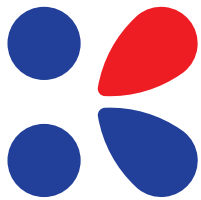


Contributing to the
advancement of medicine
through clinical research

Opening the way towards fuller,
healthier lives



Keikokai Medical Corporation



Greeting From the Chair of Keikokai Medical Corporation

Our story began in 2005 with the establishment in western Tokyo of P-One Clinic (P1 Clinic), a dedicated clinical research unit with inpatient facilities. In 2007, we incorporated under the name Keikokai, driven by the vision of enabling fuller, healthier lives for everyone through clinical research.

In 2021, a decade and a half and over 200 completed clinical trials later, we acquired a sister facility, Higashi-Shinjuku Clinic (HS Clinic), in the Shinjuku area of Tokyo, and, in April 2023, established the Keikokai home office to realize a robust system of central management. Now we aspire for ever greater synergy between our two CRUs through effective cooperation, organizational streamlining, and skill sharing.

Our trials would not be possible without the cooperation of many medical volunteers and industry partners. We believe that persisting in our efforts to explore the possibilities of new medicines together with these collaborators is the best way to show them our gratitude. Please look forward to the future of Keikokai and continue to give us your guidance on this journey. Trust that we will continue to strive together as a team to deliver new medicines as quickly as possible to the patients who need them.

Kenichi Furihata, M.D., Ph.D.
Chair, Keikokai Medical Corporation

Bio

- 1978 • Graduates from Keio University School of Medicine
- 1985 • Postdoctoral fellow at The Blood Center of Southeastern Wisconsin (now Versiti Blood Research Institute)
- 1993 • Associate professor of laboratory medicine, Shinshu University School of Medicine
- 1998 • Visiting scientist, The Scripps Research Institute
- 2005 • Found P1 Clinic as executive director
- 2007 • Establishes Keikokai Medical Corporation as chair of the board
- 2009 • Visiting professor, Tokai University School of Medicine
- 2015 • Adjunct professor, Keio University School of Medicine



IRB

Name	P1 Clinic, Keikokai Medical Corporation Institutional Review Board
Frequency	Meets once per month (date negotiable)
Location	Meets online
Documents	Electronic (paper upon request)
Members	Chairperson: Kyoichi Totsuka, M.D., Ph.D Vice Chairs: Shigeru Kageyama, M.D., Ph.D; Emiko Osuga, M.D., Ph.D Six additional regular members

Volunteer Associations

P-One Club (for Japanese volunteers)
<https://p1-club.jp/>

Medical Volunteer Network (for non-Japanese volunteers)
<https://medical-volunteer-network.com/>

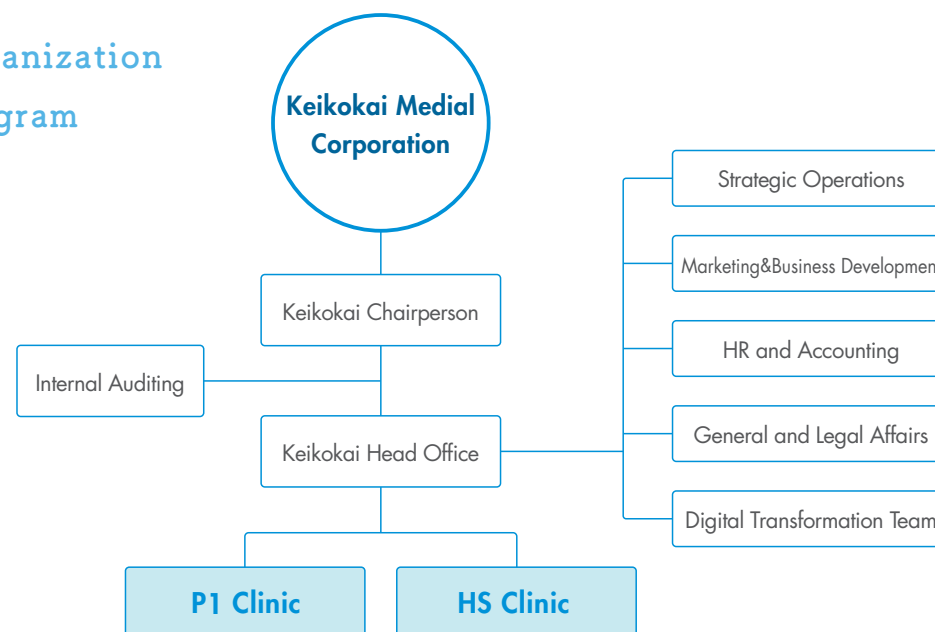
Medical Consultants

Consulting Doctors	Ryuichi Kato, M.D., Ph.D. (professor emeritus, Keio University) Shinichi Kawai, M.D., Ph.D. (professor emeritus, Toho University)
Industry Consultant	Takashi Noguchi, Ph.D. (former visiting professor, Showa University School of Medicine)

Clinic History

- 2005** • P1 Clinic established in Hachioji, Tokyo as dedicated clinical research unit
- 2007** • Incorporates as Keikokai, bringing further stability and capacity
- 2009** • P-One Club volunteer association created to facilitate Japanese recruitment
- 2011** • Medical Volunteer Network created to facilitate non-Japanese recruitment
- 2012** • Obtains ISO9001: 2008 (UKAS) certification for clinical trial services
- 2018** • Renews ISO9001: 2015 (UKAS) certification for clinical trial services
- 2021** • HS Clinic in Shinjuku, Tokyo acquired by Keikokai
- 2022** • HS Clinic begins outpatient care
(internal medicine, rheumatology, neurology, pain management, etc.)

Organization Diagram





P1 Clinic

P1 Clinic is a dedicated clinical research unit that conducts mainly phase I and pharmacology studies in healthy subjects. It also has a wealth of experience with phase I studies in patients, and late phase studies, including atopic dermatitis and dementia.



<https://p1-clinic.or.jp/>

Address

View Tower Hachioji 4F, 8-1 Yokamachi
Hachioji City, Tokyo, Japan, 192-0071

042-625-5216

Staff

Director Kenichi Furihata, M.D., Ph.D

Deputy Director Yutaka Hattori, M.D., Ph.D

Doctors, pharmacists, nurses, lab technicians, clinical psychologists, CRCs, registered cooks, nutritionists, registered dietitians, JSCPT-certificated CRCs, ACLS, BLS, bilingual staff

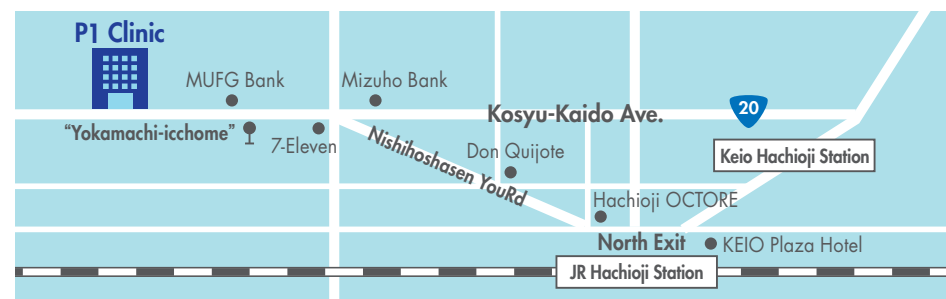
Access

From JR Hachioji Station

On foot: 15 minutes
By Bus: 6 minutes
(5 minute bus ride+1 minute walk)

From Keio Hachioji Station

On foot: 18 minutes
By Bus: 9 minutes
(8 minute bus ride +1 minute walk)



Pharmacy

Equipment biosafety cabinet (class II),
precision scale, ultrasonic cleaner
Storage temperatures room temperature,
fridge & freezer (-20°C)
Temperature control via data logger
Power backup in case of blackout
capacitor
Access control locks, entry management

Sample Storage

Storage temperature fridge (2~8°C) &
freezer (below -20°C, below -70°C)
Temperature control via data logger
Power backup in case of blackout
capacitor, generator, CO₂ auxiliary
cooling device

Archiving

Facility archive room
Temperature/ humidity recording upon entry
Access control locks, entry management
Partner contract with storage company

Internal Precision Control

X-bar and R control chart

Emergency Transport

Kowakai, Migita Hospital

External Precision Control

Japan Medical Association, Laboratory Accuracy
Precision Control Survey
Japanese Association of Medical Technologists,
Precision Control Survey
Tokyo Metropolitan Association of Medical
Technologists, Data Standardization Accuracy
Management Survey

Lab Equipment

Automated biochemical analyzer: Beckman Coulter AU680
Blood cell counter: UniCel DxH 800 (Beckman Coulter)
Automated urine analyzer: US-2200 (Eiken Chemical)
Multifunctional electrocardiograph: FCP-7541 (Fukuda Denshi)
LED slit lamp: 700GL (Takagi Seiko Co)
Applanation tonometer: AT-1 (Takagi Seiko)
Non-mydratric auto fundus camera: AFC-330 (NIDEK)
Non-contact tonometer: NT-530 (NIDEK)
Autoref keratometer: ARK-1a (NIDEK)
Cell analyzer: Guava® Muse™ (Luminex)





Area 1,238 m² **Registered Beds** 19 **Treatment beds** 27 (Total beds: 46)



- *Single-floor circuit layout
- *24-hour security system
- *Several rooms available for SDV

Recreation Rooms

2 rooms reserved for subjects. Enables peace of mind and a pleasant experience during long trials.

*Equipped with books, TV, games, Wi-Fi.



Cafeteria

Meals in conformity with protocol can be provided by our nutritionists and registered cooks, including high calorie and high or low fat menus.



Restricted Access

Hospitalization zone entry and exit only possible with dedicated keycard.

*24-hour security system



Rest Rooms & Showers

Rest rooms/showers rooms only for subjects.

*Laboratory situated in the center of clinic with surrounding restrooms allow subjects to pass samples directly to staff.



Meeting Rooms

Several rooms available for SDV or audit.



On-site Drug Preparation

Capable of on-site drug preparation by full-time pharmacists. We have experience with many different kinds of double blinding specifications.



Laboratory

On-site biochemical and hematological testing allows for rapid confirmation of data.



Timekeeper System

All tasks for trials in progress are managed to the second with an audible reminder.



Adjustable Wards

With keycard-access-controlled doors in three locations and additional doors to divide up the wards, we can comfortably hospitalize a variety of panels simultaneously, such as Japanese/non-Japanese, or males/females.



Medical Collaborators

We can handle a wide variety of studies with the assistance of a diverse network of medical collaborators, including doctors at local independent clinics, Tokai University Hachioji Hospital, and the Keio University School of Medicine.





HS Clinic

HS Clinic is a medical centre capable of both outpatient care and clinical studies, including late phase, BE, and clinical research. The clinic also has experience with large scale vaccine and other studies.



<https://hs-clinic.or.jp/>

Address

Daito Building 3F, 1-11-3 Okubo,
Shinjuku Tokyo, Japan, 169-0072

03-6233-8581

Staff

Director Jaewon Park, M.D., Ph.D

Deputy Director Shinichi Kawai, M.D., Ph.D
Hiroaki Kondo, M.D., Ph.D

Doctors, pharmacists, nurses, lab technicians, clinical psychologists, CRCs,
registered dietitians, ACLS, non-Japanese staff

Access

From Tokyo Metro
Higashi Shinjuku Station (A1 exit)

5 minutes on foot

From JR
Shin Okubo Station

8 minutes on foot

From JR
Shin Okubo Station (south exit)

8 minutes on foot

From Seibu
Shinjuku Station

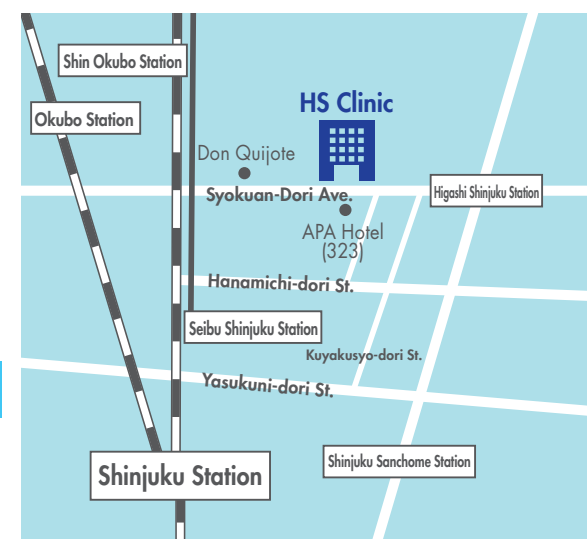
6 minutes on foot

From Tokyo Metro/Toei
Shinjuku Sanchome Station (E1 exit)

9 minutes on foot

From JR/Keio/Odakyu
Shinjuku Station (east exit)

12 minutes on foot



Pharmacy

Storage temperatures room temperature,
fridge & freezer (-20°C, -80°C)

Temperature control via data logger

Power backup in case of blackout capacitor

Access control locks, entry management

Sample Storage

Storage temperature Room temperature,
fridge & freezer (-20°C, -80°C)

Temperature control via data logger

Power backup in case of blackout capacitor

Archives

Equipment archive room

Access control locks, entry management

Partner contract with storage company

Outpatient Care Department

Internal medicine Jaewon Park, M.D., Ph.D

Rheumatology Shinichi Kawai, M.D., Ph.D

Pain management internal medicine

Noriko Miyazawa, M.D., Ph.D

Neurology Daisuke Ito, M.D., Ph.D

Emergency Transport

Tokyo Metropolitan Okubo Hospital

Lab Equipment

General radiographic X-ray equipment:

KXO-20SC/CBT-10A (Canon Medical Systems)

ECG with analyzer: FCP-8700 (Fukuda Denshi)

ECG with analyzer: ECG-1450 (Nihon Kohden)

Body composition analyzer: BC-118E (Tanita)

Non-mydiatic auto fundus camera: AFC-330 (Nidek)

Ultrasonograph: Nemio MX SSA-590A (Canon Medical Systems)

Ultrasonograph: SONIMAGE MX1 (Konica Minolta)

Micro-spirometric device: HI-201 (Nihon Kohden)

Automated sphygmomanometer: TM-2580 (A&D)

Automated sphygmomanometer: HEM-7080-IC (Omron Healthcare)

Dry clinical chemistry analyzer: Fuji DRI-CHEM NX600 (Fujifilm)

Multi-item automated blood cell counter: pocH™-80i (Sysmex)

Hand-operated audiometer: SA-1 (Minato Medical Science)

Genetic analysis device: cobas® Liat® (Roche Diagnostics K.K.)

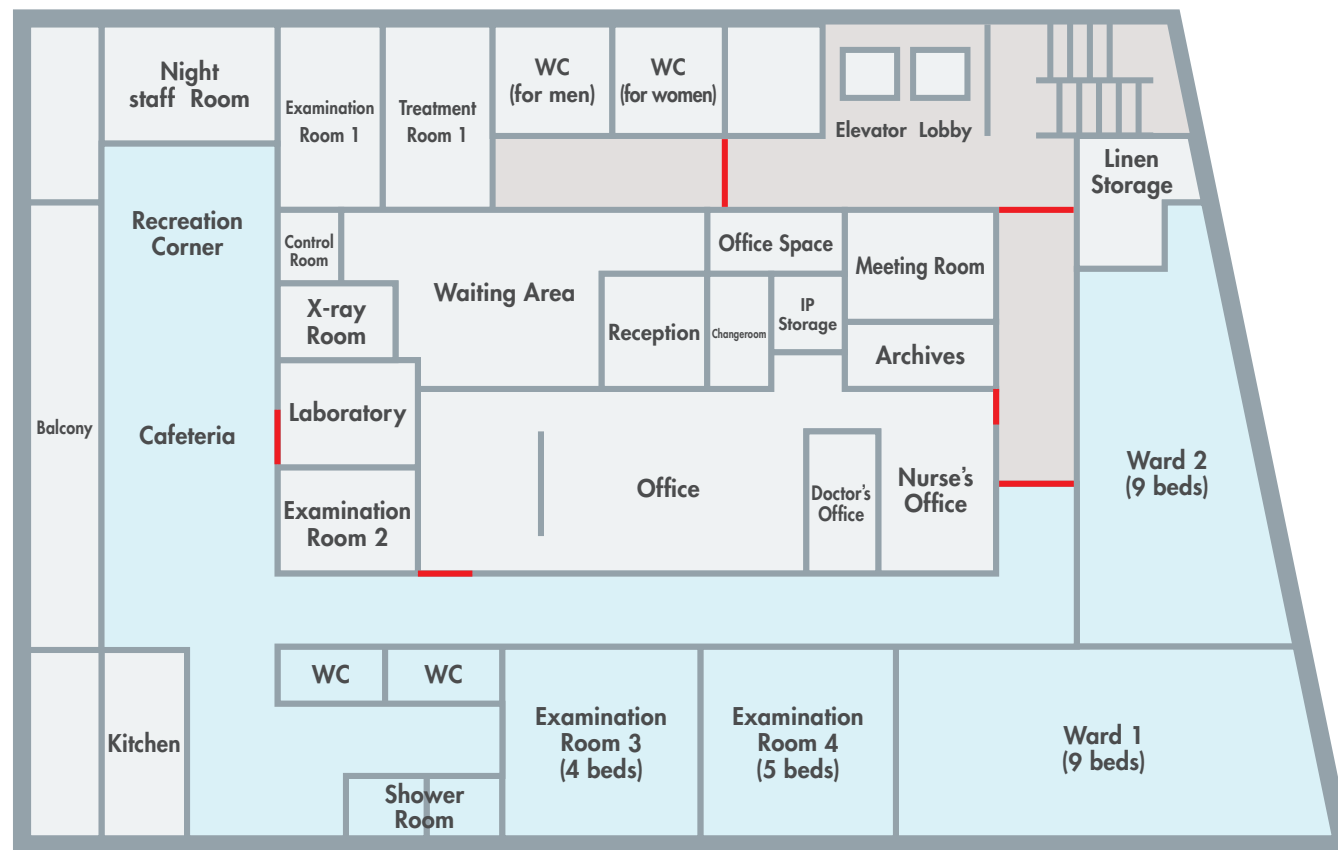
Bedside monitor: PVM-4761 (Nihon Kohden)





HS Clinic

Area 602 m² Registered Beds 18 Treatment beds 9 (Total beds: 27)



— Security lock Area available to subjects

*24-hour security system
*Several rooms available for SDV

Recreation Room

Used for subject consent, entry/discharge orientations, meals, filling out documents, and daily meals. During trials, it also serves as a lounge for subjects.



X-ray Room

Available for both outpatient and clinical trial use



Restricted Access

Hospitalization zone entry and exit only possible with dedicated keycard.

*24-hour security system



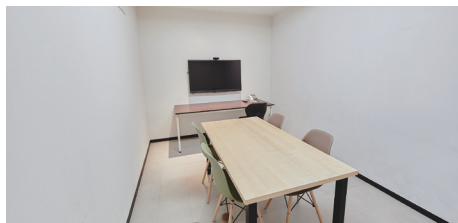
Rest Room & Showers

Dedicated for subject use



Meeting Rooms

Several rooms available for SDV or audit



Outpatient and Study Separation

Outpatient and trial subject entrances are separate. There are also separate examination rooms.



Subject Meals

Meals in conformity with protocol can be provided by vendors, including high calorie and high or low fat menus.



Subject Recreation

Wi-Fi and over 2,000 books are available.



Restricted Access

Staff can regularly monitor subjects via displays from each zone, including the office



Central Location

Six train stations are within walking distance of the clinic, allowing easy access from anywhere in Tokyo. This has enabled us to successfully complete large-scale outpatient trials with over 300 subjects.





Keikokai Medical Corporation

Head Office

View Tower Hachioji 4F, 8-1 Yokamachi

Hachioji City, Tokyo, Japan,

192-0071

042-625-5216



<https://www.keikokai-gr.or.jp/>