT A SITE WHERE PATIENTS CAN COME. IT IS A COORDINATING, GOVERNING, TRAINING, EXPERT DATA MANAGEMENT CORE, LABORATORY CORE, AND THE LIKE. NEW HANDS. YES?

AUDIENCE MEMBER: WE HAVE A STANDING BASE OF RESEARCHERS AND CLINICAL TRIALIST ALL OF THEM ARE FUNCTIONING AT SOME LEVEL WITHIN THEIR OWN DISCIPLINES. MUCH OF WHAT WE NEED TO DO IS OVERCOME THE BARRIERS LOCALLY AT OUR INSTITUTIONS, REGIONALLY WITHIN OUR COUNTIES, IN A STATE—FOR SOME STATE UNIVERSITIES SUCH AS WE ARE. TO DO THAT, WE ALSO NEED FROM YOU GOALS, BECAUSE ALL OF THE PEOPLE WHO WILL BE INVOLVED ARE GAINFULLY

EMPLOYED NOW AND DOING THINGS SUCCESSFULLY. SO YOU CAN SAY, WHAT IS IT YOU WOULD WANT FROM US AS GOALS TO SAY IN 2006, 2007 WE WILL HAVE ACCOMPLISHED THAT IS DIFFERENT FROM THE THINGS WE'RE DOING NOW.

STEVE STRAUS: I THINK YOU HAVE PUT YOUR FINGER ON ONE OF THE IMPORTANT ISSUES DRIVING THE ROADMAP. WE ALL WORK IN SILOS AND WE REALIZE THAT RESEARCH HAS TO ADVANCE THROUGH THE CREATION AND THE STIMULATION OF MULTIDISCIPLINARY TEAMS—INTER-DISCIPLINARY TEAMS—AND IT INVOLVES BREAKING DOWN PAROCHIAL BARRIERS NOT JUST BETWEEN DISCIPLINES AND DEPARTMENTS BUT BETWEEN INSTITUTIONS.

WE TALKED ABOUT HOW THE LAWYERS HELP SUSTAIN SOME OF THOSE BARRIERS. THE GOAL FOR THIS IS TO HAVE AN INFRASTRUCTURE THAT WILL ALLOW PEOPLE TO DO MORE INNOVATIVE WORK SOONER AND MORE EFFICIENTLY. IF YOU ASK IN 2009, HOW WILL WE KNOW IF THIS PROGRAM HAS BEEN SUCCESSFUL, WE WILL KNOW IF IT HAS BEEN SUCCESSFUL BECAUSE PEOPLE LIKE YOURSELVES WILL SAY: WE CAN NOW DO THINGS WE COULD NOT TO DO BEFORE; IT IS FASTER AND EASIER; OUR YOUNG INVESTIGATORS HAVE ACCESS TO MORE FACILITIES; WE HAVE MORE PROJECTS, MORE PIPELINES, MORE INDS, AND MORE PATENTS; WE HAVE A LARGER FLOW-THROUGH OF PATIENTS IN CERTAIN PROJECTS; BETTER ACCESS TO MINORITY COMMUNITIES; WE HAVE SIMPLIFIED AND HARMONIZED SOME OF THE REGULATORY MORASS THAT TORTURED US IN THE LATE '90S AND EARLY 2000s.

WHAT WOULD YOU ADD? WE ARE GOING TO TAKE TWO MORE QUESTIONS AND THEN THERE IS A WHOLE DAY OF DISCUSSION. I WANT SOME NEW HANDS. BY THE WALL.

[LOW AUDIO] AUDIENCE MEMBER

STEVE STRAUS: IT IS FOR ALL CLINICAL RESEARCH PRIORITIES, BUT WE REALIZE THERE ARE MANY HEALTH PRIORITIES AND ALSO MANY SCIENTIFIC OPPORTUNITIES. WE WANT TO PUT IN PLACE BETTER, MORE EFFICIENT INFRASTRUCTURES, SO THAT WE CAN MEET THE RANGE OF HEALTH PRIORITIES. THIS IS NOT JUST FOR EMERGING INFECTIONS. THIS IS NOT JUST FOR OBESITY. YOU KNOW THOSE PRIORITIES BUT THOSE ARE REALITIES AND WE BELIEVE SCIENCE CAN SERVE THEM WHILE IT IS TRYING TO CURE CANCER AND ARTHRITIS AND THE LIKE. ONE MORE QUESTION FOR NOW, YES IN THE BACK.

[LOW AUDIO] AUDIENCE MEMBER

STEVE ZALCMAN: THIS IS AN IMPORTANT QUESTION. YOU HEARD FROM STEVE WHEN HE WAS SAYING THAT THERE WILL BE DISCUSSIONS ABOUT WHAT WE MEAN BY REGION. BEING QUITE FRANK, WE HAVE A LOT OF DISCUSSIONS AND THERE ARE UNDERSTANDABLE CONCERNS THAT IN SOME CASES THE REGION GOES FROM IDAHO TO INDIANA AND IN SOME CASES GOES FROM ONE END OF LONGWOOD AVENUE TO THE OTHER. WHAT WE WANT TO TRY TO DO IS TO CREATE AN ENVIRONMENT WHERE MANY INSTITUTIONS COULD BE SERVED AND THAT IT WOULD BE A GEOGRAPHICAL REGION.

THERE MAY ALSO BE GROUPS THAT WANT TO COME TOGETHER TO FOCUS ON CERTAIN KINDS OF RESEARCH SO THAT THE GEOGRAPHIES OVERLAP WITH OTHER REGIONAL CENTERS. THEN IT IS ON A THEMATIC BASIS. OF COURSE, THE ENHANCED CENTERS ARE THEMSELVES FAR LARGER GEOGRAPHIES AND THEMATICALLY DEFINED. WE NEED TO HEAR FROM YOU HOW TO SET THIS UP. THIS IS ABOUT TRYING TO DISTRIBUTE ACCESS TO TRANSLATIONAL RESEARCH AND OPPORTUNITIES MORE BROADLY WITHOUT NIH HAVING TO CREATE ANOTHER 1,200 RESEARCH CENTERS.

STEVE STRAUS: I WOULD ONLY ADD TO THAT THAT THERE IS NOT GOING TO BE, LIKE THE COLLEGE BOARD EXAMS, ONE BEST ANSWER. THERE WILL PROBABLY BE MULTIPLE CORRECT ANSWERS AND IN THE PLANNING GRANT APPLICATION AND REVIEW PROCESS PRESUMABLY SEVERAL DIFFERENT SUCCESSFUL MODELS WILL EMERGE. BECAUSE IN FACT WE DON'T KNOW THE CORRECT WAY TO DO THIS AND WE'RE NOT WEDDED TO A SINGLE MODEL AND WE ARE WILLING TO EXPLORE DIFFERENT MODELS.

WHAT WE HAVE TRIED TO DO IN THE FIRST HOUR-AND-A-HALF IS TELL YOU ABOUT THE ROADMAP AND ITS GENESIS AND WHAT WE HAVE TRIED TO ACCOMPLISH. WE HAVE TALKED ABOUT THE CHALLENGES AND OPPORTUNITIES FOR RE-ENGINEERING CLINICAL RESEARCH, WE HAVE TALKED ABOUT THE CURRENT CLINICAL RESEARCH MILIEU AND THE RANGE OF RESOURCES THE NIH HAS ALREADY PUT ON THE TABLE IN TERMS OF SUPPORTING TRANSLATIONAL RESEARCH, AND WE HAVE GIVEN YOU A VERY ROUGH FIRST DRAFT OF WHERE YOU THINK WE COULD BE. WHAT WE HAVE DECIDED TO DO, AND THERE ARE A LOT OF DIFFERENT WAYS WE COULD HAVE DONE THIS, IS TO FORM FOUR BREAKOUT SESSIONS. EACH IS DESIGNED TO A ELICIT YOUR FEEDBACK TO HELP DESIGN THE CENTERS.

ONE WILL BE ON INTERACTIONS BETWEEN INTRAMURAL AND EXTRAMURAL TRANSLATIONAL RESEARCH. THIS BREAKOUT GROUP, LIKE ALL THE OTHERS WILL BE CO-CHAIRED, BY AN NIH LEADER AND AN EXTRAMURAL LEADER IN THE RELEVANT AREAS; WE ALSO HAVE AN NIH COLLEAGUE WHO IS A REPORTER FOR THE GROUP. THE SECOND GROUP HAS TO DO WITH THE SERVICES PROVIDED AND HUMAN SUBJECTS, DATA

MANAGEMENT; YOU WILL TALK MORE ABOUT THAT IN THE GROUPS. THE THIRD IS A GROUP BY ITSELF BECAUSE IT IS A VERY THORNY ONE AND HAS TO DO WITH THE ISSUE OF GOVERNANCE. ONE IS ALWAYS NATURALLY CONCERNED THAT IF YOU HAVE A RESOURCE IT BECOMES THE DOMINION OF THE PERSON WHO RUNS IT. THE ONLY WAY FOR THIS TO BE SUCCESSFUL IS TO BE SURE THAT THE GOVERNANCE IS A MORE DEMOCRATIC PROCESS AND A WHOLE GROUP FOR THE CORE SERVICES.

WE WILL BREAK FOR ABOUT 15 MINUTES AND COLLEAGUES WILL DIRECT YOU TO THE FOUR BREAKOUT ROOMS. THERE ARE COMPUTERS THERE. THE GOAL FOR THE FIRST COUPLE OF HOURS IS TO DISCUSS THE ISSUES AND COME UP WITH SOME FIRST DRAFT IDEAS FOR US. THEN THERE IS AN EXTENDED LUNCH, DURING WHICH TIME THE LEADERS OF THE BREAKOUT GROUPS AND PERHAPS A COUPLE OF OTHER SELF-IDENTIFIED INDIVIDUALS WILL DRAFT A SET OF RECOMMENDATIONS TO US.

AFTER LUNCH, THOSE DRAFT RECOMMENDATIONS WILL GO BACK TO THAT GROUP. THE GROUPS WILL DISCUSS AND REFINE THEM. FOR THE LAST 1-1/2 TO 2 HOURS OF THE DAY, WE WANT THE GROUPS TO GO THROUGH YOUR PRESENTATIONS AND ALLOW FOR DISCUSSION.

THERE ARE A LOT OF US AND WE HAVE OUR OWN INTERESTS AND WE HAVE GONE TO GREAT PAINS TO INVITE PEOPLE FROM DIFFERENT DISCIPLINES AND REGIONS OF THE COUNTRY, DIFFERENT LEVELS OF INTEREST AND EXPERTISE. WE DON'T WANT ALL 87 OF YOU TO GO TO THE SAME BREAKOUT GROUP AND HAVE NO ONE LEFT IN THE OTHERS, SO WE HAVE ASKED YOU TO SIGN UP AT THE TABLE OUTSIDE WHERE YOU CHECKED IN. THE FIRST 20-SOME-ODD PEOPLE WHO SIGNED UP ARE IN THE BREAKOUT GROUP. AFTER LUNCH, THOSE OF YOU WHO WISH COULD SEE IF THERE'S ROOM TO CIRCULATE INTO SOME OF THE OTHER BREAKOUT GROUPS, BUT YOU WILL ALL HAVE THE OPPORTUNITY TO PARTICIPATE IN THE DISCUSSION OF THE RECOMMENDATIONS FROM EVERY BREAKOUT GROUP WHEN WE COME BACK TOGETHER LATER.

[LOW AUDIO] AUDIENCE MEMBER

STEVE STRAUS: THE SECOND GROUP, SERVICES PROVIDED AND HUMAN SUBJECTS. CORE SERVICES HAS TO DO WITH WHAT YOU WOULD DO IN THESE EXPANDED CENTERS. DO YOU NEED SNP FACILITIES, DO YOU NEED PET SCANNING? THIS DEALS WITH IS EQUIPMENT AND INSTRUMENTATION. THE SECOND ONE—SERVICES PROVIDED—INVOLVES PATIENT RECRUITMENT, REGULATORY TRAINING, IND, DATA MANAGEMENT, STATISTICAL SUPPORT, ETC.

WE WILL BREAK FOR ABOUT 12 MINUTES AND THEN YOU WILL GO TO YOUR GROUPS. BE SURE TO SIGN UP, AND OUR COLLEAGUES WILL DIRECT YOU TO YOUR ROOMS. THANK YOU.

AFTERNOON SESSION: REPORT OF BREAKOUT SESSIONS AND GENERAL DISCUSSION

INTRODUCTION—STEVE STRAUS

THANK YOU. I APPRECIATE OUR ALL GETTING BACK. I HAVE CIRCULATED AT LEAST TWO OR THREE TIMES TO EVERY GROUP AND I WAS VERY IMPRESSED WITH THE HARD WORK AND THE SERIOUSNESS.

SEVERAL OF US HAVE BEEN WORKING ON THE ISSUE FOR ABOUT 15 MONTHS NOW. WE KNOW IT IS NOT EASY AND WE HAVE ALSO HEARD FROM MANY OF THE GROUPS THAT THIS IS NOT ENOUGH MONEY.

TO PUT IT INTO CONTEXT, A COMMITMENT THROUGH THE NIH ROADMAP OF $90 MILLION A YEAR OF NEW MONEY IS MORE THAN 10 PERCENT PER YEAR OF THE NEW ROADMAP MONEY. THERE ARE PRACTICAL BUDGETARY CONSTRAINTS AND THEY ARE NOT INSIGNIFICANT. THE ECONOMIC ENVIRONMENT HAS FORCED US AND IS FORCING YOU TO HELP US MAKE HARD DECISIONS. WE SIMPLY HAVE TO DO THE BEST WE CAN, UNDERSTANDING THAT WE CANNOT SOLVE ALL OF GOD'S PROBLEMS.

WHAT WE WILL DO NOW IS GO THROUGH THE FOUR GROUP REPORTS. WE WILL HAVE QUESTIONS AND ANSWERS AND DISCUSSION OF EACH OF THE REPORTS AND THEN TRY TO SAVE A LITTLE TIME AT THE END.

WE'RE GOING TO GO IN THE FOLLOWING ORDER: WE WILL HEAR FIRST FROM THE INTRAMURAL/EXTRAMURAL TRANSLATIONAL RESEARCH RESOURCES INTERFACE. WE HAD A VERY GOOD PRESENTATION FROM THAT GROUP FROM THE DIRECTOR OF THE CLINICAL CENTER TO TALK ABOUT THE RESOURCES THAT EXIST THAT CREATE A VERY ROBUST MODEL FOR TRANSLATIONAL RESEARCH.

NEXT, WE WILL TALK ABOUT THE SERVICES PROVIDED AND THE HUMAN SUBJECT ISSUES. THIRD, WE WILL TALK ABOUT THE CORE SERVICES FOR THE EXPANDED RTRCs. FOURTH IS WHEN YOU DECIDE WHAT YOU HAVE AND WHAT YOU WANT IT TO BE; THEN YOU HAVE TO FIGURE OUT HOW TO GOVERN IT. SO WE WILL DO GOVERNANCE LAST. DAN, YOU ARE PRESENTING FOR THE FIRST GROUP.

INTRAMURAL/EXTRAMURAL INTERFACE—DAN KASTNER:

THANK YOU VERY MUCH STEVE. THANK YOU ALL FOR HANGING AROUND LONG ENOUGH TO LISTEN TO THIS. ANTHONY HAYWARD AND DENNIS CHARNEY WERE MY PARTNERS IN CRIME, AS WELL AS A NUMBER OF OTHER INDIVIDUALS. IT WAS A STANDING-ROOM-ONLY GROUP. WE TALKED ABOUT THE INTRAMURAL/EXTRAMURAL TRANSLATIONAL RESOURCES INTERFACE. IF WE COULD HAVE THE ***NEXT SLIDE***.

JOHN GALLIN WAS PRESENT FOR PART OF OUR SESSION TO TALK ABOUT SOME OF THE RESOURCES AVAILABLE WITH THE NEW CLINICAL RESEARCH CENTER THAT WILL OPEN THIS FALL. I THOUGHT WE WOULD AT LEAST HIGHLIGHT A FEW OF THESE THINGS, BECAUSE IT REALLY DOES SERVE AS PERHAPS A MODEL, AT LEAST AS SOMETHING THAT IS AN ENTITY THAT COULD BE A PART OF THE RTRC NETWORK AND THE GCRC NETWORK.

THE NEW CLINICAL RESEARCH CENTER WILL HAVE 242 BEDS AND 80 DAY HOSPITAL STATIONS. IT IS CONFIGURED SO THAT IT IS EXPANDABLE; IF DEMAND INCREASES OVER TIME, THERE WILL BE EXCESS CAPACITY UP TO ABOUT 35 BEDS. THE BUDGET FOR THE CLINICAL RESEARCH CENTER IS, AT LEAST FOR THE FIRST YEAR, GOING TO BE $348 MILLION PERYEAR, WITH A TOTAL IN THE INTRAMURAL PROGRAM OF ABOUT $950 MILLION PER YEAR BEING SPENT ON CLINICAL RESEARCH. THIS INCLUDES A VERY SUBSTANTIAL CONTRIBUTION FROM THE INSTITUTE IN THE WAY OF FUNDING FOR PEOPLE'S SALARIES TO DO CLINICAL RESEARCH AND FOR THE LABORATORY PROGRAMS THAT ARE CONNECTED IN THE TRANSLATIONAL WAY WITH THE CLINICAL PROGRAM.

ALREADY ONSITE IS THE CHILDREN'S INN. THERE ALSO WILL BE A ‘GROWN-UP INN’ I CALL IT, WHICH WILL BE A FAMILY LODGE FOR FAMILIES COMING FOR OUTPATIENT STUDIES AND SO FORTH AT THE CLINICAL CENTER. IT IS GOING TO BE AN AMAZING FACILITY IN TERMS OF ITS IMAGING CAPABILITIES. THERE ARE THREE—AN NMR FACILITY WITH 25 MRI MACHINES, SOME OF WHICH ARE FOR ANIMAL SUBJECTS. THERE ARE A TOTAL OF ABOUT 1,100 PROTOCOLS ACTIVE AT THE CLINICAL CENTER AND 425 ACTIVE CLINICAL INVESTIGATORS AND PRINCIPAL INVESTIGATORS.

SOME OF THE OTHER FEATURES ALREADY INCLUDED ARE CELL LINE AND GMP FACILITIES. THERE IS A NEW COMPUTER SYSTEM FOR MANAGING CLINICAL RESEARCH DATA, THE ACRONYM IS CRIS FOR CLINICAL RESEARCH INFORMATION SYSTEM. THERE IS A NEW PROTOTYPE BUREAUCRACY BUSTER, WHICH IS A BIOINFORMATICS TOOL FOR BASICALLY PUTTING TOGETHER RESEARCH PROTOCOLS. THAT MAKES IT A LOT EASIER FOR THE INVESTIGATORS TO PUT THEIR IDEAS INTO

PROTOCOLS SUBMITABLE TO THE IRB. THERE IS THE IND WIZARD, WHICH HAS BEEN DEVELOPED TO FACILITATE INTERACTIONS WITH FDA.

THEN THERE ARE SEVERAL TRAINING PROGRAMS. THERE IS A CLINICAL RESEARCH TRAINING PROGRAM FOR MEDICAL STUDENTS, A MASTER'S DEGREE PROGRAM FOR POSTDOCTORAL FELLOWS, CLINICAL POSTDOCTORAL FELLOWS, AND THEN A VERY INNOVATIVE PROGRAM—THE BENCH-TO-BEDSIDE PROGRAM. THIS IS A PROGRAM TO ENCOURAGE INTERACTION BETWEEN BENCH RESEARCHERS AND CLINICIANS. THE IDEA IS THAT PEOPLE WOULD SUBMIT APPLICATIONS FOR STUDIES THAT BRING TOGETHER A CLINICAL RESEARCHER AND A BASIC RESEARCHER. THIS HAS BECOME AN EXTREMELY POPULAR PROGRAM IN THE LAST SEVERAL YEARS.

WHAT QUESTIONS WERE WE CHARGED TO ANSWER? THE FIRST WAS HOW WOULD PARTNERSHIPS WITH THE NIH CLINICAL CENTER SERVE EXTRAMURAL AND INTRAMURAL INVESTIGATORS NEEDS? THE FIRST POINT WE FELT WAS VERY IMPORTANT WAS THAT THE NEW CLINICAL CENTER WOULD BE A PART OF THE RTRC NETWORK. ONE OF THE THINGS THAT I FEEL IS THE GENIUS OF THE CLINICAL CENTER IS THE FACT THAT ONE CAN ADMIT PATIENTS, SEE THEM, AND ORDER STUDIES ON THEM ACCORDING TO ONE'S CURIOSITY, AS LONG AS THESE ARE THINGS AT LEAST RELATED TO THE CONDITION FOR WHICH THE PATIENT WAS ADMITTED. THIS ALLOWS ONE TO PURSUE THINGS IN A WAY THAT OFTEN IS CONSTRAINED IN THE EXTRAMURAL WORLD BECAUSE OF THIRD-PARTY PAYER ISSUES.

THE CLINICAL CENTER WOULD ALSO BE A PART OF THE GCRC NETWORK. I HEARD THAT OTHERS HAD TROUBLE DISTINGUISHING BETWEEN THE ROLE OF THE RTRC AND THE GCRC. WHAT WE FELT WAS THAT THE RTRC WOULD BE STRUCTURED TO FACILITATE THE INTERACTIONS OF GCRCs AND WOULD BE SUPRA-GCRCs. THE CLINICAL CENTER, HOWEVER, WOULD BE A PART OF THE GCRC NETWORK AS WELL.

IN TERMS OF ACCESS TO BEDS, WE FELT THERE SHOULD BE A TWO-WAY STREET WITH THE INTERACTION BETWEEN THE CLINICAL CENTER AND EITHER THE RTRC OR THE GCRCs. WE FELT THAT HIGHLY INNOVATIVE EXTRAMURAL PROTOCOLS COULD POTENTIALLY BE RUN AT THE CLINICAL RESEARCH CENTER. INTRAMURAL PROTOCOLS, INTRAMURAL INVESTIGATORS, WOULD PROBABLY LIKE TO HAVE ACCESS TO EXTRAMURAL RESOURCES AS WELL.

OUR SUGGESTION WAS THERE WOULD BE A TWO-WAY STREET WITH THIS KIND OF INTERACTION. WE ALSO THOUGHT THAT THE BENCH-TO-BEDSIDE PROGRAM IS REALLY A MODEL THAT SHOULD BE EMULATED IN OTHER VENUES. THEREFORE, WE SHOULD THINK ABOUT SOME SORT OF

INTRAMURAL/EXTRAMURAL BENCH-TO-BEDSIDE PROGRAM IN WHICH BENCH RESEARCHERS IN THE EXTRAMURAL COMMUNITY COULD PROPOSE COLLABORATING WITH CLINICIANS IN THE INTRAMURAL PROGRAM OR VICE VERSA. HOWEVER, THERE WOULD BE A COLLABORATIVE COMPONENT TO THIS BENCH-TO-BEDSIDE PROGRAM. FINALLY, WE FELT THERE SHOULD BE COMBINED ACCESS TO UNIQUE COHORTS OF PATIENTS THAT MIGHT BE ACCESSIBLE EITHER AT THE CLINICAL RESEARCH CENTER THROUGH THE INTRAMURAL PROGRAM OR THAT DERIVE FROM THE RTRC.

WE ALSO HAVE SEVERAL SUGGESTIONS IN ANSWERING THE FIRST QUESTION ABOUT PARTNERSHIPS ADVANCING BOTH INTRAMURAL AND EXTRAMURAL NEEDS. WE FELT THERE SHOULD BE SHARING OF TECHNOLOGICAL ADVANCEMENTS IN PERSONALIZED MEDICINE IN GENE THERAPY. IF THERE ARE, FOR EXAMPLE, ASSAYS FOR PARTICULAR SINGLE NUCLEOTIDE POLYMORPHISMS THAT MIGHT DETERMINE THE SUITABILITY OF A PARTICULAR PATIENT THROUGH A TREATMENT PROTOCOL, THIS WOULD BE SOMETHING THAT WOULD BE IN A GLOBAL NETWORK THAT WOULD INVOLVE BOTH THE CLINICAL RESEARCH CENTER AND THE NETWORK OF RTRC. GENE THERAPY WAS ANOTHER EXAMPLE THAT THE GROUP THOUGHT COULD BE AN AREA FOR POTENTIAL COLLABORATION.

WE ALSO THOUGHT THAT TISSUE BANKS AND GENOMIC AND PROTEOMIC SAMPLES COULD BE SHARED BETWEEN THE INTRAMURAL CLINICAL RESEARCH CENTER AND THE RTRC AND THAT THERE SHOULD OR COULD BE SHARING OF MOLECULAR LIBRARIES AND NOVEL THERAPEUTICS IN A TIMELY FASHION. WITH BIOINFORMATICS AND PARTICULARLY TOOLS SUCH AS THE IND WIZARD AND THE BUREAUCRACY-BUSTING PROTOTYPER, WE FELT THAT THESE WERE MODELS THAT COULD BE EMULATED IN THE EXTRAMURAL COMMUNITY AND THERE SHOULD BE SHARING OF BIOINFORMATICS AND CREATION OF A COMMON LANGUAGE FOR SHARING OF DATA BETWEEN CENTERS.

WE ALSO TALKED ABOUT THE IDEA OF SABBATICALS, WHEREBY EXTRAMURAL INVESTIGATORS COULD SPEND TIME AT THE CLINICAL RESEARCH CENTER FOR UP TO 1 YEAR, AS WELL AS VARIOUS ARRANGEMENTS THAT COULD BE SHORTER OR PART TIME.

ALTHOUGH TRAINING IS AN AREA THAT WILL PROBABLY BE COVERED IN OTHER COMPONENTS OF THE ROADMAP, THE GROUP THOUGHT IT IMPORTANT TO PUT OUT THE IDEA THAT THE NETWORK OF RTRCs THAT WOULD INCLUDE THE CLINICAL RESEARCH CENTER WOULD BE AN EXCELLENT WAY OF COORDINATING NEW MECHANISMS FOR TRAINING IN CLINICAL RESEARCH, INCLUDING MEDICAL STUDENTS, FELLOWS AND OTHER HEALTH PROFESSIONALS.

THE NEXT QUESTION WE ADDRESSED WERE GOVERNANCE ISSUES, FOCUSING ON THE INTERACTION OF THE INTRAMURAL AND EXTRAMURAL COMMUNITIES. WE RECOGNIZED THERE ARE PROBLEMS WITH FUNDING MECHANISMS FOR INTRAMURAL/EXTRAMURAL COLLABORATIONS. BECAUSE INTRAMURAL INVESTIGATORS CANNOT RECEIVE FUNDING FROM EXTRAMURAL INVESTIGATORS FOR PARTICULAR PROJECTS, THERE MAY NEED TO BE NEW MECHANISMS TO FACILITATE SUCH COLLABORATIONS. SECONDLY, IF NUMEROUS INDIVIDUALS IN THE INTRAMURAL AND EXTRAMURAL COMMUNITIES WANT TO INTERACT, THEN A MECHANISM FOR PRIORITIZING THESE INTERACTIONS WILL BE NEEDED.

ON THE OTHER SIDE OF THE COIN, WE FELT THERE NEEDED TO BE MECHANISMS IN PLACE TO CREATE INCENTIVES SO THAT THERE WOULD BE INTERACTION ON BOTH SIDES. WE TALKED ABOUT THE NEED FOR PEER REVIEW, FOR PROJECTS INVOLVING INTRAMURAL AND EXTRAMURAL RESOURCES, AND FOR DEVELOPMENT OF COMMON STRUCTURES FOR IRB REVIEW, PROTOCOL MONITORING, AND SHARING OF IND.

THE NEXT ISSUE WE ADDRESSED WAS THIRD-PARTY PAYMENTS AND TRAVEL COSTS. THE GROUP RECOGNIZED THAT FOR EXTRAMURAL INVESTIGATORS, A GOOD PART OF CLINICAL RESEARCH FUNDING IN THE EXTRAMURAL COMMUNITY MAY BE PAID FOR BY THIRD-PARTY PAYERS. THE INTRAMURAL PROGRAM DOES NOT HAVE THAT COMPONENT, AS IT DOES NOT ACCEPT FUNDING FROM THIRD-PARTY PAYERS. THIS IS AN AREA OF INEQUITY BETWEEN THE TWO COMMUNITIES AND THAT MAY NEED SOME COORDINATION. ALSO NOTED WAS THAT AT LEAST SOME OF THE INSTITUTES PROVIDED TRAVEL REIMBURSEMENT FOR CLINICAL CENTER PATIENTS IN THE INTRAMURAL PROGRAM, WHICH DOES NOT COMMONLY HAPPEN IN THE EXTRAMURAL WORLD.

THE LAST QUESTION WE CONSIDERED WAS HOW RESEARCH SUBJECTS CAN BEST BE IDENTIFIED AND RECRUITED IN THESE KINDS OF COLLABORATIVE INTERACTIONS. WE CONSIDERED THE POSSIBILITY OF PATIENT ADVOCACY WEBSITES, THE CLINICALTRIALS.GOV WEBSITE AND COMMUNICATION LINKS BETWEEN THE GCRC, THE NIH CLINICAL RESEARCH CENTER, THE RTRCs, AND THE DISEASE-SPECIFIC CENTERS FOR RECRUITMENT.

THAT IS WHAT WE CONSIDERED. I AM HAPPY TO ANSWER ANY QUESTIONS.

STEVE STRAUS: QUESTIONS OR COMMENTS?

AUDIENCE MEMBER: IN LOOKING AT THE GOVERNANCE ISSUE, IT SEEMS YOU LOOKED WITHIN THE NIH STRUCTURE. DID YOU DISCUSS GOVERNANCE ISSUES WHERE THE NIH STRUCTURE MIGHT NOT BE THE MAJOR COMPONENT OF A REGIONAL CENTER?

DAN KASTNER: WE DID NOT SPEND A LOT OF TIME THINKING ABOUT THAT, BUT CERTAINLY THAT IS AN IMPORTANT ISSUE.

IF THE CLINICAL CENTER WERE TO SERVE AS ONE OF THE RTRCs, IT WOULD NOT NEED NEW MONEY. IT WOULD NOT DETRACT FROM OTHER EXISTING EXTRAMURAL FUNDING. WE WOULD HAVE TO ABIDE BY THE SAME KINDS OF GOVERNANCE RULES THAT WOULD EXIST FOR THE OTHER TRANSLATIONAL RESOURCE CENTERS.

AUDIENCE MEMBER: WAS THERE ANY QUESTIONS THAT THIS WOULD BE AN EXCITING IDEA? IS THERE CAPACITY AT THE CLINICAL CENTER TO ABSORB, FOR EXAMPLE, SOME OF THE TRIALS FROM THE EXTRAMURAL WORLD?

DAN KASTNER: WE HEARD FROM JOHN GALLIN THAT IF THAT QUESTION HAD BEEN ASKED A YEAR AGO, THE ANSWER WOULD HAVE BEEN A RESOUNDING 'YES, THERE'S PLENTY OF EXCESS CAPACITY.' BUT HE RELATED TO US THAT JUST WITHIN THE LAST WEEK, THE CENSUS WAS UP TO LIKE 93 PERCENT, AND SO IT MAY BE LESS SO RIGHT NOW. AS I MENTIONED, THERE IS CAPACITY TO EXPAND THE NUMBER OF BEDS IN THE CLINICAL RESEARCH CENTER. WE COULD GO UP FROM 242 OR WHATEVER THE NUMBER WAS TO 350. I THINK THE BOTTOM LINE IS THERE WOULD BE THE CAPACITY TO DO THAT.

STEVE STRAUS: MANY OF US HAVE PARTICIPATED IN MULTICENTER TRIALS. I HAVE A STUDY NOW in which I HAVE ENROLLED 1,740 PATIENTS AS A PART OF THE NATIONWIDE VACCINE STUDY.

DAN KASTNER: WE DISCUSSED THE POSSIBILTY THAT SOME __ PROJECTS COULD BE DONE BY EXTRAMURAL SCIENTISTS AND NOT NECESSARILY REQUIRE A COLLABORATOR IN THE INTRAMURAL PROGRAM. THE QUESITON WOULD BE WHERE NEW SPACE WOULD COME FROM FOR THE HOUSE INVESTIGATORS WHO DO RESEARCH SABBATICALS AT THE NIH CLINCAL CENTER.

STEVE STRAUS: HOWARD HUGHES IS DEVELOPING A NEW CAMPUS IN VIRGINIA WHERE THEY'RE GOING TO HAVE LABORATORY SPACE AND ROTATING SCIENTISTS. THOSE OF US WHO HAVE LIVED IN THE CLINICAL CENTER STAGE HAVE NOT FOUND SUCH SPACE YET, BUT AT LEAST THERE IS THAT POTENTIAL.

THERE'S A COMMENT OR QUESTION IN THE BACK.

AUDIENCE MEMBER: I NOTICE ONE OF YOUR BULLETS TALKED ABOUT THIRD-PARTY PAYERS FUNDING THE CLINICAL RESEARCH. I THINK WE NEED TO BE CAREFUL THAT THEY DON'T SUPPORT RESEARCH COSTS.

STEVE STRAUS: WE GET NO REIMBURSEMENT FOR PATIENT CARE COSTS AT THE NIH CLINICAL CENTER.

[LOW AUDIO] AUDIENCE MEMBER

STEVE STRAUS: YOU MEAN IN THE EXTRAMURAL WORLD? THE INTRAMURAL COMMUNITY DOES NOT GET ANY THIRD-PARTY REIMBURSEMENT, AS I NOTED THERE. BUT YOUR POINT WAS __

[LOW AUDIO] AUDIENCE MEMBER

STEVE STRAUS: A LOT OF THE RESEARCH WE'RE TALKING ABOUT IS NATURAL HISTORY STUDIES, BASIC BIOLOGY, BENCHSIDE TO BENCHWORK, AND EARLY-PHASE STUFF, NOT REALLY TRIALS. THERE ARE A LOT OF CLINICAL CARE COMPONENTS, BUT WE DO NOT RECRUIT THAT, WHICH IS WHY OUR PATIENT COST IS SO HIGH. ANY OTHER COMMENTS OR QUESTIONS? ANTHONY AND THEN OVER HERE.

[LOW AUDIO]

YOU ARE RIGHT. SURE. I AGREE.

AUDIENCE MEMBER: WHEN WE SAID "WHAT DO YOU MOST NEED?" HE KEPT SAYING TRAINING. THE THING THAT I MOST NEED IS THE TRAINING.

STEVE STRAUS: THAT IS THE TIME FOR THE FIRST GROUP. THAT WAS EXCELLENT. WE'RE GOING TO MOVE TO THE SECOND AND YOU WILL TAKE CARE OF THIS, THIS IS THE RESOURCES PROVIDED, THE SERVICES.

SERVICES PROVIDES/HUMAN SUBJECTS—STEVE ZALCMAN:

OF THE THREE OF US LISTED, I WAS VOTED THE LEAST CONTRIBUTORY, SO I WAS ASKED TO TALK ABOUT WHAT MY COLLEAGUES DID. WE LOOKED AT OF THE LIST OF SERVICES I SHOWED THIS MORNING AND THEN ASKED ‘ARE THERE OTHER SERVICES THAT RTRC MIGHT PROVIDE.’ THEN WE TRIED TO GO THROUGH THE FRAMING QUESTIONS AT THE END AND RESPOND TO A FEW OF THOSE.

WITH PATIENT RECRUITMENT CORES, OUR GROUP NOTED THAT THE NEEDS VARY FROM POPULATION TO POPULATION. IN TRUTH, RECRUITMENT WAS NOT EXACTLY THE KEY ACTIVITY TO SUCCESSFULLY RECRUIT PATIENTS. IT WAS REALLY ABOUT BUILDING RELATIONSHIPS WITH COMMUNITIES, WHICH IS VERY TIME- AND LABOR-INTENSIVE AND THEREFORE EXTRAORDINARILY EXPENSIVE AND PROBABLY BEYOND THE BUDGET OF THE GENEROUS RTRC SET-ASIDE, WHATEVER THAT TURNS OUT TO BE. AND ENCOURAGEMENT TO GROUPS TO THINK ABOUT HOW TO PARTNER IN THIS VERY IMPORTANT ENDEAVOR.

IT WAS ALSO POINTED OUT THAT IF ONE HOPED SUCCESSFULLY TO ENROLL THE SAME PATIENT OR PATIENTS FROM THE SAME GROUP MORE THAN ONCE THAT YOU OUGHT TO CLOSE THE LOOP WITH THEM. THAT IS, NOT ONLY ENROLL THEM IN A STUDY, BUT PROVIDE SOME FEEDBACK TO THEM INDIVIDUALLY OR TO THE GROUP AS TO WHAT HAPPENED WITH THAT STUDY. THE PERCEPTION IN THE PAST IS THAT THIS HAS NOT ALWAYS HAPPENED.

IT WAS FELT THAT EVERY RTRC WOULD NEED TO HAVE AN APPROPRIATE RECRUITMENT PLAN, AGAIN PROVIDING COMMUNITY FEEDBACK. IT WAS THOUGHT THAT __ AND THIS WAS TRUE. MANY OF THE SERVICES WE ARE GOING TO TALK ABOUT __ THAT IF A GIVEN CENTER OR SUBSET OF CENTERS SEEM TO GET IT MORE RIGHT THAN OTHERS THAT THEY SHOULD SHARE THIS TEMPLATE ACROSS THE NETWORK OF CENTERS AND POSSIBLY AT SOME TIME IN THE FUTURE THERE COULD BE COORDINATED EFFORTS ACROSS MORE THAN ONE CENTER TO SHARE RECRUITMENT EFFORTS AND THE RESULTS OF THAT. THE LAST POINT ON THIS SLIDE WAS THAT RECRUITING FOR PHASE I AND II STUDIES IS A DIFFERENT ENDEAVOR THAN FOR PHASE III STUDIES, WHICH NEEDS TO BE BORNE IN MIND BY THE PEOPLE IN THE CENTER.

THE NEXT TWO QUESTIONS WERE ABOUT DEALING WITH REGULATORY BURDENS AND IRB ISSUES. OUR DISCUSSION ON THESE TWO POINTS GOT MELDED, SO OUR ANSWERS GOT MELDED. MUCH TIME WAS SPENT TALKING ABOUT THE NEED AND DESIRABILITY OF HAVING CENTRAL IRBs. A GREAT DEAL OF DISCUSSION CENTERED ON WHAT NIH MIGHT TO DO TO FACILITATE THIS AND SERVE AS AN HONEST BROKER WITH OHRP TO TRY TO LIFT WHATEVER ELEMENT OF THAT BURDEN IS GOVERNMENT-IMPOSED AS OPPOSED TO INSTITUTION-IMPOSED.

WE ALSO HAD DISCUSSIONS ABOUT TRYING TO ASSURE THAT EVERY POSSIBLE ROADBLOCK WAS ELIMINATED. ONE OF OUR GROUP MEMBERS HEADS THE IRB AT COLUMBIA AND CITED A CASE IN WHICH ONE PROTOCOL HAD TO GO THROUGH 68 DIFFERENT APPROVALS. THIS IS NOT THE MODEL THAT WE ARE ASPIRING TO.

ALSO NOTED WERE FURTHER EFFORTS TO ENHANCE COLLABORATIVE AGREEMENTS BETWEEN INSTITUTIONS, AS ONE OF OUR GROUP MEMBERS CITED INSTANCES IN WHICH MULTIPLE INSTITUTIONS HAD AGREED TO SHARE A SINGLE IRB IN MULTI-SITE STUDIES—A GOAL IN TRYING TO OVERCOME SOME INSTITUTIONAL BARRIERS. THE THOUGHT WAS TO TRY TO CHANGE THE DISCUSSION FROM A QUESTION OF CONTROL TO ONE OF SHARED EXPERTISE, WITH THAT BEING THE CARROT. THE NOTION WAS THAT MULTIPLE INSTITUTIONS SHARING PROTOCOLS MIGHT PUT TOGETHER A SINGLE IRB WITH ENHANCED EXPERTISE REPRESENTATIVE OF ALL MIGHT SEAL THE PROPOSITION.

THE NEXT QUESTION WAS A REMINDER TO ME TO NOTE THAT OUR GROUP WAS SOMEWHAT CONFUSED. I GUESS I WAS IMPERFECT AT ELIMINATING THE CONFUSION OF WHETHER THE CENTERS ARE CONFINED TO PHASE I AND II STUDIES. WITH RESPECT TO DRUG STUDIES, I THINK THEY WILL GO NO FURTHER THAN __. THAT IS MY UNDERSTANDING, BUT THEY WILL DO MANY THINGS THAT OCCUR PRIOR TO THAT.

THE NEXT POINT WAS THAT FOR PHASE 1 STUDIES, A CONCERN WAS RAISED THAT TO GET MULTIPLE INSTITUTIONS TO PARTICIPATE IN A SHARED IRB, THERE MIGHT BE A GREATER IMPEDIMENT WITH PHASE 1 STUDIES BECAUSE OF THE CONCERN THAT THESE ARE INHERENTLY SOMEWHAT HIGHER RISK. THERE IS ALSO A RELUCTANCE FOR INDIVIDUAL INSTITUTIONS TO CEDE THAT AUTHORITY TO OTHERS.

THE LAST POINT IS THAT INDIVIDUAL CENTERS OR GROUPS OF CENTERS COULD PROVIDE HUMAN SUBJECTS TRAINING TO THEIR REGIONS. IT WAS HOPED AND THOUGHT A DESIRABLE GOAL TO HAVE CENTRALIZED SYSTEMS FOR COLLECTING, REPORTING, AND ANALYZING ADVERSE EVENTS, AS WELL AS FOR MONITORING, COMPLIANCE WITH STORAGE, AND USE OF INVESTIGATIONAL AGENTS TO TRY AND COMPLY WITH VARIOUS REGULATORY REQUIREMENTS.

ONE OF OUR GROUP MEMBERS FELT THAT ACADEMIC HEALTH CENTERS MIGHT BENEFIT FROM INCREASED INTERACTION WITH INDUSTRY, WHICH HAS BUILT IN GREATER EXPERTISE IN DEALING WITH THE REGULATORY BURDEN—AN EXPERTISE THAT WAS NOT FULLY TAPPED. THE NEXT POINT REALLY AGAIN IS GENERIC, PRESENTED HERE AS ONE EXAMPLE: WHATEVER RESOURCES CAN AND SHOULD BE SHARED AND THE CENTER SHOULD CAPITALIZE ON THEM. A FEW EXAMPLES RELATED TO REGULATORY REQUIREMENTS ARE CITED HERE, BUT IT GOES BEYOND THESE ISSUES.

AGAIN, THERE IS THE POSSIBILITY THAT THE CENTERS COULD OUTLINE APPROPRIATE STANDARDS THAT COULD BE ADOPTED MORE BROADLY. WITH DATA MANAGEMENT, ACCRUAL, CURATION, ETC. IT WAS

SUGGESTED THAT THE CENTERS COULD ESTABLISH DATABASES FOR DATA ENTRY TO ASSIST A P.I. AS A MANAGEMENT TOOL FOR QUALITY CONTROL AND EVALUATION, ASSIST WITH DATA SECURITY AND THE UTILIZATION OF DATA FROM SECONDARY ANALYSES.

AS IS FREQUENTLY POINTED OUT, PARTICULARLY BY STATISTICIANS OF STUDY SECTIONS, IT IS A GOOD THING TO HAVE THE STATISTICAL EXPERTISE COME TO BEAR AT THIS STAGE OF STUDY DESIGN RATHER THAN AT STUDY COMPLETION, AND AS NEWER TOOLS SUCH AS COMPLEX GENETICS, MICROARRAYS, ETC. ARE COMING ON-LINE TO GENERATE NEW SOURCES OF DATA SETS. MAYBE THE CENTERS CAN HELP IN THE DEVELOPMENT OF NEW, MORE ROBUST TECHNIQUES THAT WILL BE NECESSARY TO FULLY TO TAKE ADVANTAGE OF THEM.

ALSO, A PLUG WAS MADE FOR DEVELOPMENT OF SOFTWARE TO BETTER SUPPORT AUDIT TRAILS. WITH CLINICAL INFORMATICS, IT WAS SUGGESTED THAT SYNERGISM EXISTS AND SHOULD BE EXPLOITED BETWEEN REGULATORY AND NIH DATA STRUCTURES FOR THE AUTOMATIC CREATION, THE AUTOMATIC MEETING OF DATA MANAGEMENT NEEDS TO INCREASE QUALITY AND SHARING OF CASE REPORT FORMS AMONGST DIFFERENT STUDIES, ETC. AGAIN, IT WAS SUGGESTED TO PROVIDE DATABASE LINKS TO TOOLS SUCH AS THE PROTOTYPE THAT DAN MENTIONED, CASE REPORT FORMS, PROGRESS MONITORING, ETC.

SPECIALIZED STAFF RECEIVED A FAIR AMOUNT OF DISCUSSION. TRANSLATIONAL RESEARCH FELLOWS WAS THE SINGLE EXAMPLE THAT WE CITED AND WAS CHARACTERIZED BY ONE OF OUR GROUP MEMBERS—I THINK VERY APTLY—AS THE GLUE THAT BRINGS MENTORS FROM DIFFERENT DISCIPLINES TOGETHER. FOR THIS UNDERTAKING, THIS IS A KEY POINT. ANOTHER ONE OF OUR GROUP MEMBERS MADE A VERY COGENT POINT ABOUT THE POSSIBILITY OF USING VIRTUAL STAFF POOLS AND IN A REGION, DEFINING STAFF MEMBERS BY EXPERTISE AND HAVING THIS EXPERTISE AVAILABLE TO SHARE ACROSS A REGION.

IN SOME INSTANCES, DEPENDING ON THE FOCUS OF A GIVEN CENTER, HAVING PHARMACOKINETICS, PHARMACODYNAMIC EXPERTISE WOULD BE QUITE USEFUL. TO BRING NURSING SCIENCE TO BEAR ON ISSUES OF QUALITY-OF-LIFE OUTCOMES AND UTILIZATION OF FAMILY ADVOCATES WAS THOUGHT TO BE VERY IMPORTANT. ALSO DISCUSSED WAS THE NOTION OF FULLY LEVERAGING AND UTILIZING THE SCIENCE OF COLLABORATION AND HOW TO MAKE THESE NOVEL COLLABORATIONS ACTUALLY WORK SUCCESSFULLY. THIS TIES IN VERY CLOSELY WITH TRAINING NEEDS. A COUPLE OF OTHER TYPES OF SPECIALIZED EXPERTISE WERE NOTED—EITHER MOLECULAR OR CLINICAL PATHOLOGY OR EPIDEMIOLOGY.

WE DISCUSSED PILOT RESEARCH PROJECTS, WHICH WE LEARNED THIS MORNING ARE NEAR AND DEAR TO ANTHONY'S HEART, SO WE WERE SURE TO SPEND A DISPROPORTIONATE AMOUNT OF TIME ON THAT. IT WAS FELT WHILE THESE WERE LIKELY TO ACCOUNT FOR A SMALL PART OF THE BUDGET IN ANY ONE OF THE CENTERS, THEY WOULD LIKELY ULTIMATELY SHAPE THE IDENTITY OF THE INDIVIDUAL CENTERS AND SHOULD BE FOCUSED TO ADDRESS THE MISSION OF A PARTICULAR CENTER, WHICH OBVIOUSLY WILL VARY FROM ONE CENTER TO THE NEXT. BY THE VERY NATURE OR PURPOSE OF THE CENTERS, SUCH PILOT PROJECTS SHOULD BE INTERDISCIPLINARY. THEY WERE SEEN AS A CRITICAL MECHANISM TO FOSTER RELATIONSHIPS BETWEEN GROUPS AND INDIVIDUALS WHO MIGHT OTHERWISE NOT WORK COOPERATIVELY AND COULD ALSO FOSTER RESEARCH IN UNDERSERVED DISCIPLINES.

OTHER NOTIONS FOR SERVICES THAT HAD NOT BEEN PUT FORWARD INITIALLY INCLUDED THOSE LISTED HERE: INNOVATIONS AND VIDEO CONFERENCING, COMPUTATIONAL RESOURCES, EPIDEMIOLOGY OCCURS TWICE, DEALING WITH INTELLECTUAL PROPERTY ISSUES. ONE OF OUR GROUP MEMBERS FELT VERY STRONGLY THAT APPROPRIATE INTERACTION WITH TECHNOLOGY TRANSFER OFFICES AND PEOPLE WITH BUSINESS EXPERTISE OCCUR EARLY ON WHEN TRYING TO DEVELOP A FIRST-IN-USE COMPOUND IS REALLY CRITICALLY IMPORTANT. IT WAS FELT THAT IF YOU DID NOT DO THIS PROPERLY AT THE END OF THE DAY, YOU MIGHT NOT BE ABLE EVER TO DO IT. AGAIN NOTED WAS EDUCATIONAL OUTREACH, WHICH WILL SERVE MULTIPLE PURPOSES BUT CERTAINLY IMPORTANTLY HELP INFORM THE COMMUNITY AND IMPROVE COMMUNITY RELATIONSHIPS. SO, WE DEALT WITH ONLY A SUBSET OF THESE FRAMING QUESTIONS, THE ONES WE THOUGHT WERE MOST COGENT AND FOR WHICH WE HAD ENOUGH TIME TO HAVE DISCUSSION.

WHETHER IT WAS FEASIBLE AND REASONABLE TO HAVE THESE SERVICES BE REGIONALIZED, WE FELT THE DEFAULT ANSWER SHOULD BE ‘YES,’ UNLESS THERE WAS SOME COMPELLING REASON FOR IT TO BE OTHERWISE AND THAT ONE SHOULD UTILIZE THE BEST AVAILABLE EXPERTISE AND ALLOW FOR THE POSSIBILITY OF DISTRIBUTED OR VIRTUAL SERVICES. LIKEWISE, IT WAS FELT THAT SPATIALLY DISTRIBUTED CENTERS WITH LOCAL CENTERS OF EXCELLENCE WAS OUR GROUP'S DEFAULT RECOMMENDATION AND—TO MAXIMIZE PRODUCTIVITY AND WORKING RELATIONSHIPS—TO ESTABLISH APPROPRIATE INCENTIVES FOR COLLABORATIONS.

THE LAST TWO WERE POINTS TO NIH STAFF TO KEEP IN MIND WHEN RFAs ARE BEING WRITTEN. IF YOU HAVE A SET OF REGIONAL CENTERS WITH MULTIPLE INDIVIDUAL SITES, CONCERN WAS EXPRESSED THAT NOT ALL THE DOLLARS AWARDED BE EATEN UP BY INDIRECT COST, SO THAT THERE WOULD BE MONEY LEFT TO SUPPORT THE CORES. THE

SUGGESTION WAS TO PERHAPS INCLUDE LANGUAGE ABOUT THE USE OF SUBCONTRACTS. IN TERMS OF THE LEVEL OF COMMITMENT, RFAs SHOULD SPECIFY WHAT ONE MIGHT OR SHOULD EXPECT FROM PARTICIPATING INSTITUTIONS IN REGIONS. THE BEST WAY TO ENCOURAGE COLLABORATION WOULD BE TO INCLUDE THIS AMONG THE REVIEW CRITERIA. ONE OF THE EXAMPLES CITED WAS AGAIN TRY TO HAVE CENTRALIZED IRBs, WHICH WE HAVE ENDORSED OVER AND OVER AGAIN. PERHAPS THIS IS ONE WAY THAT A REGION MIGHT SHOW ITS COMMITMENT TO TRYING TO DO SOMETHING IN A DIFFERENT WAY. I THINK THIS MAY BE OUR LAST ***SLIDE.***

IT ASKS HOW WILL THE RTRCs BE UNIQUE? IT WAS FELT IN MANY RESPECTS THAT THE BURDEN OF MAKING THIS CASE WOULD FALL ON THE APPLICANTS, BUT A NUMBER OF THESE POINTS, WHICH ARE REALLY REPETITIONS FROM MANY OF THE EARLIER SLIDES, WOULD SET THEM ASIDE. THE SCIENTIFIC COLLABORATION, UTILIZATION OF VIRTUAL STAFF POOL, CREATIVITY IN DESCRIBING FUNDING PILOT PROJECTS, ENROLLMENT OF MINORITY POPULATIONS AND ELDERLY POPULATIONS, OVERLAPPING SCIENTIFIC DOMAINS, CROSS- DISCIPLINARY WORK AMONG INSTITUTIONS, AND RAISING THE BAR IN TERMS OF A TRULY ITERATIVE PROCESS FROM THE BEDSIDE TO THE BENCH AND BACK UNTIL THE PROPER ANSWERS ARE FOUND.

STEVE STRAUS: THE QUESTION IS: DID YOUR GROUP ATTEMPT TO PRIORITIZE AMONG ALL OF THESE IDEAS, OR DID THE GROUP FEEL YOU SHOULD LEAVE IT TO THE POTENTIAL APPLICANTS TO DECIDE WHAT SET OF RESOURCES WOULD BEST BE BROUGHT TOGETHER TO SERVE THEIR VISION OF A CENTER?

STEVE ZALCMAN: IT WAS VERY MUCH THE LATTER. IT WAS NOT ADDRESSED QUITE AS SPECIFICALLY AS THAT, BUT IT WAS ADDRESSED AND A FEW OF THESE SERVICES WERE CLEARLY REGARDED AS ABSOLUTELY ESSENTIAL, SUCH AS PATIENT RECRUITMENT, STATISTICS, ETC. SEVERAL OF THE OTHERS SHOULD BE USED WHEN THEY SERVE THE PURPOSES OF A GIVEN CENTER AS THEY DECIDED TO CONFIGURE THEMSELVES.

STEVE STRAUS: WAS THERE ANY DISCUSSION ON LEVERAGING SOURCES FROM OTHER INSTITUTIONAL RESOURCES, OTHER NIH-FUNDED CENTER RESOURCES, AND INDUSTRY AND PRIVATE SECTOR RESOURCES?

STEVE ZALCMAN: NOT VERY EXTENSIVE, BUT IMPLICIT. AGAIN, IN TALKING ABOUT PATIENT RECRUITMENT, IT WAS MADE EXPLICIT. THERE WAS A MODEST AMOUNT OF DISCUSSION ABOUT INDUSTRY COLLABORATIONS. IT BECAME CLEAR, AND IT WAS MENTIONED IN OUR GROUP AS IN OTHERS, THAT HOWEVER MUCH MONEY YOU WERE GOING

TO HAVE IS NOT GOING TO BE ENOUGH. SO I THINK IN THAT CONTEXT IT WAS CLEAR THAT TO FULLY ACCOMPLISH WHAT NEEDED TO BE DONE THERE WOULD HAVE TO BE LEVERAGING OF OTHER RESOURCES.

STEVE STRAUS: DENNIS.

DENNIS CHARNEY: IN THE FIRST GROUP, WE WERE OPERATING UNDER THE ASSUMPTION THAT THE RTRCs WOULD NOT DO THAT MUCH IN TERMS OF PATIENT CARE AND RECRUITMENT. SO, I'M A LITTLE CONFUSED NOW ABOUT THE CONCEPT OF THE RTRCs.

STEVE STRAUS: THEY WOULD PROVIDE SOME EXPERTISE IN RECRUITMENT AND STRATEGIES, BUT NOT SPECIFICALLY DOING THE RECRUITMENT. RATHER THAN EVERY INSTITUTION DEVELOPING ITS OWN RECRUITMENT OFFICES, YOU WOULD NEED SOME EXPERTISE IN HOW YOU ADVERTISE, HOW YOU COMMUNICATE, AND HOW YOU REACH INTO THE COMMUNITY. THAT IS ANOTHER POSSIBILITY BALANCING __ . BUT I AM SEEING SOME HEADS HERE SHAKING NO. YOU UNDERSTOOD IT DIFFERENTLY?

AUDIENCE MEMBER: ONE OF THE THINGS WE TALKED ABOUT IS GETTING THE DIFFERENT TERMINOLOGY OF PHASE I AND PHASE II, BECAUSE THAT LIMITS OUR THINKING TO A CERTAIN KIND OF RESEARCH SETTING. MAYBE BECAUSE THERE WERE SEVERAL NURSES IN THIS GROUP AND WE BANDED TOGETHER, WE WANTED TO SAY THAT NURSING CAN INCLUDE WHAT PEOPLE THINK OF AS BENCH RESEARCH. THEN TO TEST THAT AT AN EARLY PHASE WILL REQUIRE A GIVEN GROUP OF PATIENTS. SO RECRUITMENT WOULD BE IMPORTANT. BUT IT DOES THE SAME THING. IF YOU'RE LOOKING AT THE BENCH RESEARCH, ALLOCATION, AND AT THEORY AS YOU'RE LOOKING AT ALLOCATION, WHEN YOU CONFINE IT TO THE TERMINOLOGY OF A PHASE, OR WHATEVER, IT MAKES US ALL GO INTO A PARTICULAR THINKING PATTERN. I THINK YOU HAD IT UP THERE. THAT WAS WHAT SOME OF US WERE REQUESTING.

DENNIS, IF THE UNDERLYING NOTION OF THE CENTERS IS A MECHANISM FOR HELPING OVERCOME EXISTING BARRIERS TO MORE TRANSLATIONAL RESEARCH, AND ONE OF THOSE BARRIERS IS THE INABILITY TO IDENTIFY AND RECRUIT AND ENROLL PATIENTS, THEN HAVING THAT AMONG THE CORES IN SOME OF THE CENTERS AS ONE OF THE ACTIVITIES SEEMED APPROPRIATE TO OUR GROUP.

AUDIENCE MEMBER: I AM STILL A LITTLE CONFUSED. THERE WAS THE ONE POINT ABOUT PEOPLE WHO MOVED BETWEEN INSTITUTIONS IN THE REGIONAL CENTERS, AND YOU TALKED ABOUT THE TRANSLATIONAL FELLOW AS THE GLUE. IN THE RIGHT UP THERE WAS TALK OF TRANSLATIONAL FELLOWS __ AND SPECIALIZED NURSING AND OTHER __.

I AM NOT REALLY CLEAR—ARE THERE PEOPLE RIDING A CIRCUIT? IS THAT YOUR IDEA? I HAVE TROUBLE THINKING OF NURSING, OR FOR THAT MATTER PHYSICIANS, GOING FROM INSTITUTION TO INSTITUTION PRACTICING, DOING THEIR CARE. THEY HAVE TO BE CREDENTIALED AT EACH ONE OF THE INSTITUTIONS. IS THAT THE CONCEPT?

STEVE STRAUS: I THINK PRIMARILY THE CONCEPT WILL BE THE CONCEPT THAT YOU PRESENT TO US.

AUDIENCE MEMBER: BUT IF YOU THINK ABOUT A TRANSLATIONAL FELLOW AS SOMEONE WHO TO BE FULLY SUCCESSFUL IN HIS TENURED CAREER WOULD NEED TO BE EXPERT IN MULTIPLE DISCIPLINES, THEN ONE COULD IMAGINE SUCH A FELLOW MOVING FROM ONE LABORATORY TO ANOTHER DURING THE COURSE OF HIS OR HER TRAINING. AND YOU CAN IMAGINE THAT TRAINING MIGHT TAKE PLACE AT MORE THAN ONE PLACE.

STEVE STRAUS: JUST LIKE FELLOWS OR RESIDENTS ROTATE ON SERVICES NOW. BUT YOU'RE RIGHT, THEY'RE NOT PRACTICING AT MULTIPLE PLACES OR HAVING NURSES DO HOME VISITS. YES?

[LOW AUDIO]

BUT THERE MAY BE MORE THAN ONE MENTOR FOR SOME INDIVIDUALS DEPENDING ON WHAT THEY DO. THERE MAY BE A LABORATORY MENTOR AND CLINICAL MENTOR.

STEVE ZALCMAN: ONE OF THE THINGS WE TALKED ABOUT WAS THE IDEA OF A VIRTUAL FACULTY POSITION—THAT EXPERTISE BE AVAILABLE TO INSTITUTIONS THAT MEET THEIR NEEDS FOR SPECIALIST AND PROTOCOLS LIKE THAT. IN VIRTUAL SENSE NOT HAVING A PERSON AT EACH INSTITUTION, BUT PROVIDING THE RESOURCES SO THAT IT CAN BE PUT INTO PLACE.

AUDIENCE MEMBER: I HAVE A LITTLE TROUBLE WITH THE CONCEPT OF A SINGLE INDIVIDUAL BEING AN EXPERT IN SEVERAL DIFFERENT DISCIPLINES AS OPPOSED TO HAVING A DISCIPLINED TEAM. I DON'T THINK THERE'S A CAREER PATH FOR THOSE INDIVIDUALS, AS FAR AS WE KNOW HOW SCIENCE AND MEDICINE IS GOING TO GO. WE ARE PROBABLY POTENTIALLY DOING A DISSERVICE THINKING THAT THEY CAN BE SPECIALTY TRAINED IN TWO OR THREE DISCIPLINES, AS OPPOSED TO LEARNING HOW TO WORK IN A TEAM WITH A SPECIALIST IN TWO OR THREE DISCIPLINES. THAT IS NOT OBVIOUSLY PART OF THIS ALONE BECAUSE IT IS A BROADER QUESTION, BUT I DON'T THINK THERE IS SUCH A CAREER FOR THESE INDIVIDUALS IN THE LONG RUN BECAUSE YOU CANNOT KEEP UP WITH EVERYTHING.

STEVE STRAUS: ONE LAST QUESTION PLEASE.

[LOW AUDIO] AUDIENCE MEMBER
[LAUGHTER]

STEVE STRAUS: WE WILL NOT HAVE VIRTUAL PHYSICIANS. ERIC, DID YOU WANT TO SAY SOMETHING? ERIC.

[LOW AUDIO] ERIC REIMAN

STEVE STRAUS: WE HAVE A LOT MORE TO LEARN ABOUT THIS. WE WILL GO AHEAD TO THE NEXT ONE. THIS HAS BEEN HELPFUL. ROSS, ARE YOU DOING THE CORES?

CORE SERVICES—ROSS McKINNEY:

OUR DISCUSSION WAS SO HEATED THAT THE AIR-CONDITIONING ESSENTIALLY WAS GOING OUT IN THE ROOM DURING OUR CONVERSATION. IN FACT, IT WAS SO INTENSE THAT LINDA'S TYPING RAN THE COMPUTER OUT OF POWER HALFWAY THROUGH THE SESSION AND WE HAD TO BRING IN TECHNICAL SUPPORT TO REACTIVATE THE COMPUTER. WE HAD A VERY LIVELY GROUP. I THOUGHT IT WAS VERY CONSTRUCTIVE.

THE APPROACH THAT WE TOOK WAS TO BEGIN WITH __ WE HAD SET UP A SERIES OF QUESTIONS. ROBERT STAR, WHO HAS LEFT FOR CALIFORNIA, AND I COMMUNICATED BY EMAIL TO DISCUSS WHAT THE MAP SHOULD BE FOR OUR DISCUSSION OF THE CORES AND WE ARRIVED AND FOLLOWED THE MAP WE HAD OUTLINED.

THE FIRST THING WE HAD TO DO WAS DEFINE WHAT THE EXPANDED CENTERS WOULD BE. SHOULD THEY BE AUTONOMOUS UNITS, OR ARE THEY JUST AN ADJUNCT TO AN RTRC? OUR FINAL METHOD FOR CONCEPTUALIZING WAS THAT OTHER PEOPLE AT AN RTRC COULD IN FACT APPLY FOR THIS. THERE WOULD PROBABLY BE A PREFERENTIAL ARGUMENT, BUT FOR THIS KIND OF CORE, COULD BE IF THE RIGHT FACILITY EXISTED A SEPARATE FACILITY AND COULD BE CONCEPTUALIZED AS A SEPARATE CORE THAT WILL PROVIDE RESOURCES TO ALL OF THE RTRCs.

THEN OUR MISSION BECAME WHAT KIND OF FACILITIES SHOULD BE PRESENT IN AN EXPANDED RTRC AND THESE E-UNITS THAT ARE BEYOND THE STANDARD RTRC. WE LOOKED AT WHAT CRITERIA WE SHOULD USE SO THAT WHEN PEOPLE ARE SUBMITTING THEIR APPLICATIONS—BECAUSE WE ASSUME THESE WILL BE IDEAS THAT COME FROM THE

INVESTIGATORS—WHAT KIND OF CRITERIA SHOULD BE ESTABLISHED TO DEFINE WHETHER TO FUND OR NOT TO FUND ONE OF OUR RTRC EXPANDED UNITS, AND I WOULD JUST CALL IT THE E-UNIT FOR NOW.

[LOW AUDIO]

THE KIND OF THINGS WE TALKED ABOUT USING WERE FIRST THING AS A CRITERIA THIS, WHAT EVER THE E-UNITS DO, THEY SHOULD EXPAND THE TRANSLATION OR ACCELERATE TRANSLATIONAL RESOURCES. THEY SHOULD BE WIDELY NEEDED. SOMETHING THAT IS ONLY APPLICABLE TO ONE CENTER IS OF NO VALUE TO ANYBODY. THEY SHOULD BE SOMETHING THAT CAN BE WIDELY APPLICABLE IN THE TRANSLATIONAL RESEARCH COMMUNITY. THERE SHOULD BE A WILLINGNESS ON THE PART OF THE APPLICANTS TO BE SERVICE-ORIENTED. THIS IS NOT TO BE THEIR RESEARCH. THEY MAY DO THEIR RESEARCH, BUT THIS HAS TO BE RESEARCH THAT IS IN THE SERVICE OF THE TRANSLATIONAL RESEARCH COMMUNITY AND IS DISTINCT FROM THEIR OWN WORK.

IT SHOULD NOT BE, WHATEVER THIS LABORATORY IS IN THE E-UNIT, IT SHOULD PROBABLY BE ONE OF THE FACILITIES THAT SHOULD NOT BE REPLICATED BY EVERY ACADEMIC MEDICAL CENTER, BUT PROBABLY WOULD BE IF IT WAS NOT AVAILABLE REGIONALLY. THINGS THAT THOSE FACILITIES YOU HAVE AT YOUR INSTITUTION THAT SOMEBODY GOT THE GRANT FOR AND ARE USED 30 PERCENT OF THE TIME THAT WOULD BE FAR BETTER AND MORE EFFECTIVELY USED IF EVERYBODY, IF IT WAS FULLY USED—THAT IS THE KIND OF FACILITY THAT WE THINK THESE E-UNITS SHOULD INCLUDE. THEY SHOULD BE FEASIBLE AS A REGIONAL RESOURCE. SOMETIMES WORK CANNOT BE DONE REGIONALLY—SHIPMENT OF SPECIMENS OR PATIENTS MAY NOT WORK.

THE PEOPLE WHO ARE WORKING IN THE FACILITY SHOULD BE AWARE OF THE CUTTING EDGE. IT WAS A KEY POINT THAT THERE DOES HAVE TO BE STANDARD—SO THAT WHILE THEY MAY BE AWARE OF THE CUTTING EDGE, THEY HAVE TO BE MAKING PROGRESS, THAT THIS IS NOT NECESSARILY WHERE THE CUTTING EDGE IS BECAUSE THE STANDARDS HAVE TO BE CONSISTENT. WE WERE AWARE OF THE DISTINCTION BETWEEN HAVING PEOPLE THAT WERE ON TOP OF THE RESEARCH IN THE AREA AND PROVIDING SERVICE.

FINALLY THEY SHOULD BE SOMETHING WHERE ECONOMIES OF SCALE MATTER. THESE E-UNITS WOULD PROBABLY BE BUILT ON EXISTING LOCAL FOUNDATIONS. THE MONEY WILL COME IN TO SUPPLEMENT WHAT PROBABLY IS ALREADY A GOOD LOCAL FACILITY THAT PROBABLY HAS A TRACK RECORD, BUT TO SCALE IT UP AND ALSO PROVIDE THE INFRASTRUCTURE TO RECEIVE THINGS FROM THE OUTSIDE WORLD AND

TO DISTRIBUTE INFORMATION BACK. OUR ASSUMPTION IS THE PEOPLE MAKING THE APPLICATIONS PROBABLY ARE ALREADY WORKING IN THE AREAS THAT THEY SERVICE WILL BE PROVIDED.

THE BUDGET SHOULD BE APPROPRIATE TO THE SCALE. PEOPLE SHOULD NOT TAKE ON THINGS THAT ARE OUTSIDE OF THE SCALE OF WHAT IS AVAILABLE. THEY SHOULD BE COST-EFFECTIVE, RELATIVE TO COMMERCIAL PROVIDERS AND IN FACT THAT GOES TO CHEAPER, FASTER, BETTER. BECAUSE IF IT CAN BE DONE BY A COMMERCIAL OUTFIT AND THE COMMERCIAL OUTFIT CAN DO IT CHEAPER, FASTER, BETTER, NO ONE IS GOING TO USE THE E-UNIT FACILITIES SO IT HAS TO BE HIGH STANDARDS, IT HAS TO BE RELATIVELY FAST, AND IT HAS TO BE COST EFFECTIVE. FINALLY, THE INSTITUTION, WHOEVER IT IS THAT APPLIES, MUST HAVE AN INSTITUTIONAL COMMITMENT FOR SPACE AND RESOURCES THAT SHOW THAT THE INSTITUTION CARES ABOUT THIS.

WE LOOKED AT WHAT ARE SOME OF THE BARRIERS. HOW MANY PEOPLE HERE ARE READY TO SHIP THEIR VALUABLE SPECIMENS, THEIR CRITICAL STEPS IN THEIR TRANSLATIONAL RESEARCH PROCESS? HOW MANY ARE READY TO SHIP THIS OFF TO SOMEBODY THEY DON'T KNOW IN WISCONSIN IF THEY'RE WORKING IN FLORIDA? THAT IS WHAT THIS IS ALL ABOUT. ONE OF THE BARRIERS TO REGIONALIZATION IS THE TRADITIONAL PRIMACY OF THE INDIVIDUAL INVESTIGATOR AND THE SENSE THAT YOU'RE GOING TO HAVE TO SHARE SOMETHING WITH SOMEONE ELSE AT AN OUTSIDE RESOURCE AND BE WILLING TO DO THAT.

WE SAW THAT ANOTHER BARRIER WAS THAT THE BALANCE OF THE CENTER WOULD HAVE TO BE ACHIEVED BETWEEN INNOVATION AND SERVICE. THAT THE PEOPLE WHO YOU WANT DOING THIS KIND OF WORK ARE GOING TO BE PEOPLE WHO WANT TO BE DOING CUTTING-EDGE RESEARCH AND AT THE SAME TIME WE'RE ASKING THEM TO PROVIDE A SERVICE. FOR THEM THAT IS A POTENTIAL BARRIER. THAT ALSO FITS WITH THE ACADEMIC AWARDS FOR SERVICE FUNCTIONS BECAUSE THE REALLY GOOD ACADEMICS ARE NOT GOING TO BE REWARDED, NOT GOING TO BE HAPPY TO DO SERVICES. THE PRIMARY MISSION IS THEIR REWARD STRUCTURE IS BUILT ON INNOVATION AND PUBLICATION AND BEING A SERVICE FUNCTION IS NOT GOING TO BE IN A TRADITIONAL SENSE ACADEMICALLY REWARDING. WE WORRIED ABOUT TIMELINES, THE FACT THAT IF YOU'RE GOING TO HAVE A REGIONAL RESOURCE, YOU'RE GOING TO HAVE TO DECIDE WHO GETS TO USE IT.

THE PROBABILITY IS THAT PEOPLE MAKING THE TRIAGE ARE GOING TO BE REGIONAL, AND THE COMMITTEE THAT DOES THE GOVERNANCE IS PROBABLY NOT GOING TO HAVE WEEKLY CALLS. THEREFORE, THE MONTHLY MEETINGS DECIDE WHO GETS ACCESS TO THE FACILITY.

THERE'S AN AUTOMATIC __ BUILT IN. THERE WILL BE THE STANDARD SET OF REQUIREMENTS TO PREPARE AN APPLICATION IN ORDER TO BE ABLE TO USE A REGIONAL FACILITY. THAT IS A BARRIER THAT WILL BE PRESENT THAT PEOPLE HAVE TO BE AWARE OF. THERE'S A LOT OF INTELLECTUAL PROPERTY ISSUES THAT WE THINK CAN BE TEMPLATED OUT. THAT IS A SOLVABLE PROBLEM. THERE ARE MODELS, BUT THAT IS A POTENTIAL PROBLEM.

ANOTHER POTENTIAL PROBLEM IS SILOS AND RIVALRIES. WILL ONE INSTITUTION BE WILLING TO SEND THEIR MATERIALS TO ANOTHER COMPETITIVE PETITION DOWN THE STREET IF THEIR PRIMARY COMPETITOR IN THEIR RESEARCH HAPPENS TO BE RUNNING THE E-UNIT OF THE RTRC? ARE THEY GOING TO BE WILLING TO SEND THEM THE SPECIMENS AND THE MATERIALS, AND WILL THE INTELLECTUAL PROPERTY BE HONORED?

AND FINALLY, WE ALSO HAVE TO WORRY ABOUT PRIORITIZATION, DONE BY A BODY THAT IS SUFFICIENTLY AUTONOMOUS TO AVOID THE DEVELOPMENT OF FIEFDOMS AND __ RELATIONSHIPS IN THESE LABORATORIES. WE WERE WORRIED ABOUT UNCLEAR EXPECTATIONS FOR MANAGEMENT AND GOVERNANCE AS POTENTIAL BARRIERS. WE WORRY ABOUT PROBLEMS WITH MOVING PATIENTS AND SAMPLES FROM PLACE TO PLACE. WE WERE VERY WORRIED ABOUT UNDERFUNDING THE FACILITIES. BUT THE BASIC SOLUTION WE SAW HERE WAS THE PROBABLY THE FACILITY, THE GRANT WILL BE TO GENERATE THE INFRASTRUCTURE. THE OPERATING COSTS WILL COME OUT OF THE OPERATING REVENUE FOR PEOPLE WHO HAVE GRANTS ARE GOING __ AND ARE GOING TO USE THE FACILITIES.

SO WHAT WE'RE PAYING FOR IS AN INFRASTRUCTURE UNIT AND A SUPPORT FOR THAT YOU ARE NOT NECESSARILY PAY FOR THE OPERATING COST. WE WOULD HAVE TO DEVELOP BENCHMARKS FOR EVALUATING PROGRESS, THAT IS A POTENTIAL PROBLEM. THERE'S A POTENTIAL PROBLEM OF DEVELOPING MULTIPLE IRBs.

WE ALSO HAVE TO SOLVE PRIVATE-SECTOR INTEGRATION ISSUES. GIVEN THOSE BARRIERS AND CRITERIA, WHAT ARE SOME OF THE THINGS THAT WE CAN CONCEIVE OF? WE WILL FUND POTENTIALLY 4-8 EXPANDED RTRC UNITS. IT IS NOT LIKE ALL THIS LIST IS GOING TO HAPPEN. IT IS NOT LIKE ANY OF THE LIST IS NECESSARILY GOING TO HAPPEN BUT THESE ARE THE THINGS THAT WE SAW AS MODELS THAT COULD BE INCLUDED IN AN RFA AS THE KIND OF EXPANDED FACILITY THAT PEOPLE MIGHT APPLY TO DO.

GENOTYPING CENTERS. THE QUESTION IS IF THE TECHNOLOGY IS ALREADY TOO MATURE AND IF IT IS COMMERCIALLY AVAILABLE SO THAT PEOPLE WON'T FEEL A NEED TO USE A FACILITY LIKE THIS. WE

MIGHT THINK ABOUT HAVING COURSE FOR SMALL ANIMAL ADVANCED MOLECULAR IMAGING. PARTICULARLY PREPARATION OF RE-AGENTS OR IN FACT DOING THE IMAGING BECAUSE APPARENTLY IT IS REASONABLY EASY TO SHIP A MOUSE TO HAVE THEM IMAGED FOR A VARIETY OF DIFFERENT PHENOTYPIC CHARACTERIZATIONS.

SOME OF THESE YOU WILL SEE IN __. WE THOUGHT THERE COULD BE ONE NATIONAL CENTER THAT WOULD ADDRESS THE ISSUE. WE THOUGHT THAT HAVING SPECIALIZED BIOSTATISTICS, ABOUT GENETIC ARRAYS. MATCHING POPULATIONS AND REALIZING THIS IS FOR TRANSLATIONAL RESEARCH AND GIVEN THE CONTEXT WE STILL THOUGHT THERE WERE SPECIALIZED STATISTICAL EXPERTISE AND COMPUTER POWER THAT WOULD BE WORTH HAVING AT A GIVEN CENTER. WE HAD A LONG DISCUSSION ABOUT THE ISSUE OF PROTEOMICS, GENOMICS, METABOLOMICS, AND DEBATED CALLING THIS THE 'OMICS.'

A SPECIALIZED 'OMIC' FACILITY WOULD BE A POTENTIAL E-FACILITY. CHOOSE YOUR OMIC AND PROPOSE. ONE OF THE MORE INTERESTING CONCEPTS THAT CAME UP WAS THE POSSIBILITY OF HAVING A CENTER WHICH WOULD HOLD INFORMATION FROM CONSENTED PATIENTS WITH EITHER RARE DISEASES OR HEALTHY PATIENTS FOR CONTROLS IN COHORTS. THOSE COHORTS CAN BE DEFINED A LOT OF DIFFERENT WAYS, BUT WE WOULD HAVE A CENTRAL FACILITY TO WHICH CONSENTED PATIENTS AND THEIR GENETIC MATERIAL PARTICULARLY COULD BE TRANSFERRED TO USE AS A REPOSITORY. WE THOUGHT THAT WOULD BE A LOGICAL KIND OF CORE FACILITY, E-FACILITY

[LOW AUDIO]

__THE MATERIALS AND/OR THE PATIENTS. THE PATIENT'S INFORMATION WOULD BE PROVIDED BUT THE MATERIALS WOULD ALSO PROBABLY BE SENT TO A REPOSITORY. SO THAT IT IS MOST USEFUL. THE CONSTRUCTS HERE—THERE ARE A VARIETY OF DIFFERENT CONSTRUCTS—AS TO HOW THIS CAN BE DONE.

IT COULD BE A COHORT OF PATIENTS THAT CONSENT TO BE CONTACTED AS PART OF AN E-FACILITY. WE HAD DISCUSSIONS ABOUT IMAGING CENTERS—THERE ARE TWO DIFFERENT KINDS THAT WE COULD CONCEIVE OF. ONE IS THE HARDWARE FOCUS WHERE YOU HAVE VERY EXPENSIVE EQUIPMENT AND WHERE THE PATIENT HAS TO BE SHIPPED TO THAT KIND OF A FACILITY THAT IS ONE SORT OF POTENTIAL EXPANDED RTRC FACILITY. THE OTHER KIND IS THE ANALYTICALLY BASED ONE. FOR EXAMPLE, TRANSFERRING INFORMATION USING STANDARD EQUIPMENT FOR A DIFFERENT KIND OF ANALYSIS, USING A DIFFERENT KIND OF ALGORITHM FOR BETTER IMAGING OR NEW KINDS OF IMAGING. IN FACT, THIS IS ONGOING. THERE ARE ALREADY CENTERS DOING THIS USING THE

BRIN PROGRAM. IT CAN EITHER BE ANIMAL IMAGING OR IMAGING OF HUMANS DEPENDING ON THE CIRCUMSTANCE. THE "N" MEANS A NATIONAL CENTER. IT MEANS YOU COULD DO ONE BECAUSE THE HARDWARE ONE YOU WILL HAVE TO SHIP PATIENTS__THAT IS MORE LIKELY TO BE REGIONAL. THE ONE WHERE IT IS ANALYTICAL, YOU CAN SHIP THE DATA FROM ANYWHERE IN THE WORLD TO A SINGLE CENTER THAT WOULD DO THE ANALYSIS IN THAT KIND OF ANALYTICALLY BASED IMAGING CENTER.

WE PROPOSE THAT YOU MIGHT HAVE A GENOMIC-BASED DIAGNOSTIC UNIT AND GIVE THE NATIONAL LOOKING FOR A SPECIFIC SNPS LOOKING FOR SPECIFIC DISEASES. WE PROPOSE THAT YOU MIGHT HAVE A FACILITY THAT WOULD SYNTHESIZE ADVANCED MRI AND PET PROBES, AND THIS IS LRM BECAUSE THE ABILITY OF THIS TO BE A NATIONAL CENTER DEPENDS ON THE HALF-LIFE OF THE ISOTOPES. AND THAT IT MAY ONLY BE AVAILABLE LOCALLY. IT MAY BE AVAILABLE REGIONALLY IT MAY BE AVAILABLE NATIONALLY.

WE LOOKED AT THE POSSIBILITY OF HAVING ADVANCED FLOWCYTOMETRY TO LOOK AT INTRACELLULAR AND SURFACE MARKERS. WE LOOKED AT THE POSSIBILITY OF HAVING A CENTER THAT HAS SPECIALIZED REGULATORY EXPERTISE. THERE WAS SOME SKEPTICISM ABOUT THIS ONE—IF IT WAS NECESSARY—BUT THERE WERE SOME PEOPLE WHO ARGUED THAT SOME OF THE AREAS OF EXPERTISE WERE SO UNIQUE THAT THERE NEEDED TO BE ONE CENTER FOR THE TRANSLATIONAL EFFORT NATIONALLY THAT COULD BE TAPPED INTO TO SOLVE PROBLEMS WITHOUT HAVING TO GO TO THE FDA. AND ALSO A DISCUSSION ABOUT HAVING COMPUTATIONAL BIOLOGY FACILITY PARTICULARLY FOR COMPLEX GENE SYSTEMS.

WE DISCUSSED HAVING A TISSUE BANK AND ARRAY. THE KEY WITH A TISSUE BANK THAT WOULD BE GOOD WOULD BE THAT IT WOULD HAVE TO BE WELL CHARACTERIZED, ANNOTATED, AND DEFINED. IT WOULD PREPARE SPECIMENS IN A STANDARDIZED WAY FOR DISTRIBUTION TO PEOPLE WHO WORK IN THIS AREA. WE HAD A DISCUSSION ABOUT RE-AGENT REPOSITORIES AND NATIONAL ONES TO TRY AND SAVE PEOPLE FROM DOING REDUNDANT WORK IN OTHER AREAS. THIS HAS NOT WORKED. IN SOME AREAS IT HAS.

YOU CAN IMAGINE THAT IN SOME SCIENTIFIC DISCIPLINES THERE WOULD BE A USEFUL RE-AGENT REPOSITORY. THE CELL PROPER FACILITIES TO DO A GMP FACILITY THAT COULD PREPARE MATERIALS FOR INFUSION, PERHAPS FROM STEM CELLS, PERHAPS OTHER KINDS OF CELLS. THE ISSUE THERE WAS HOW MUCH COULD BE REGIONAL, HOW MUCH COULD BE NATIONAL, AND HOW MUCH HAD TO BE LOCAL DEPENDING ON WHAT THE CELL TYPE IS AND WHAT ITS PURPOSE IS. WE PROPOSE THAT WE MIGHT

HAVE EXPANDED USE OF THE PHARMACOKINETICS OF PHARMACODYNAMIC ANALYSIS AND ASSAYS AS WELL. ALSO __ SPECIALIZED CHEMICAL INFORMATICS TOOL TO BE ABLE TO TAP INTO DATABASES THAT ALREADY EXIST.

FINALLY, WE HAD A LONG AND NOT ENTIRELY FRUITFUL DISCUSSION ABOUT __ WITH INDUSTRY AND THE POSSIBILITY THAT HYBRID MODELS WE HAVE TO DEFINE ISSUES BY CONTROL, WHO PAYS, WHAT THE COST WOULD BE, WHAT THE INTELLECTUAL PROPERTY DISTRIBUTION WOULD BE, AND HOW TO HANDLE IT IF THERE MULTIPLE CENTERS, MULTIPLE ACADEMIC CENTERS AND INDUSTRY IN A COLLABORATIVE FACILITY. WE DID SOME OPERATIONAL WORK REGARDING THE FACT THAT THERE NEEDED TO BE REGIONAL EVALUATION COMMITTEES AT THE AXIS PORTAL, HOW WOULD THEY BALANCE THE DISEASES SO THAT ALL THE CENTERS CONTRIBUTING TO THIS FELT LIKE THEY GOT THEIR FAIR SHARE OF ACCESS? AND WE THOUGHT IT WAS KEY THAT THE CENTERS FOCUS ON MERIT FIRST.

THERE WOULD PROBABLY BE EDUCATION AND OUTREACH WITH EACH OF THESE EXPANDED PROGRAMS AND THERE WOULD NEED TO BE EVALUATION CRITERIA. ANY QUESTIONS PEOPLE HAVE?

STEVE STRAUS: VERY CLEAR ROSS. QUESTIONS OR COMMENTS, IF YOU'RE NOT TIRED OUT YET? WE'RE JUST STARTING.

[LOW AUDIO] AUDIENCE MEMBER

ROSS McKINNEY: WE DID NOT ADDRESS THAT SPECIFICALLY AND I WOULD LEAVE IT TO NIH TO SORT SOMETHING LIKE THAT OUT.

STEVE STRAUS: THEORETICALLY, YES, WE WOULD HAVE TO DISCUSS THAT. OTHER COMMENTS OR QUESTIONS? IN FACT, THERE MAY BE AN ADVISABILITY TO DE-LINK THESE BECAUSE OF THE COMPLEXITY OF ALL OF THE NEEDS AND SERVICES. ONE OF THE PROBLEMS IS THAT THE MENU IS SO LARGE, HOW YOU DECIDE WHAT YOU CAN DO WELL AS OPPOSED TO TRYING TO DO EVERYTHING POORLY? OTHER COMMENTS OR QUESTIONS? YES?

[LOW AUDIO] AUDIENCE MEMBER

ROSS McKINNEY: WE HAD HOPED TO TRY TO ARTICULATE A LOT OF DIFFERENCES OF WHICH THE BENCH PART, THE PILOT PROJECT PART, IS UNIQUE. AND MUCH DEEPER SERVICES IN CERTAIN AREAS THAN THE GCRCSs CAN PROVIDE. GCRC PROVIDES A GOOD CLINICAL ENVIRONMENT NOT AS MUCH BIOSTATITICAL SUPPORT AND BIOINFORMATICS SUPPORT AND THE LIKE. STEVE WILL YOU ADD TO THAT?

[LOW AUDIO]

STEVE STRAUS: NO, IT IS A PROBLEM. YES, YOU ASKED IF IT IS A PROBLEM, I'M SAYING, YES, IT IS A PROBLEM. THIS IS NOT TO AUGMENT THE GCRC. GCRCs SERVE AN INSTITUTION AND THE ONE OR MORE GCRCs WITHIN A REGION CAN PARTICIPATE IN A CONSORTIUM THAT WOULD APPLY FOR THIS. AT LEAST THE PEOPLE WHO RUN IT AND ARE SERVED BY IT CAN APPLY FOR IT. BUT THIS IS NOT TO ENLARGE A GCRC OR EXPAND ITS SERVICES, SIMPLY BECAUSE THE GCRCs ARE A ROBUST PROGRAM THAT DOES NOT NEED TAMPERING WITH. WE'RE TRYING TO EXPERIMENT WITH A NEW KIND OF SERVICE WITH DIFFERENT KINDS OF NEEDS. WOULD YOU AGREE, ANTHONY?

ANTHONY HAYWARD: YES. I THINK THE IDEA OF SOMETHING THAT GOES BEYOND, THAT IS GREATER THAN A GCRC IS AN IMPORTANT COMPONENT, AND WHAT WE TALKED A LOT ABOUT IS TO SAY TO POTENTIAL FOR PARTNERING AN EXISTING__.

[LOW AUDIO]
[LOW AUDIO] AUDIENCE MEMBER

STEVE STRAUS: THAT, YES. ABSOLUTELY. PLEASE.

[LOW AUDIO] AUDIENCE MEMBER

STEVE STRAUS: IT CAN TAKE ADVANTAGE OF IT IN ALL THE OTHER ENVELOPES OF EXISTING RESOURCES THAT SERVE TRANSLATIONAL RESEARCH WITHIN THAT REGION, BE IT VIRTUAL, GEOGRAPHICAL, OR THEMATIC, HOWEVER YOU DEFINE IT, THE ANSWER IS, YES. EXCEPT THAT THERE'S NOT A CO-MINGLING OF FUNDS, FOR EXAMPLE. YES, IF YOU WANT TO FOLLOW UP.

[LOW AUDIO] AUDIENCE MEMBER

STEVE STRAUS: CORRECT.

[LOW AUDIO] AUDIENCE MEMBER

STEVE STRAUS: YOU TAKE THAT PROBLEM UP WITH THE NATIONAL CENTER FOR RESEARCH RESOURCES.

[LAUGHTER]
[LOW AUDIO]

STEVE STRAUS: YOU MAY REMEMBER, JERRY __, THE QUESTION HAS TO DO WITH WHERE YOU GET THE PRODUCTION. YOU MAY REMEMBER ONE

OF THE EARLY COMMENTS I MADE ABOUT THE TRANSLATIONAL RESEARCH CORES THAT JOSIE BRIGGS IS SPEARHEADING. WE ARE EXPANDING THE CONTRACT FACILITIES THAT NCI HAS AND WE ARE STARTING WITH THE SYNTHESIS UNDER GMP OF SMALL MOLECULES WITH A MAJOR EMPHASIS ON PROJECT OVERSIGHT AND CONTROL, AND IT ISSUES. WE HOPE IN TIME TO EXPAND THAT TO BIOLOGICALS AND NOT JUST SMALL MOLECULES. YOU'RE ABSOLUTELY RIGHT.

THE OTHER POINT THAT A COUPLE OF YOU MADE TO ME IN VARIOUS BREAKS IS THAT THERE ARE ALREADY MANY PLACES WHERE THOSE PRODUCTS ARE AVAILABLE, THE BIOTECH INDUSTRY, DRUG INDUSTRY HAS ALL SORTS OF MOLECULES THEY DON'T WANT TO INVEST IN PHASE I STUDIES AS OF YET BECAUSE THEY'RE NOT SURE THERE IS A MARKET TO IT. BUT IT IS A PRODUCT THAT COULD BE MADE AVAILABLE, SO ANY PLACE AN INVESTIGATOR COULD GET A RE-AGENT THAT IS WORTH THIS PHASE I STUDY IS AN ENVIRONMENT.

WE ENDED THE LAST PRESENTATION WITH THE ISSUE OF GOVERNANCE OF THESE COMPLEX CORES AND TO DEAL MORE WITH THE GOVERNANCE WE WILL END WITH THAT GROUP, BECAUSE ONCE YOU CAN AGREE HOWEVER DIFFICULT IT IS WHAT THE THINGS ARE SUPPOSED TO BE THEN THE HARD THING IS THE RULES.

GOVERNANCE OF CENTERS—GORDON WILLIAMS:

I AM GLAD TO SEE THAT THERE IS A LEAST 10 PERCENT OF THE CREW STILL HERE TO FIND OUT HOW WE WILL GOVERN IT. MAYBE THEY HAVE GIVEN UP BECAUSE THEY DON'T THINK IT CAN BE GOVERNED WELL. OUR GROUP WAS CHALLENGED WITH THIS AND WE __. IT IS OBVIOUSLY A LITTLE HARD TO PROVIDE A STRUCTURE UNLESS YOU KNOW WHAT THE FUNCTION IS.

SO, WE HAD TO MAKE SOME ASSUMPTIONS IN WHAT WE THOUGHT THE FUNCTION OF THESE RTRCS IS GOING TO BE. THE FIRST THING WE DID WAS TO SIMPLY PREPARE A LIST OF WHAT WE THOUGHT WOULD BE THE GOALS OF THE RTRC: BETTER UNDERSTANDING OF DISEASE PROCESSES, ACCELERATED DEVELOPMENT OF IMPROVED APPROACHES TO DIAGNOSE, TREAT, AND PREVENT DISEASES AND CONDITIONS, ANDFACILITATE THE TRANS-DISCIPLINARY CROSS-TALK AS THE OVERALL GOALS.

THEN WE HAD A LIST OF AIMS THAT WE THOUGHT WOULD COME OUT OF THESE GOALS, CREATING A SEAMLESS INTERFACE BETWEEN INDUSTRY AND ACADEMIA. WE REALLY THOUGHT THIS WAS GOING TO BE A CRITICALLY IMPORTANT ELEMENT OF THE ENTIRE PROCESS OF THE RTRCs. THAT IS, TO FIGURE OUT THE WAY TO BRING TOGETHER THESE

TWO MAJOR 800-POUND GORILLAS IN THIS WAR AGAINST DISEASE. THAT IS INDIVIDUALS FROM INDUSTRY AND INDIVIDUALS FROM ACADEMIA, WHICH WE HAVE NOT BEEN VERY SUCCESSFUL OVER THE LAST 30 YEARS OR LONGER IN DOING. PROVIDING THE INFRASTRUCTURE FOR INTERACTION AMONG EXISTING CENTERS, WHICH HAS BEEN DISCUSSED, DEVELOP HARMONIZED APPROACHES AND RESOURCES THAT YOU HAVE HEARD ABOUT ALREADY.

PATIENT RECRUITMENT, DATABASE, CENTRAL IRB. ELIMINATE REDUNDANCY, RATHER THAN PRODUCE ADDITIONAL REDUNDANCY. ESTABLISH INSTITUTIONAL COMMITMENT, AND ENCOURAGE INCLUSION OF MINORITY OR UNDERSERVED POPULATIONS THAT MAY ACTUALLY BE NOT NECESSARILY MINORITIES, BUT UNDERSERVED GROUPS OF INDIVIDUALS.

WE THEN DECIDED TO DIVIDE IT INTO THREE MAJOR TOPICS THAT WE ADDRESSED: STRUCTURE, GOVERNANCE, AND FINANCE, NOT NECESSARILY IN THAT ORDER. THE STRUCTURE WE ASSUMED THAT THE PRIMARY SUPPORT AND THESE WOULD BE SOME OF THE CRITERIA THAT WOULD BE USED IN JUDGING PRESUMABLY THE RTRCs, PRIMARY SUPPORT INFRASTRUCTURE COST RATHER THAN ACTUAL COST OF RUNNING AN OPERATION CAN BE GEOGRAPHIC OR THEMATIC POTENTIALLY. ENGAGE PRIVATE INDUSTRY WE THINK WOULD BE A VERY USEFUL AND IMPORTANT CRITERIA, PROVIDE LONG-TERM FUNDING, SUPPORT TEAM INFRASTRUCTURE RATHER THAN INDIVIDUAL INFRASTRUCTURE. ORGANIZE TRAINING EFFORTS, NOT ANY NEW TRAINING INITIATIVES. WE THINK THERE ARE ENOUGH OUT THERE, BUT MAKE SURE THEY ARE ORGANIZED EFFECTIVELY IN THAT PARTICULAR REGIONAL CENTER, DISSEMINATE EFFECTIVE PRACTICES AND DISTRIBUTE GRANT CREDIT APPROPRIATELY AND FAIRLY AMONGST THE VARIOUS INDIVIDUAL COMPONENTS OF THE CENTER.

NOW, THE STRUCTURE. THESE ARE THE POTENTIAL MODELS WE CAME UP WITH FOR THE GOVERNANCE OF THESE CENTERS. THE ONE THAT WAS THE MOST ATTRACTIVE FOR THE GROUP WAS SOMETHING THAT IS VERY DIFFERENT THAN WHAT WE NORMALLY DO. INSTEAD OF USING THE NORMAL APPROACH, BECAUSE WE WERE TOLD TO THINK OUT OF THE BOX AND REALLY THOUGHT OUT OF THE BOX.

THE NUMBER ONE, I CAN'T SAY THAT THEY ALL HAVE TO FIT THIS MODEL BUT THE NUMBER ONE POSSIBILITY IS TO FORM A 501C. A NOT-FOR-PROFIT CORPORATION THAT ACTUALLY WOULD BE THE RTRC. IT WOULD BE A CONSORTIUM OF ACADEMIC CENTERS, INDUSTRY, ADVISORY BOARDS, SUBCONTRACTING PARTICIPATING UNITS MODELED ON EXISTING PROGRAMS LIKE THE ARIZONA TRANSLATIONAL GENOMIC INSTITUTE. WE THINK THIS HAS A LOT OF THE POSSIBILITIES TO GET RID

OF SOME OF THE PROBLEMS WE HEARD IN THE PREVIOUS THREE PRESENTATIONS IN TERMS OF HOW YOU GET THESE THINGS TO INTERACT EFFECTIVELY, PARTICULARLY INDUSTRY, ACADEMIA, THE INDIVIDUAL CENTERS, HOSPITALS, THE UNIVERSITY, AND SO FORTH. THAT WAS ONE WE THOUGHT WOULD BE WORTHWHILE, PUTTING PUT IN THE RFA AS A POTENTIAL FORM OF HOW THEY COULD BE RESPONDING.

THE OTHER TWO ARE MORE TRADITIONAL: AN ORGANIZATION LIKE A CONSORTIUM, FOR EXAMPLE, THAT INTERFACES AMONG UNIVERSITIES, HOSPITALS, AND INDUSTRY TO PROVIDE CORES AND SERVICES TO THE REGIONAL CENTER.

THE THIRD ONE IS MORE OF AN ADMINISTRATIVE ENTITY OR A COORDINATING CENTER LIKE ACTIVITY LINKING EXISTING SYSTEM AND __ CENTERS TOGETHER PROVIDE SERVICES LIKE CENTRAL IT SYSTEMS, TISSUE DATABASES, AND SO FORTH. THOSE WERE THE THREE MODELS IN TERMS OF THE STRUCTURE AND __ OF THE ENTITY OR THE GOVERNANCE, AND THE SPECIFIC GOVERNANCE WOULD FLOW FROM THAT.

THESE ARE SOME OF THE THINGS THAT WOULD HAVE TO BE CONSIDERED IN TERMS OF THE SPECIFIC GOVERNANCE. FIRST THERE ARE THE FINANCIAL ISSUES. IMPLEMENT MECHANISMS FOR CHARGEBACK, INCLUDE DEVELOPMENTAL AND PILOT PROJECT FUNDS FOR COLLABORATIONS WITH OTHER NIH-FUNDED CENTERS AS WE DISCUSSED, DEFINE MECHANISMS FOR INDUSTRY PARTICIPATION WHICH WE THINK WOULD BE A CRITICAL COMPONENT FOR THE REGIONAL CENTERS, CLARIFY FINANCIAL ARRANGEMENTS FOR IT AND LICENSING AGREEMENTS AND SO FORTH THAT YOU HAVE ALREADY HEARD SOMETHING ABOUT.

GOVERNANCE OF EACH RTRC WOULD NEED TO ESTABLISH GUIDANCE FOR ASSURING, THEY WON'T ALL BE THE SAME WE THINK, BUT FOR ASSURING ACCOUNTABILITY, ACCESS OF AN INSTITUTION AND INVESTIGATORS TO THE RESOURCES AVAILABLE, AND QUALITY CONTROL OF THE PRODUCT BEING PRODUCED IN THE END. DEFINE INTERACTIONS WITH OTHER EXISTING NETWORKS; DON'T ASSUME THEY WILL OCCUR. SPECIFICALLY DEFINE HOW YOU'RE GOING TO INTERACT WITH EXISTING NETWORKS, CENTERS, AND CORES THAT ARE ALREADY AVAILABLE IN THAT PARTICULAR REGIONAL CENTER ENVIRONMENT. DESCRIBE HOW EACH INSTITUTION AND INDUSTRY PARTNER IN THE RTRC GOVERNANCE STRUCTURE. DEFINE INTERACTIONS WITH OTHER RTRCS. THAT WAS THE DELIBERATION THAT WE HAD. I THINK THE NOVEL THING WAS TO DEFINE A DIFFERENT MECHANISM BY WHICH YOU WOULD PUT THIS TOGETHER BEYOND WHAT WE TRADITIONALLY WOULD THINK IN ACTIVITIES THAT ARE FUNDED FROM NIH.

STEVE STRAUS: COMMENTS OR QUESTIONS FOR GORDON?

STEVE STRAUS: WE WERE VERY WORRIED THAT THIS WOULD BECOME A SYSTEM IN WHICH THE SERVICES WOULD NOT BE DISTRIBUTED FAIRLY AND ACCORDING TO THE MERIT OF THE IDEAS EMERGING FROM EACH OF THE REGIONAL SITES. WE NEED TO AVOID THE POSSIBILITY THAT PRIORITY COULD BE GIVEN TO WORK BY THE PEOPLE WHO LEAD THE CENTERS. IT IS CRITICAL THAT WE AVOID THAT AND THAT THERE BE SOME SHARED GOVERNANCE AMONG THAT. YOU HAVE GIVEN US A LOT OF IDEAS FOR OPTIONS ABOUT HOW TO WRITE THIS. THREE DIFFERENT MODELS, THE 501C STRUCK ME OF COURSE. HOW DO THE OTHER TWO DIFFER, 2 AND 3?

GORDON WILLIAMS: 2 AND 3 DIFFER DEPENDING ON HOW MUCH SERVICES YOU WANT TO PROVIDE DIRECTLY TO IT. ONE IS LIKE A TRADITIONAL COORDINATING CENTER. THEY TAKE ALL THE SERVICES THAT ALREADY AVAILABLE IN THAT PARTICULAR REGION WORK OUT WAYS TO BUILD BRIDGES OR CONNECTIONS BETWEEN THEM FOR THE INDIVIDUAL INVESTIGATORS SO THEY DON'T HAVE TO WANDER THROUGH TRYING TO FIGURE IT OUT ON THEIR OWN AND FILL IN THE GAPS WHERE THERE MIGHT BE GAPS IN A PARTICULAR SERVICE. IT IS KIND OF A SUPER-COORDINATING CENTER.

THAT IS THE WAY WE DESCRIBE IT. THE CONSORTIUM APPROACH IS THE MORE STRUCTURED INTERACTION OF THE INDIVIDUAL COMPONENT OF THE CENTER—OF THE REGIONAL CENTER—WHERE THERE WOULD BE MUCH MORE INTERACTION AND PROBABLY MORE PROGRESS IN TERMS OF DEVELOPING A SPECIFIC GAME PLAN THAN WHAT YOU WOULD HAVE WITH THE COORDINATING CENTER ALONE. WE DID NOT WANT TO RESTRICT WHAT PEOPLE MIGHT WANT TO DO BECAUSE IN DIFFERENT CENTERS SOME MIGHT WORK OUT MUCH BETTER THAN OTHERS. BUT I THINK IF YOU TOOK A VOTE OF—WHAT DID WE HAVE, ABOUT 25 PEOPLE IN THE ROOM—I THINK THEY WOULD GO DOWN IF YOU WANT TO RATE THEM 1 TO 10, 10 BEING THE BEST, IT WOULD BE 10, 5 AND 1.

THE THREE WE STRUCTURED MIGHT BE BEST, GIVEN THE COMPLEXITY OF WHAT WE'RE TALKING ABOUT AND WE HAD A STRONG, STRONG COMMITMENT FROM THE GROUP THAT YOU NEED TO FIGURE OUT WAYS TO INVOLVE INDUSTRY. AND IT LOOKED LIKE THE 501C WOULD BE THE EASIEST WAY TO ACCOMPLISH THAT GIVEN THE COMPLEXITY OF THE RELATIONSHIPS.

STEVE STRAUS: ROSS?

[LOW AUDIO] ROSS McKINNEY

GORDON WILLIAMS: WE DEBATED THAT AND DECIDED TO LEAVE THAT UP TO THE INDIVIDUAL APPLICANT.

STEVE STRAUS: WE WILL HAVE TO TALK TO THE NIH LAWYERS.

GORDON WILLIAMS: WE SORT OF LEFT IT BECAUSE OBVIOUSLY THIS IS PRETTY NOVEL. NIH HAS TO THINK IF THEY WANT TO BE THIS CREATIVE, WE WILL USE THAT TERM. ON ONE LEVEL, YOU CAN SAY A SINGLE ONE WITH THESE INDIVIDUAL CENTERS BEING COMPONENTS OF IT MIGHT HAVE SOME UTILITY IN A LOT OF DIFFERENT WAYS. BUT ON THE OTHER HAND, WE ALSO THOUGHT THE DISADVANTAGES OF THAT APPROACH BECAUSE OF THE POTENTIAL FOR COMPLEXITY THAT MIGHT MAKE IT UNWIELDY TO WORK THROUGHOUT THE ENTIRE COUNTRY.

[LOW AUDIO]

STEVE STRAUS: WHAT WE DECIDED, BECAUSE THERE ARE A LOT OF DIFFERENT WAYS YOU CAN DO THIS, WE ARE GOING TO LET THE INDIVIDUAL INSTITUTION COME AND THE REVIEW CRITERIA WILL DETERMINE WHICH ONE SOUNDS REASONABLE AND MORE IMPORTANTLY WHICH ONE WILL WORK IN A PARTICULAR REGIONAL CENTER. SOME CASES IT WILL WORK ONE WAY, AND SOME CASES IT WILL WORK ANOTHER BECAUSE THE RENT IS ONLY ONE PART OF IT, THERE ARE A NUMBER OF OTHER ASPECTS AS YOU MIGHT IMAGINE, BUT WHAT THIS DOES IS CREATE THE FLEXIBILITY TO ALLOW YOU TO DO A VARIETY OF DIFFERENT THINGS THAT IN THE USUAL APPROACH WHERE OUR HANDS ARE TIED AND YOU CAN NOT DO SOME THINGS THAT YOU CAN DO WITH A REGIONAL CENTER.

[LOW AUDIO]

WILLIAMS: NO BECAUSE IT WOULD NOT BE A LABORATORY. WE WOULD NOT—I WOULD SUSPECT ANY OF THE CORES THAT END UP BEING LABORATORIES THAT YOU HEARD ABOUT BEFORE IF WE CAN DO THAT OBVIOUSLY SOME CORES CANNOT BE CLEAR REGISTER BECAUSE THERE'S NO CLEAR REQUIREMENT SET UP YET BUT WHEREVER THERE IS A—I WOULD ASSUME THAT ANY OF THE CORES THAT HAD TO HAVE IT WOULD HAVE TO BE CLEAR REGISTERED BECAUSE YOU CANNOT DO THE SAMPLE TRANSPORT, SAMPLE ANALYSIS THAT YOU NEED.

[LOW AUDIO]

WILLIAMS: THAT IS POSSIBLE. WE DID NOT REALLY THINK ABOUT THAT PER SE BECAUSE WE ARE CONCENTRATING ON THE RESEARCH PART OF IT AND I STILL THINK THAT IS WHAT NEEDS TO BE THE FOCUS. ONCE YOU HAVE THIS IDEA OF HAVING THIS 501C AROUND THAT COULD LINK THESE

THINGS YOU CAN THINK OF A LOT OF DIFFERENT THINGS BUT I THINK FIRST WE HAVE TO PILOT HOW THIS IS GOING TO WORK FOR THE THINGS WE ARE INTERESTED IN, WHICH I THINK IS TRANSLATIONAL RESEARCH HERE.

[LOW AUDIO]

STRAUS: IT DEPENDS ON HOW IT IS WRITTEN AND I DON'T THINK WE ARE CONSTRAINED THAT WAY.

[LOW AUDIO]

STRAUS: EXACTLY RIGHT. ONCE YOU HAVE THOUGHT ABOUT IT YOU HAVE A LOT OF CREATIVITY. IT WAS A VERY EXCITING DISCUSSION.

[LOW AUDIO]

WILLIAMS: I THINK THAT SUMMED UP OUR OPINION ALSO. THAT IS WHY DID NOT WANT TO BE TOO SPECIFIC, [INSTEAD] GIVING THEM THE GENERAL APPROACH AND LET THEM DECIDE HOW THEY WANT TO PACKAGE IT BUT GIVE THEM ANOTHER OPTION BEYOND THEIR USUAL OPTIONS FOR NIH GRANTS.

STEVE STRAUS: THERE ARE MANY TRIAL NETWORKS, FOR EXAMPLE, THAT HAVE THEIR OWN PLANNING MEETINGS, WRITING COMMITTEES, PRIORITIZATION COMMITTEES, AND HUMAN USE COMMITTEES. BY THE TIME THE PROTOCOL GETS THROUGH THE BABY IS BORN IS GOING TO HIGH SCHOOL. WHAT WE WANTED TO DO WAS TO TRY TO CREATE A FAST AND MORE FLEXIBLE NIH-DRIVEN PROCESS AND THAT THE CONTROLS DO NOT EXERT THEMSELVES OR ADD REDUNDANCY. THAT IS WHY WE TALKED ABOUT CENTRAL IRBs, FOR EXAMPLE, RATHER THAN HAVING MULTIPLE IRBs.

ANY OTHER COMMENTS FOR GORDON OR QUESTIONS?

LET ME TRY TO SUM UP. THE REASON PEOPLE LEFT IS BECAUSE IT IS A FRIDAY AFTERNOON IN THE SUMMERTIME AND GOD KNOWS SOME PEOPLE HAVE OTHER LIVES. I DON'T KNOW ANY OF THEM PERSONALLY, BUT LET'S SUM UP. WE STARTED THE DAY BY SHARING WITH YOU WHAT WE LEARNED FROM THE COMMUNITY WAS NEEDED IN TERMS OF THE ROADMAP AS A WHOLE, IN TERMS OF CLINICAL RE-ENGINEERING, IN TERMS OF THE PROPOSALS WE'VE HAD TO TRY AND AUGMENT THE CAPACITY TO DO RTRCs AND DO IT IN A RELATIVELY FASTER WAY THAT WAS LOCALLY DRIVEN THAT WOULD HAVE SOME ECONOMIES OF SCALE. WE SENT OUT A STRAW MAN FOR YOU TO REFLECT UPON.

WHAT I'VE SEEN HAPPEN OVER THE DAY IS IN A MANNER OF SEVERAL HOURS, YOU HAVE COME TO APPRECIATE WHAT TOOK US A LOT OF MONTHS TO APPRECIATE, WHICH IS HOW COMPLICATED THIS IS AND HOW MANY DIFFERENT MODELS THERE ARE. WE HAVE HAD SOME VERY GOOD SUGGESTIONS. WE OBVIOUSLY HAVE NOT RESOLVED SOME OF THE THORNY ISSUES OF WHICH CORES AND WHICH SERVICES, ALTHOUGH WE'VE HEARD ABOUT SOME PRIORITIES. MORE IMPORTANTLY, WE HAVE HEARD SOME SETS OF RULES BY WHICH TO MAKE THESE DECISIONS. WE HAVE HEARD SOME RESOUNDING SUPPORT FOR THE IDEA OF THERE BEING FLEXIBILITY, RATHER THAN A MONOLITHIC APPROACH, AND ALLOWING PEOPLE TO JUSTIFY THEIR APPROACHES WITHIN CERTAIN RELATIVELY WIDE BOUNDS AS LONG AS THEY SERVED OUR NEEDS.

OUR RESPONSIBILITY IS TO TAKE ALL THESE BULLETED COMMENTS AND POST THEM ON OUR WEB SO THAT OTHER PEOPLE CAN GIVE US FEEDBACK AND COMMENTS ON THEM. OUR WORKING GROUP IS MEETING NEXT WEEK. WE WILL START DRAFTING THIS RFA AND WILL TRY TO HAVE AN RFA ON THE STREET BY OCTOBER 1ST.

ONE OF THE ADVANTAGES OF HAVING 1 OR 2 YEARS OF PLANNING TIME IS IT REALLY MEANS THAT WE AT NIH ALSO HAVE A YEAR OR TWO TO PLAN BETTER FOR WHAT THE CENTER SHOULD BE AND TO LEARN FROM YOU AND YOUR APPLICATIONS WHAT WORKS AND WHAT DOESN'T. THERE'S A LOT OF NEW MONEY BUT NOT ENOUGH NEW MONEY. BUT AT LEAST THERE IS A COMMITMENT TO TRY TO DO THIS BETTER.

LET ME ASK STEVE, ANTHONY, KAREN, ANY OF YOU, IF THERE ARE ADDITIONAL SUMMARY POINTS THAT YOU WOULD WANT TO MAKE AT THIS POINT. ANTHONY?

ANTHONY HAYWARD: NO. I HAVE ENORMOUSLY VALUED THE FEEDBACK WE HAVE RECEIVED TODAY AND IT HAS BEEN TREMENDOUSLY USEFUL.

STEVE ZALCMAN: WE RECEIVED SOME VERY INTERESTING IDEAS, PROPOSALS THAT WE WERE NOT CLEVER ENOUGH TO THINK OF.

STEVE STRAUS: IT IS HUMBLING THAT WE AT THE NIH CANNOT FIGURE THIS ALL OUT OURSELVES, BUT IT IS QUITE TRUE. THOSE OF YOU WHO HAVE BEEN THE RAPPORTEURS, I WOULD LIKE TO THANK YOU. THOSE PARTICULARLY FROM THE OUTSIDE WHO CO-CHAIRED THE GROUPS—ROSS, DENNIS, GORDON, AND ERIC—I AM REALLY PLEASED THAT YOU WERE ABLE TO COME AND SPEND TIME WITH US AND HELP SHAPE THIS. I WANT TO THANK YOU FOR COMING AND WISH YOU A SAFE TRIP HOME. WE PROMISED TO GET YOU OUT ON TIME, WHICH IS HOW I TRY TO LEAD MY LIFE. THERE ARE SHUTTLES AVAILABLE AND ALL I CAN SAY IS WE WILL KEEP IN TOUCH. THANK YOU VERY MUCH.