

## Examples

### Supported seeds

#### Next-generation Fetal ECG monitoring system IRIS MONITOR®

**Joint R&D partner: Atom Medical Cooperation**

This is a successfully commercialized next-generation fetal ECG monitoring system based on the work of Professor Yoshitaka Kimura, Advanced Interdisciplinary Biomedical Engineering, Tohoku University School of Medicine. IRIS MONITOR, a heart rate monitor capable of non-invasively measuring fetal heart rate through the mother's abdominal wall, is the world's first such system to be successfully applied within clinical trials from the 24th week of pregnancy. Developed entirely in Japan within a perinatal clinical environment, IRIS MONITOR comes as a result of industry-academia collaboration in all facets of development, IP management, clinical trials, and commercialization. The development, commercialization and overseas expansion of genuine domestically made medical equipment are strongly hoped for in Japan, and the system has also attracted much attention in overseas markets, with future developments expected.

### Academic Science Unit (ASU)

#### Kedclean cleaning solutions for medical instruments

**Joint R&D partner: KEDC Co., Ltd.**

An Academic Science Unit (ASU) participating company inspected our Central Supply Division and, based on its findings, developed the Kedclean line of cleaning solutions for medical instruments. Dental instruments are susceptible to depositions of protein and dental cement. Both can be difficult to remove with cleaning devices alone and often entail a preliminary cleaning or subsequent brushing step. Kedclean TZK, a solution that can simultaneously remove protein and dental cement under ultrasonic cleaning, and Kedclean EX, a medical alkaline solution for shower cleaning, reduce the burden and the cost of instrument cleaning.

# Staff Description

## Deputy Director, CRIETO Department of Clinical Research Network



Deputy Director, CRIETO  
Director, Department of  
Clinical Research Network  
**Masashi Aoki, MD, PhD.**  
Professor, Neurology, Tohoku University  
Graduate School of Medicine

We participate in the development of the "Tohoku Translational Research Center Development Network (TTN)" in the Tohoku region, in the Academic Research Organization (ARO), a nationwide organization, the Clinical Research Promotion Council, a national university hospital, Clinical Research Core Hospital Liaison Conference, etc., and we are collaborating with the clinical trial promotion organizations of each academy. Moreover, we intend to develop human resources that can work internationally, by constructing a network with overseas academies.

**Dr. Aoki's research and specialized areas**  
Uncovering clinical conditions of rare diseases, including amyotrophic lateral sclerosis and distal myopathy. Performed the first-in-human trials for rare diseases at Tohoku University Hospital through investigator-initiated clinical trials, etc.

## Deputy Director, CRIETO

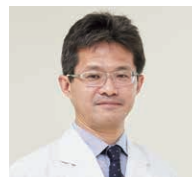


Deputy Director, CRIETO  
**Masahiro Saito, MD, PhD.**  
Operative Dentistry,  
Graduate School of Dentistry,  
Tohoku University

I am committed to strengthening CRIETO's research support structure to stimulate R&D aimed at practical application of results at Tohoku University Hospital, including clinical research and investigator-initiated trials. Furthermore, we nurture entrepreneurs aspiring to develop advanced medical technologies and promote R&D, within Tohoku University, of medical devices and drugs.

**Dr. Saito's research and specialized areas**  
Development of tooth regeneration therapy. In particular, R&D on scaffolds and cells aimed at investigator-initiated clinical trials for bone regeneration therapy. Also, development of dental therapy techniques with a view to whole body healthcare.

## Department for Bedside Solution Program



Director,  
Department for Bedside Solution  
Program  
**Atsuhiro Nakagawa, MD, PhD.**  
Special Appointment Professor, CRIETO  
Tohoku University Hospital

We have been organizing the Academic Science Unit (ASU), infrastructure that enables medical and healthcare developers to identify bedside needs that have commercial potential. Over the last five years since its inception in 2014, we have accepted more than 1,200 corporate researchers in Tohoku University Hospital to find medical needs with the support of medical professionals. We also try to develop the way to create new value for the patients and medical professionals more speedily by educating more medical professional who can be liaison for other fields including business and technology. We also try to accommodate emerging technology, such as augmented reality (AR) to medical environment, changing way of our workstyle.

**Dr. Nakagawa's research and specialized areas**  
Neurosurgery (traumatic brain injury)

## Department of Intellectual Property



Director,  
Department of Intellectual Property  
**Yasuyuki Togoe**  
Special Appointment Professor CRIETO  
Tohoku University Hospital

The Department of Intellectual Property uncovers and isolates inventions relating to the various research seeds at CRIETO, and cooperates with the Tohoku University Office of Cooperative Research and Development here in implementing strategic acquisition, maintenance, and management of rights with a view to utilization inside and outside Japan. We also utilize our intellectual property holdings to support technology transfer to enterprises, entrepreneurship, and other such activities as part of our commitment to providing powerful support for the practical application of all research seeds.

**Mr. Togoe's research and specialized areas**  
Intellectual Property

## Deputy Director, CRIETO



Deputy Director, CRIETO  
**Toru Nakazawa, MD, PhD.**  
Professor, Ophthalmology,  
Tohoku University  
Graduate School of Medicine

We seek to advance clinical research at Tohoku University Hospital and stimulate R&D activities at Tohoku University as well as to become an institutional hub for departments/units within these two institutions, and for related facilities throughout the Tohoku region. We are also committed to serving as a translational bridge for the Advanced Research Center for Innovations in Next-Generation Medicine (INGEM) efforts to develop next-generation medicine based on systems of personalized medicine and prevention.

**Dr. Nakazawa's research and specialized areas**  
Ophthalmology, neuronal protection and treatment, glaucoma, nano-ocular instillation, biomarker identification, regenerative medicine

## Deputy Director, CRIETO Department of Development Promotion



Deputy Director, CRIETO  
Director, Department of  
Development Promotion  
**Koji Ikeda, PhD.**  
Special Appointment Professor CRIETO  
Tohoku University Hospital

The Department of Development Promotion is in charge of research seed consultation, progress management, and advising on non-clinical trials. It is the contact point regarding all research seeds for anyone who wishes to receive CRIETO support, whether or not he/she is from Tohoku University. Based on its understanding of the overview of research seeds and progress, the department liaises for research seeds receiving support. The most critical task when support is first provided to research seeds is supporting the establishment of development strategies.

**Dr. Ikeda's research and specialized areas**  
Regulatory science  
Medical device development  
Translational research

## Department of International Affairs



Director,  
Department of International Affairs  
**Yuka Suzuki, PhD.**  
Special Appointment Professor CRIETO  
Tohoku University Hospital

The Department of International Affairs supports global development and practical application of research seeds. Specifically, we promote collaborations with overseas academic research organizations, investigate overseas regulatory policies and standards, seek global clinical trial opportunities, and advise on overseas expansion and development efforts. We assist academia, and domestic and foreign companies in these endeavors. Please contact us at any time if you are interested in global development.

**Dr. Suzuki's research and specialized areas**  
Regulatory Science  
Development and International Activities (Medical Devices)

## Department of Protocol Creation Support



Director,  
Department of Protocol  
Creation Support  
**Tadao Takano, MD, PhD.**  
Special Appointment Professor CRIETO  
Tohoku University Hospital

The Department of Protocol Creation Support offers consultation from the initial phase of research, questioning, and research planning. It collaborates actively with not only principal investigators but also relevant departments. It supports the creation of "good protocols", which are of course in line with the laws and guidelines, and have taken into account their strategic nature, feasibility, and impact on results.

**Dr. Takano's research and specialized areas**  
Gynecological oncology  
Clinical research

## Department of Information Policy



Director,  
Department of Information Policy  
**Takashi Shiroto, MD, PhD.**  
Special Appointment  
Associate Professor CRIETO  
Tohoku University Hospital

The Department of Information Policy collects information regarding policies and budgets timely and shares them with all concerned immediately, through close communication with central government ministries and agencies and local authorities. The department also supports principal investigators in securing a budget for research and development through proper counseling.

**Dr. Shiroto's research and specialized areas**  
Cardiovascular medicine

## Department of Public Relations



Director, Department of  
Public Relations  
**Keiichi Jingu, MD, PhD.**  
Professor Radiation Oncology  
Tohoku University Graduate School of Medicine

The mission for the department of Public Relations is to foster information sharing regarding clinical trials, as well as to promote the active pursuit of clinical research, development, and education programs as the hub of information within and outside CRIETO. By disseminating information from Tohoku University to the world, the department will promote and spread awareness regarding clinical research. As a bridge that translates research findings into social applications, the department engages in public relations activities that will promote this research area all across the globe.

**Dr. Jingu's research and specialized areas**  
Radiotherapy for cancer, especially for intestinal cancer

## PET Clinical Research Unit

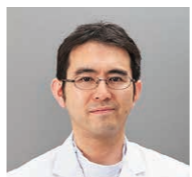


Director, PET Clinical Research Unit  
**Kei Takase, MD, PhD.**  
Department of Diagnostic Radiology,  
Tohoku University Graduate School of Medicine  
Chief of Tohoku University Dispensary in CYRIC

The PET Clinical Research Unit is collaborating closely with the Nuclear Medicine, Nuclear Pharmacy Research Department, and Radiation Protection and Safety Control Division of the Cyclotron and Radioisotope Center (CYRIC) on the Aobayama Campus, and the PET groups inside the university hospital (Diagnostic Radiology Department, Radiology Section, Pharmaceutical Department, etc.) to vigorously conduct clinical trials using PET molecular imaging.

**Dr. Takase's research and specialized areas**  
Diagnostic Radiology, Interventional Radiology

## Clinical Research QA Office



Director,  
Clinical Research QA Office  
**Akira Inoue, MD, PhD.**  
Professor, Palliative Medicine,  
Tohoku University  
Graduate School of Medicine

The purpose of the Clinical Research QA Office is to assure the quality of clinical trials including registration trial and clinical researches. As a department that is independent from CRIETO, we perform third-party audits to determine whether each clinical trial or clinical research is observing good clinical practice (GCP) and/or Ethical Guidelines for Medical and Health Research Involving Human Subjects, and study protocols, whether they are complying with relevant laws and regulations, whether appropriate systems have been created for them, and other such matters.

**Dr. Inoue's research and specialized areas**  
Palliative Medicine, Clinical Oncology

## Department of Clinical Trial Implementation Department of Clinical Research Safety Management

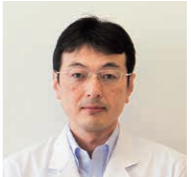


Director, Department of  
Clinical Trial Implementation  
Director, Department of  
Clinical Research Safety Management  
**Tomonori Ishii, MD, PhD.**  
Special Appointment Professor CRIETO  
Tohoku University Hospital

The Department of Clinical Trial Implementation is comprised of CRCs and staff of the Clinical Trial Secretariat. Its mission is to support the smooth implementation of all aspects of clinical trials, including research, and improve the quality of clinical trials. The department is committed to carrying out safe and high quality ethical and scientific clinical trials, as well as to simplify procedures to provide a "friendly" environment for all people involved in clinical trials, including patients, clients, and clinicians.

**Dr. Ishii's research and specialized areas**  
Rheumatology, Clinical immunology

## Department of Medical Informatics



Director, Department of  
Medical Informatics  
**Masaharu Nakayama, MD, PhD.**  
Professor, Medical Informatics  
Tohoku University Graduate School of Medicine  
Director, Medical IT Center, Tohoku University Hospital

The Department of Medical Informatics contributes to the creation of systems to smoothly pursue clinical research. In concrete terms it builds clinical trial and clinical research support systems and databases, and establishes a collaboration platform for electronic medical records and other clinical department data. It enables the provision of data to clinicians without imposing any burden upon them, and eventually aims to prepare an environment "from bedside to bench and back to bedside" in which research results are returned to the appropriate parties as a matter of course.

**Dr. Nakayama's research and specialized areas**  
Medical informatics, Cardiovascular medicine

## Regenerative Medicine Unit



Director, Regenerative Medicine Unit  
**Masafumi Goto, MD, PhD.**  
Professor, United Centers for  
Advanced Research and  
Translational Medicine,  
Tohoku University Graduate School of Medicine

In the cell processing process in cell therapy, the utilization of the Cell Processing Center (CPC) is essential for securing safety and quality in the same way as when manufacturing pharmaceuticals. Via the operation and management of and provision of work assistance for GMP-compatible CPC, the Regenerative Medicine Unit provides support to researchers attempting to commercialize cutting-edge cell therapy and regenerative medicine.

**Dr. Goto's research and specialized areas**  
Cell transplantation therapies such as pancreatic islet transplantation and hepatocellular transplantation, etc.  
Regenerative medicine

## Clinical Research Data Center



Director, Clinical Research Data Center  
**Takuhiro Yamaguchi, PhD.**  
Professor Biostatistics  
Tohoku University  
Graduate School of Medicine

The Data Center supports investigators through various activities, including development of a protocol and case report forms (CRFs), registration and randomization of patients, project data management, central monitoring, statistical analysis, and report preparation. The Center manages quality control in order to maintain the reliability of clinical research findings.

**Dr. Yamaguchi's research and specialized areas**  
Biostatistics  
Clinical information management  
Clinical research methodology

## CRIETO Tokyo site

We have recently opened the CRIETO Tokyo site in Nihonbashi, Tokyo, which will facilitate R&D-related consultation in the greater Tokyo area, support seed developmental efforts there and at other sites, and strengthen private-sector collaboration.

CRIETO Tokyo is staffed by personnel from the Department of International Affairs, Department of Development Promotion and Clinical Testing Data Center, now on station to provide advice and support for the development of medical equipment and pharmaceuticals.

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