

General Clinical Research Center (GCRC) At Johns Hopkins

For over 40 years, the General Clinical Research Center (GCRC) has been the place for Johns Hopkins faculty to do their patient-oriented research. Many of the most important clinical investigators in the world have worked on the Hopkins GCRC or its predecessor units-names like George Thorn, Fuller Albright, Helen Taussig, Victor McKusick, Saul Brusilow and Richard Ross. GCRC's mission is to support outstanding clinical research at all stages (pilot studies to multi-center trials). The GCRC supports adult inpatient and outpatient and pediatric units as well as a neurobehavioral research unit. Protocol applications are reviewed monthly. GCRC support a wide range of services. The primary role of the GCRC staff is to work with investigators, to help them accomplish the most ethical and scientifically sound research.

Units & Services

Adult Inpatient Unit

Services Offered:

- Nursing support, including a Research Nurse Specialist
- Nutritional support, including a metabolic kitchen
- Expertise in pharmacokinetic sampling
- ACLS certified nursing staff
- On-site processing for laboratory specimens
- Cardiac monitoring

Facilities Available:

- 14 beds (6 double and 2 single rooms)
- 2 negative pressure rooms
- Sample collection Area
- Centrifuge
- Lounge area for Study participants

Outpatient Unit

Services Offered:

- Scheduling of patients in EPIC
- Phlebotomy
- Nursing support and vital signs
- Nutritional support, including meal preparation
- Interviewing
- Dexa scanning
- Pharmacokinetic sampling
- Medication administration
- Electrocardiograms
- Laboratory processing of samples
- Temporary sample storage

Facilities Available:

- 9 Exam rooms
- 2 Interview rooms
- Infusion room
- Sample processing lab
- Dexa scanner
- Conference room
- Patient rest rooms
- Phlebotomy space
- Reception/waiting area

Services Offered (continued):

- Fax services
- Computer access
- Emergency equipment and CPR
- Student nursing/phlebotomist internships

Pediatric Clinical Research Unit (PCRU)

Services Offered:

- Phlebotomy
- Nursing support that's skilled in the care of children
- Nutritional support - including a metabolic kitchen
- DEXA scanning
- Sleep lab for sleep studies
- Child Life services

Facilities Available:

- 7 beds (3 single rooms and 2 double rooms)
- Treatment room
- Procedure room
- Outpatient clinic with 4 exam rooms

Neurobehavioral Research Unit (NBRU)

Services Offered:

- Neurobehavioral assessments:
Neuropsychological testing
Operant performance measures
Customized assessments
- Neuroimaging:
Structural and functional MRI
Spectroscopic and diffusion analysis
Fiber track mapping
- Inpatient services
- Auditory function assessments
- Movement assessments
- Protocol development assistance
- Participant behavior training

Facilities Available:

- 1.5 and 3.0 Tesla scanners
- MRI compatible EEG
- High resolution evoked potentials (EP)
- MRI simulator
- Motion analysis laboratory
- Audiology laboratory
- Neurobehavioral inpatient unit (NBU)
- Brain injury inpatient unit (BIU)

Nutrition Education Material

The GCRC can provide Research Nutrition Services for your research protocol. This service has two primary roles: to assure that the nutritional requirements of research protocols are met, and to encourage use of our nutritionists' expertise in planning and executing protocols.

Biostatistics

The Biostatistics core supports clinical investigators through Protocol Review, Consultation, Collaboration, Teaching, Methodologic Innovation, and Bridge Building Meeting with investigators can both improve the study design and speed protocol review since design and analysis issues are addressed up-front. It is strongly suggested that a biostatistician review the protocol prior to submission.

Data & Computing

- Provide the advice and support of a System Manager to help GCRC investigators with their computer/data needs.
- Provide advice on database design, data security and alternative methods of data collection.
- Provide state-of-the-art computing for GCRC funded studies

Research Subject Advocate

The primary responsibility of the Research Subject Advocate (RSA) is to provide assurance to the Principal Investigator (PI) of the General Clinical Research Center (GCRC) that appropriate efforts are being made throughout any clinical research activity at the GCRC to protect the participating individuals and to ensure that their safety receives the highest priority.



Johns Hopkins Medicine International, LLC

JHMI is a corporate vehicle formed and wholly owned by Johns Hopkins Medicine (“JHM”)¹ and is charged with advancing the institutional vision to improve health care through excellence in high quality research, teaching, and patient care on a global scale. For more than a decade, JHMI has specialized in helping government and non-governmental organizations, academic institutions, health care providers and other health care and life science organizations reinvigorate or develop radically new standards and models of patient care, medical education and research.

Serving as the central interface between JHM and certain other Johns Hopkins institutions, JHMI’s Global Ventures and Global Services divisions are a team of professionals that specialize in enterprise development and strategy consulting, as well as encompass experienced project managers that have extensive knowledge transfer experience to assist with providing guidance on programmatic development; offering on-site hospital and technical management services; and coordinating the relevant talent and resources to meet a clients objectives.

We fully understand that the diversity of the world’s populations means that we must craft consultancy and management services solutions that are unique to regions, cultures, and health care practices and standards. That knowledge, combined with our analytical ability, project management expertise, and our access to the Johns Hopkins institution’s extraordinary assets – *intellectual property, cutting-edge diagnostic and therapeutic capabilities, and state-of-the-art health care infrastructure* – allows us to customize solutions to specific health system and cultural needs and requirements.

Our approach to clinical, operations, management and administrative consultancy and management services is to generate a clear course of action. We are a data-driven organization and for every engagement, big or small, we employ leading health care domain experts to establish a framework and an analytical tool that will guide action. We collaborate with our clients to develop a range of practical strategic options that achieve long-term goals by maximizing short-term outcomes and performance. Our process has yielded remarkable results – rapid growth of our business and enormous value creation for our international partners.

¹ JHM is a term used in referring to certain collaborative activities of the Johns Hopkins Health System and the Johns Hopkins University School of Medicine.

Clients see this value in everything from the design and development of high-technology facilities, increased demand for premium services, reduced overhead, streamlined operations, improved safety and standards of excellence, industry accreditations, and relationships that maximally leverage direct access to patient care, education and research technology and innovations.

Institutional Excellence

Whether we are collaborating on health care consultancy and management services solutions for a complex, large-scale master planned development project, a clinical programmatic development project or an academic collaboration, we achieve our objectives through creative vision, outstanding teamwork and a strong commitment from the leading JHM experts. Statistically, the human capital within JHM includes more than 3,600 faculty members and approximately 10,000 medical staff and registered nurses that make up the 28,000 total employees that generates approximately US\$ 4 billion in annual revenue and have earned the honor of becoming the United States' #1 hospital ranked by *U.S. News and World Report* for seventeen years in a row. The following clinical specialties listed below demonstrate JHM's leadership position in health care delivery:

- #1 in Ear, Nose and Throat; Gynecology; Rheumatology; and Urology
- #2 in Neurology and Neurosurgery; Ophthalmology; Geriatrics; and Psychiatry
- #3 in Cancer, Digestive Disorders; Endocrinology; and Respiratory Disorders
- #4 in Heart and Heart Surgery
- #5 in Orthopedics
- #6 in Kidney Disease

Academically, the Johns Hopkins University School of Medicine is recognized as one of the top two medical institutions in the United States. In 2007, the Johns Hopkins faculty conducted greater than US\$600 million in National Institute of Health ("NIH") funded research. This amount places Johns Hopkins as the top recipient of NIH research dollars, an honor that the faculty members have continuously earned for the past fifteen years.

In addition to accessing the intellectual capital and property of JHM, JHMI works closely with its colleagues at the Johns Hopkins University School of Nursing and the Bloomberg School of Public Health² to utilize their expertise in offering a full spectrum of clinical and health care advisory services to its international partners. This combination of medical, nursing and public health expertise and experience enables JHMI to create a truly unique professional service offering that creates value for its clients all over the world.

² Johns Hopkins Bloomberg School of Public Health is ranked #1 by *U.S. News and World Report*.



Japan National Center for Neurology and Psychiatry ("NCNP")

March 11, 2008

-- NCNP seeks to develop an overall research strategy and a concrete plan to improve the current clinical trial infrastructure to support their research activities.

GUESTS:

- Izuru Miyoshi, M.D., Ph.D. Director, Division of Clinical Research, National Center for Neurology and Psychiatry
- Akemi Tamaura, R.N. Deputy Director, Nursing Department, Division of Clinical Research, National Center for Neurology and Psychiatry
- Yujiro Tsutsumi
- Asuka Hayashi, M.D.
- Hiro Okayasu, M.D.

JOHNS HOPKINS PARTICIPANTS:

- Daniel Ford, M.D., M.P.H. Professor of Medicine and Vice Dean for Clinical Investigation, Johns Hopkins University School of Medicine
Departmental Affiliations in Psychiatry at the Johns Hopkins University School of Medicine and the Department of Epidemiology and Health Policy and Management, Johns Hopkins University School of Public Health
- Justin McArthur, M.D., M.P.H. Professor of Neurology, Pathology and Epidemiology, Interim Chair, Department of Neurology, Johns Hopkins University School of Medicine
- Paul S. Lietman, M.D., Ph.D. Professor of Medicine, Pharmacology and Molecular Sciences, and Pediatrics, Johns Hopkins University School of Medicine
Director of Academic Relations, Johns Hopkins Medicine International

Dean F. Wong, M.D., Ph.D.	Professor of Radiology, Psychiatry , Neuroscience and Environmental Health Sciences, Radiology Vice Chair for Research Administration and Training Director, High Resolution Brain PET Imaging, Johns Hopkins University School of Medicine
John W. McDonald, M.D., Ph.D.	Director of the International Center for Spinal Cord Injury, Kennedy Krieger Institute Associate Professor of Neurology, Johns Hopkins University School of Medicine
Akira Sawa, M.D.	Associate Professor of Psychiatry and Behavioral Sciences, Johns Hopkins University School of Medicine
Mohan Chellappa, M.D.	President of Global Ventures, Johns Hopkins Medicine International
Sanford Wu	Managing Director of Global Ventures, Johns Hopkins Medicine International
Yota Moniodis	Project Analyst of Global Ventures, Johns Hopkins Medicine International

MEETINGS SCHEDULE:

9:50am	Meet Yota Moniodis (Mobile Number +1-443-226-7851) Location: Broadway Research Building Main Entrance, 733 N. Broadway
10:00am – 10:50am	Dr. Paul Lietman, Sanford Wu, Yota Moniodis Subject: Introductory discussion on NCNP project and clinical trials overview. Location: Broadway Research Building Room 181, 733 N. Broadway
11:00am – 12:00pm	Dr. John McDonald, Sanford Wu, Yota Moniodis Subject: Research activities focusing on regeneration and restoration of function in spinal cord injury and other disorders of paralysis. Location: Kennedy Krieger Institute, 707 N. Broadway
12:00pm – 1:15pm	Lunch Location: Kennedy Krieger Institute Conference Room 512, 707 N. Broadway

1:30pm – 2:30pm

Dr. Dean Wong, Dr. Akira Sawa, Sanford Wu, Yota Moniodis
Subject: Demonstration and discussion of HHRT, the highest resolution human brain PET scanner in the world, and its applications for clinical research in the field of neurology and psychiatry.

Location: Johns Hopkins Outpatient Center Room 3224 , 601 N. Caroline Street

3:00pm – 4:00pm

Dr. Daniel Ford, Sanford Wu, Yota Moniodis
Subject: Organizational and operational issues of division of clinical investigation. Overview of clinical research activities at Johns Hopkins.

Location: Wilmer Portrait Room, 600 N. Wolfe Street

4:30pm – 6:00pm

Dr. Justin McArthur, Dr. Mohan Chellappa, Sanford Wu, Yota Moniodis
Subject: Department of Neurology clinical research activities.

Location: Wilmer Portrait Room, 600 N. Wolfe Street

6:15pm – 8:00pm

Dr. Mohan Chellappa, Sanford Wu, Yota Moniodis
Subject: Dinner and drinks. Closing discussions, including review and assessment of visit.

Location: Mezze, 1606 Thames St, Baltimore, MD 21231



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Akemi Tamaura, R.N. Deputy Director, Nursing Department, Division of Clinical Research, National Center for Neurology and Psychiatry

Yujiro Tsutsumi

Asuka Hayashi, M.D.

Hiro Okayasu, M.D.

JOHNS HOPKINS PARTICIPANTS:

Daniel Ford, M.D., M.P.H. Professor of Medicine and Vice Dean for Clinical Investigation, Johns Hopkins University School of Medicine
Departmental Affiliations in Psychiatry at the Johns Hopkins University School of Medicine and the Department of Epidemiology and Health Policy and Management, Johns Hopkins University School of Public Health

Justin McArthur, M.D., M.P.H. Professor of Neurology, Pathology and Epidemiology, Interim Chair, Department of Neurology, Johns Hopkins University School of Medicine

Christopher D. Saudek, M.D. Professor of Medicine and Endocrinology, Johns Hopkins University School of Medicine
Program Director of General Clinical Research Center, Johns Hopkins Medical Institutions
Director of the Johns Hopkins Comprehensive Diabetes Center

Paul S. Lietman, M.D., Ph.D.	Professor of Medicine, Pharmacology and Molecular Sciences, and Pediatrics, Johns Hopkins University School of Medicine Director of Academic Relations, Johns Hopkins Medicine International
Dean F. Wong, M.D., Ph.D.	Professor of Radiology, Psychiatry, Neuroscience and Environmental Health Sciences, Radiology Vice Chair for Research Administration and Training Director, High Resolution Brain PET Imaging, Johns Hopkins University School of Medicine
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12:00pm – 12:35pm Lunch

Location: Kennedy Krieger Institute Conference Room 512, 707 N. Broadway

12:45pm-1:15pm Dr. Christopher Saudek, Sanford Wu, Yota Moniodis
Subject: Tour and introduction of Adult Inpatient and Outpatient General Clinical Research Center.

Location: Osler Room 575, 600 N. Wolfe Street

1:30pm – 2:30pm Dr. Dean Wong, Dr. Akira Sawa, Sanford Wu, Yota Moniodis
Subject: Demonstration and discussion of HHRT, the highest resolution human brain PET scanner in the world, and its applications for clinical research in the field of neurology and psychiatry.

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MASSACHUSETTS
GENERAL HOSPITAL

Office for Visitor Education Programs
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Boston, MA 02114
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www.massgeneral.org/vep

March 10, 2008

Hiromasa Okayasu, MD

600 Campus Drive
Florham Park, NJ 07932

Dear Dr. Okayasu,

The following is a proposal for the Massachusetts General Hospital to provide discussions on MGH Psychiatry / Psychiatry Clinical Trials Network & Institute for you and up to nine (9) of your colleagues on Thursday, March 13, 2008. Please note that there may be some shifting of schedules due to the clinical and administrative obligations of the professional staff involved, but all areas listed below will be addressed at some point during your visit.

12:45pm

Welcome

MGH White Lobby (Main / Emergency
Entrance)

Shelly Riley, *Manager, MGH Office for Visitor
Education Programs*

1pm – 2:30pm

Meeting: David Henderson, MD

***Associate Professor of Psychiatry, Harvard
Medical School & Director of International
Division of MGH Psychiatry***

25 Staniford Street, 2nd Floor

2:30pm – 3pm

Tour: MGH Ether Dome

Bulfinch Building, 4th Floor

3pm – 4pm

Meeting: Maurizio Fava, MD

***Professor of Psychiatry, Harvard Medical
School & Director of Clinical Network Trials,
MGH Psychiatry***

Bulfinch Building, 3rd Floor, Suite 351

4pm

Depart MGH



MASSACHUSETTS GENERAL
PHYSICIANS ORGANIZATION



HARVARD
MEDICAL SCHOOL



The fee for this agenda is USD \$1,750 and includes:

- Attendance for up to 10 people (please add \$300 for each additional attendant over 10)
- Informational presentations by professional staff
- Question & Answer opportunities
- Educational materials

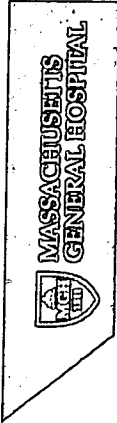
The fees are payable in US currency, and appreciated upon your arrival on March 13th. We gladly accept wire transfers, checks, Visa, MasterCard and American Express for your convenience.

We welcome your comments and feedback regarding the information outlined above. Please do not hesitate to contact me if you wish to discuss this proposal further. We look forward to your visit!

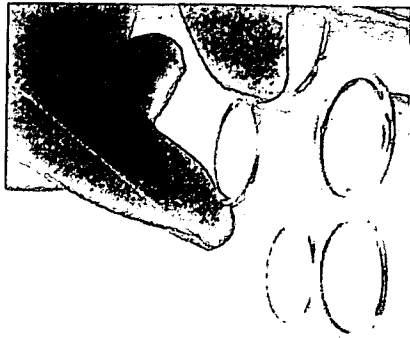
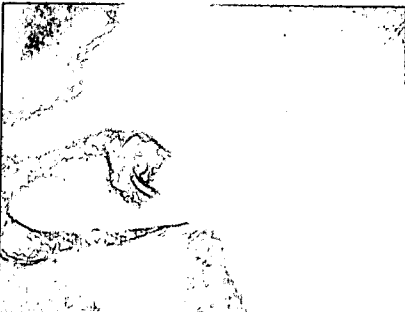
Yours truly,

Shelly Riley

Manager, MGH Visitor Education Programs



PSYCHIATRY CLINICAL TRIALS NETWORK AND INSTITUTE [CTNI]



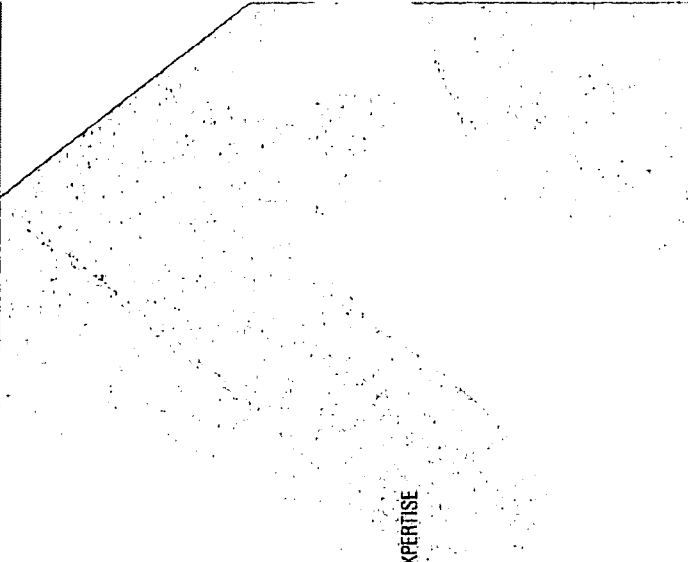
TO LEARN MORE about our services and capabilities,
please contact the Mass General Psychiatry Clinical
Trials Network and Institute at 617-726-4734. Visit
us at www.mghctni.org for additional information.

**MASSACHUSETTS
GENERAL HOSPITAL**
Psychiatry Clinical Trials Network and Institute
55 Fruit Street, Boston, MA 02114

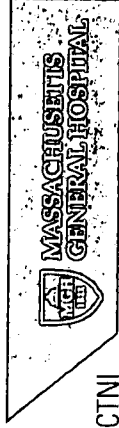
SETTING STANDARDS IN PSYCHIATRIC CLINICAL RESEARCH

- Leader in scientific and clinical research in psychiatry
- Extensive experience in industry-sponsored trials
- Comprehensive trial management resources
- Quality, integrity, and follow-through
- Sophisticated study analysis plans
- Skilled, responsive, trusted staff
- Resourceful trial strategies
- Innovative trial designs

EXCEPTIONAL LEADERSHIP... UNPARALLELED EXPERTISE



WHY SPONSORS CHOOSE THE MASS GENERAL CTNI



By partnering with The Massachusetts General Hospital (MGH) Psychiatry Clinical Trials Network and Institute (CTNI), industry sponsors benefit from our outstanding reputation, and long and storied track record in academic, scientific, and clinical research in the field of psychiatry. Because the MGH Psychiatry CTNI is affiliated with the renowned Massachusetts General Hospital,

"Our pioneering scientific and clinical research has been instrumental in defining the standards for the state-of-the-art practice of psychiatry."

sponsors will have access to some of the most prominent physicians and scientists and advanced technologies in the world.

The MGH Psychiatry CTNI is a division of the MGH Psychiatry Department, one of the leading academic research programs in the world — with over \$35 million in research programs last year alone. Our department has extensive experience over the past 25 years in industry-sponsored clinical trials.

Our innovative research methods are unmatched in helping sponsors meet their research goals. By exploring the brain science, genetics, and neurobiology of psychiatric disorders, the MGH Psychiatry CTNI has been instrumental in the development of novel treatments and surrogate markers of illness and of therapeutic response. Our pioneering scientific and clinical research has been instrumental in defining the standards for the state-of-the-art practice of psychiatry.

The MGH Psychiatry CTNI is dedicated to being responsive to our sponsors' needs and expectations by ensuring quality and integrity in our research activities and providing sound fiscal management of the study enterprise. Our attention to detail is oriented to producing trials meeting the highest regulatory and professional standards. Working with the best psychiatry clinical research sites in the US and Canada, the MGH Psychiatry CTNI is also able to meet high enrollment expectations.



SPONSORS BENEFIT FROM COMPREHENSIVE SERVICES

The MGH Psychiatry CTNI offers industry sponsors access to a broad range of state-of-the-art services, including the most advanced technology and methodology.

"CTNI has the research infrastructure needed to help sponsors determine the effectiveness, tolerability, and utility of new therapies."

INNOVATIVE DESIGN . . . COMPREHENSIVE MANAGEMENT . . . DETAILED FOLLOW-THROUGH

The MGH Psychiatry CTNI has the research infrastructure needed to help sponsors determine the effectiveness, tolerability, and utility of new therapies. The highest level of quality control and data integrity is maintained throughout every stage of research, from design to completion.

The appropriate study objectives are individualized and defined up front and trials are designed to generate the critical data to address the crucial questions. Our meticulous data gathering processes, our state-of-the-art electronic data capture methods, and our advanced analysis methods ensure a finely tuned, efficient, and timely study process.

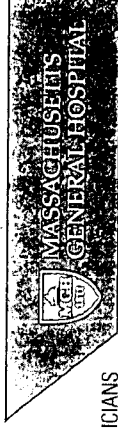
The MGH Psychiatry CTNI services include:

- Resourceful project planning
- Innovative trial designs
- Comprehensive project administration
- Reliable data management and electronic data capture *(when requested)*
- Thoughtful and accurate analysis
- Clearly presented Results
- Scrupulous follow-through



... OF FINEST MINDS... MAXIMUM SKILLS... OUTSTANDING TALENT

A WELL RESPECTED TEAM OF RESEARCHERS AND CLINICIANS



Because our clinical researchers are also active and skilled clinicians, industry sponsors who work with the MGH Psychiatry CTNI benefit from our unique perspective and track record of performing cutting edge clinical research, with direct relevance to improving patient care.

The strength of the MGH Psychiatry CTNI lies in the experience and the breadth of expertise of our accomplished staff. Their skills, integrity, and steadfast commitment to advancing the field bring results, and inspire confidence and trust. Industry sponsors who partner with us to achieve their goals know they are placing their trials in the best hands. They count on our research team to excel.

"Our expert research team utilizes the most effective methods available to create trials that answer critical questions and generate essential data."

Positioned at the very forefront of clinical trial research, our expert research team utilizes the most effective methods available to create trials that answer critical questions and generate essential data. To ensure success, they anticipate possible problems and design trials that withstand unexpected pressures and demands.

The MGH Psychiatry CTNI researchers and clinicians are skilled in the latest methods of analyzing and interpreting complex data. They

understand the intricate data management processes required for the most challenging research studies.

With the MGH Psychiatry CTNI, sponsors work with researchers who are recognized as world leaders in many areas of psychiatric research, including anxiety, depression, bipolar disorder, women's mental health, schizophrenia, geriatrics/Alzheimer's, pharmacogenetics, neuroimaging, and pediatric psychopharmacology.

MGH psychiatrists are currently serving as principal investigators or site investigators on over 50 industry sponsored clinical trials across the spectrum. They have taken on leadership roles in many of today's most significant multi-center trials.

With over 400 MD and PhD level staff, the MGH Psychiatry Department is also a well-established leader in education, with a resource of over 35,000 members of the MGH Psychiatry Academy worldwide.

To learn more about our services and capabilities, please contact the Mass General Psychiatry Clinical Trials Network and Institute at **617-726-4794**. Visit us at www.mghctni.org for additional information.

Korean College of Neuropsychopharmacology

2008. 03. 27-28

Past and Future Clinical Trials of Psychiatry in Japan

**National Center of Neurology and Psychiatry, Japan
Division of Clinical Research, Director
Izuru Miyoshi, M.D., Ph.D**

Past and Future Clinical Trials of Psychiatry in Japan

- Our center
- Current situation in Japan
- How to improve the situation in Japan
- Future plans

Past and Future Clinical Trials of Psychiatry in Japan

- Our center

