

**FACILITY NAME & ADDRESS**

| Facility Name                 | Facility Type              | Facility Address                                      |
|-------------------------------|----------------------------|---|
| Yamaguchi University Hospital | Hospital or Medical Center | 1-1-1 Minami-kogushi, Ube, Yamaguchi, Japan, 755-8505 |

**FACILITY CONTACTS**

| Primary FPM? | Name          | Email Address              | Roles                    |
|--------------|---------------|----------------------------|--------------------------|
| Yes          | Kondo, Tomoko | sktomoko@yamaguchi-u.ac.jp | Facility Profile Manager |

**THERAPEUTIC AREAS & PATIENT POPULATION**

| Therapeutic Area(s)   |   |
|---|---|
| Therapeutic Area  | Sub-Therapeutic Area                            |
| Allergy   | Allergy   |
| Bacterial Infections and Mycoses                                | Bacterial Infections                            |
| Bacterial Infections and Mycoses                                | Central Nervous System Infections               |
| Bacterial Infections and Mycoses                                | Infection                                       |
| Bacterial Infections and Mycoses                                | Mycoses   |
| Bacterial Infections and Mycoses                                | Zoonoses  |
| Bone  | Bone  |
| Bone  | Osteoporosis                                    |
| Cardiovascular Diseases   | Cardiovascular Abnormalities                    |
| Cardiovascular Diseases   | Cardiovascular Infections                       |
| Cardiovascular Diseases   | Heart Diseases                                  |
| Cardiovascular Diseases   | Kidney Diseases                                 |
| Cardiovascular Diseases   | Metabolic                                       |
| Cardiovascular Diseases   | Pregnancy Complications, Cardiovascular         |
| Cardiovascular Diseases   | Vascular Diseases                               |
| Chemically-induced Disorders                                    | Drug-Related Side Effects and Adverse Reactions |
| Chemically-induced Disorders                                    | Poisoning                                       |
| Chemically-induced Disorders                                    | Substance-Related Disorders                     |
| Congenital, Hereditary, and Neonatal Diseases and Abnormalities | Congenital Abnormalities                        |
| Congenital, Hereditary, and Neonatal Diseases and Abnormalities | Fetal Diseases                                  |
| Congenital, Hereditary, and Neonatal Diseases and Abnormalities | Genetic Diseases, Inborn                        |
| Congenital, Hereditary, and Neonatal Diseases and Abnormalities | Infant, Newborn, Diseases                       |
| Device  | Device  |
| Digestive System Diseases                                       | Biliary Tract Diseases                          |
| Digestive System Diseases                                       | Digestive System Abnormalities                  |
| Digestive System Diseases                                       | Digestive System Fistula                        |
| Digestive System Diseases                                       | Digestive System Neoplasms                      |
| Digestive System Diseases                                       | Gastrointestinal Diseases                       |
| Digestive System Diseases                                       | Inflammatory Bowel Disease                      |
| Digestive System Diseases                                       | Liver Diseases                                  |
| Digestive System Diseases                                       | Pancreatic Diseases                             |
| Digestive System Diseases                                       | Peritoneal Diseases                             |
| Disorders of Environmental Origin                               | Environmental Illness                           |
| Disorders of Environmental Origin                               | Preconception Injuries                          |
| Endocrine System Diseases                                       | Adrenal Gland Diseases                          |
| Endocrine System Diseases                                       | Bone Diseases, Endocrine                        |
| Endocrine System Diseases                                       | Diabetes Mellitus                               |
| Endocrine System Diseases                                       | Dwarfism  |
| Endocrine System Diseases                                       | Endocrine Gland Neoplasms                       |
| Endocrine System Diseases                                       | Female Athlete Triad Syndrome                   |
| Endocrine System Diseases                                       | Gonadal Disorders                               |
| Endocrine System Diseases                                       | Parathyroid Diseases                            |



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| Endocrine System Diseases                              | Pituitary Diseases                                 |
| Endocrine System Diseases                              | Polyendocrinopathies, Autoimmune                   |
| Endocrine System Diseases                              | Thyroid Diseases                                   |
| Endocrine System Diseases                              | Tuberculosis, Endocrine                            |
| Eye Diseases   | Asthenopia   |
| Eye Diseases   | Cogan Syndrome                                     |
| Eye Diseases   | Conjunctival Diseases                              |
| Eye Diseases   | Corneal Diseases                                   |
| Eye Diseases   | Eye Abnormalities                                  |
| Eye Diseases   | Eye Diseases, Hereditary                           |
| Eye Diseases   | Eye Hemorrhage                                     |
| Eye Diseases   | Eye Infections                                     |
| Eye Diseases   | Eye Injuries                                       |
| Eye Diseases   | Eye Manifestations                                 |
| Eye Diseases   | Eye Neoplasms                                      |
| Eye Diseases   | Eyelid Diseases                                    |
| Eye Diseases   | Lacrimal Apparatus Diseases                        |
| Eye Diseases   | Lens Diseases                                      |
| Eye Diseases   | Ocular Hypertension                                |
| Eye Diseases   | Ocular Hypotension                                 |
| Eye Diseases   | Ocular Motility Disorders                          |
| Eye Diseases   | Optic Nerve Diseases                               |
| Eye Diseases   | Orbital Diseases                                   |
| Eye Diseases   | Pupil Disorders                                    |
| Eye Diseases   | Refractive Errors                                  |
| Eye Diseases   | Retinal Diseases                                   |
| Eye Diseases   | Scleral Diseases                                   |
| Eye Diseases   | Uveal Diseases                                     |
| Eye Diseases   | Vision Disorders                                   |
| Eye Diseases   | Vitreous Detachment                                |
| Female Urogenital Diseases and Pregnancy Complications | Female Urogenital Diseases                         |
| Female Urogenital Diseases and Pregnancy Complications | Pregnancy Complications                            |
| Fertility  | Fertility  |
| Hemic and Lymphatic Diseases                           | Anemia   |
| Hemic and Lymphatic Diseases                           | Hematologic Diseases                               |
| Hemic and Lymphatic Diseases                           | Hemophilia   |
| Hemic and Lymphatic Diseases                           | Lymphatic Diseases                                 |
| Immune System Diseases                                 | Autoimmune Diseases                                |
| Immune System Diseases                                 | Erythroblastosis, Fetal                            |
| Immune System Diseases                                 | Glomerulonephritis, Membranoproliferative          |
| Immune System Diseases                                 | Graft vs Host Disease                              |
| Immune System Diseases                                 | Hypersensitivity                                   |
| Immune System Diseases                                 | Immune Reconstitution Inflammatory Syndrome        |
| Immune System Diseases                                 | Immunologic Deficiency Syndromes                   |
| Immune System Diseases                                 | Immunoproliferative Disorders                      |
| Immune System Diseases                                 | Purpura, Thrombocytopenic                          |
| Immune System Diseases                                 | Transfusion Reaction                               |
| Infectious Diseases                                    | Infectious Diseases                                |
| Inflammation   | Inflammation                                       |
| Internal Medicine                                      | Internal Medicine                                  |
| Male Urogenital Diseases                               | Genital Diseases, Male                             |
| Male Urogenital Diseases                               | Pelvic Floor Disorders                             |
| Male Urogenital Diseases                               | Tuberculosis, Urogenital                           |
| Male Urogenital Diseases                               | Urogenital Abnormalities                           |
| Male Urogenital Diseases                               | Urogenital Neoplasms                               |
| Male Urogenital Diseases                               | Urologic Diseases                                  |
| Mental disorders                                       | Anxiety Disorders                                  |
| Mental disorders                                       | Bipolar and Related Disorders                      |
| Mental disorders                                       | Disruptive, Impulse Control, and Conduct Disorders |



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| Mental disorders         | Dissociative Disorders                               |
| Mental disorders         | Elimination Disorders                                |
| Mental disorders         | Feeding and Eating Disorders                         |
| Mental disorders         | Mood Disorders                                       |
| Mental disorders         | Motor Disorders                                      |
| Mental disorders         | Neurocognitive Disorders                             |
| Mental disorders         | Neurodevelopmental Disorders                         |
| Mental disorders         | Neurotic Disorders                                   |
| Mental disorders         | Paraphilic Disorders                                 |
| Mental disorders         | Personality Disorders                                |
| Mental disorders         | Schizophrenia Spectrum and Other Psychotic Disorders |
| Mental disorders         | Sexual Dysfunctions, Psychological                   |
| Mental disorders         | Sleep Wake Disorders                                 |
| Mental disorders         | Somatoform Disorders                                 |
| Mental disorders         | Substance-Related Disorders                          |
| Mental disorders         | Trauma and Stressor Related Disorders                |
| Musculoskeletal Diseases | Arthritis  |
| Musculoskeletal Diseases | Bone Diseases  |
| Musculoskeletal Diseases | Cartilage Diseases                                   |
| Musculoskeletal Diseases | Fasciitis  |
| Musculoskeletal Diseases | Foot Deformities                                     |
| Musculoskeletal Diseases | Foot Diseases  |
| Musculoskeletal Diseases | Hand Deformities                                     |
| Musculoskeletal Diseases | Jaw Diseases   |
| Musculoskeletal Diseases | Joint Diseases                                       |
| Musculoskeletal Diseases | Muscular Diseases                                    |
| Musculoskeletal Diseases | Musculoskeletal Abnormalities                        |
| Musculoskeletal Diseases | Rheumatic Diseases                                   |
| Neoplasms                | Cysts  |
| Neoplasms                | Hamartoma  |
| Neoplasms                | Neoplasms by Histologic Type                         |
| Neoplasms                | Neoplasms by Site                                    |
| Neoplasms                | Neoplasms, Experimental                              |
| Neoplasms                | Neoplasms, Hormone-Dependent                         |
| Neoplasms                | Neoplasms, Multiple Primary                          |
| Neoplasms                | Neoplasms, Post-Traumatic                            |
| Neoplasms                | Neoplasms, Radiation-Induced                         |
| Neoplasms                | Neoplasms, Second Primary                            |
| Neoplasms                | Neoplastic Processes                                 |
| Neoplasms                | Neoplastic Syndromes, Hereditary                     |
| Neoplasms                | Paraneoplastic Syndromes                             |
| Neoplasms                | Precancerous Conditions                              |
| Neoplasms                | Pregnancy Complications, Neoplastic                  |
| Nephrology               | Nephrology   |
| Nervous System Diseases  | Autoimmune Diseases of the Nervous System            |
| Nervous System Diseases  | Autonomic Nervous System Diseases                    |
| Nervous System Diseases  | Central Nervous System Diseases                      |
| Nervous System Diseases  | Chronobiology Disorders                              |
| Nervous System Diseases  | Cranial Nerve Diseases                               |
| Nervous System Diseases  | Demyelinating Diseases                               |
| Nervous System Diseases  | Nervous System Malformations                         |
| Nervous System Diseases  | Nervous System Neoplasms                             |
| Nervous System Diseases  | Neurocutaneous Syndromes                             |
| Nervous System Diseases  | Neurodegenerative Diseases                           |
| Nervous System Diseases  | Neurologic Manifestations                            |
| Nervous System Diseases  | Neuromuscular Diseases                               |
| Nervous System Diseases  | Neurotoxicity Syndromes                              |
| Nervous System Diseases  | Restless Legs Syndrome                               |
| Nervous System Diseases  | Sleep Wake Disorders                                 |



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| Nervous System Diseases            | Trauma, Nervous System                      |
| Neuroscience                       | Neuroscience                                |
| Nutritional and Metabolic Diseases | Metabolic Diseases                          |
| Nutritional and Metabolic Diseases | Nutrition Disorders                         |
| Ob-Gyn                             | Ob-Gyn                                      |
| Occupational Diseases              | Agricultural Workers' Diseases              |
| Occupational Diseases              | Asthma, Occupational                        |
| Occupational Diseases              | Bird Fancier's Lung                         |
| Occupational Diseases              | Burnout, Professional                       |
| Occupational Diseases              | Dermatitis, Occupational                    |
| Occupational Diseases              | Hand-Arm Vibration Syndrome                 |
| Occupational Diseases              | High Pressure Neurological Syndrome         |
| Occupational Diseases              | Inert Gas Narcosis                          |
| Occupational Diseases              | Laboratory Infection                        |
| Occupational Diseases              | Persian Gulf Syndrome                       |
| Occupational Diseases              | Pneumoconiosis                              |
| Occupational Diseases              | Sleep Disorders, Circadian Rhythm           |
| Oncology                           | Bladder                                     |
| Oncology                           | Brain                                       |
| Oncology                           | Breast                                      |
| Oncology                           | Carcinoma                                   |
| Oncology                           | Central Nervous System                      |
| Oncology                           | Cervical                                    |
| Oncology                           | Colorectal                                  |
| Oncology                           | Esophagael                                  |
| Oncology                           | Gastric                                     |
| Oncology                           | Gastrointestinal                            |
| Oncology                           | Genitourinary                               |
| Oncology                           | Head and Neck                               |
| Oncology                           | Hematologic Malignancies                    |
| Oncology                           | Hepatocellular Carcinoma                    |
| Oncology                           | Leukemia                                    |
| Oncology                           | Lung  |
| Oncology                           | Lymphoma                                    |
| Oncology                           | Melanoma                                    |
| Oncology                           | Multiple Myeloma                            |
| Oncology                           | Ovarian                                     |
| Oncology                           | Pediatrics                                  |
| Oncology                           | Prostate                                    |
| Oncology                           | Radiation Oncology                          |
| Oncology                           | Renal                                       |
| Oncology                           | Sarcoma                                     |
| Oncology                           | Skin  |
| Oncology                           | Uterine                                     |
| Orthopedics                        | Orthopedics                                 |
| Otorhinolaryngologic Diseases      | Ciliary Motility Disorders                  |
| Otorhinolaryngologic Diseases      | Ear Diseases                                |
| Otorhinolaryngologic Diseases      | Laryngeal Diseases                          |
| Otorhinolaryngologic Diseases      | Nose Diseases                               |
| Otorhinolaryngologic Diseases      | Otorhinolaryngologic Neoplasms              |
| Otorhinolaryngologic Diseases      | Pharyngeal Diseases                         |
| Pain                               | Pain  |
| Parasitic Diseases                 | Central Nervous System Parasitic Infections |
| Parasitic Diseases                 | Coinfection                                 |
| Parasitic Diseases                 | Eye Infections, Parasitic                   |
| Parasitic Diseases                 | Helminthiasis                               |
| Parasitic Diseases                 | Intestinal Diseases, Parasitic              |
| Parasitic Diseases                 | Liver Diseases, Parasitic                   |
| Parasitic Diseases                 | Lung Diseases, Parasitic                    |



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| Parasitic Diseases                          | Mesomycetozoea Infections              |
| Parasitic Diseases                          | Opportunistic Infections               |
| Parasitic Diseases                          | Parasitemia                            |
| Parasitic Diseases                          | Parasitic Diseases, Animal             |
| Parasitic Diseases                          | Pregnancy Complications, Parasitic     |
| Parasitic Diseases                          | Protozoan Infections                   |
| Parasitic Diseases                          | Skin Diseases, Parasitic               |
| Parasitic Diseases                          | Zoonoses                               |
| Pathological Conditions, Signs and Symptoms | Morphological and Microscopic Findings |
| Pathological Conditions, Signs and Symptoms | Pathologic Processes                   |
| Pathological Conditions, Signs and Symptoms | Pathological Conditions, Anatomical    |
| Pathological Conditions, Signs and Symptoms | Signs and Symptoms                     |
| Pediatrics                                  | Pediatrics                             |
| Respiratory Tract Diseases                  | Bronchial Diseases                     |
| Respiratory Tract Diseases                  | Ciliary Motility Disorders             |
| Respiratory Tract Diseases                  | Granuloma, Respiratory Tract           |
| Respiratory Tract Diseases                  | Laryngeal Diseases                     |
| Respiratory Tract Diseases                  | Lung Diseases                          |
| Respiratory Tract Diseases                  | Nose Diseases                          |
| Respiratory Tract Diseases                  | Pleural Diseases                       |
| Respiratory Tract Diseases                  | Respiration Disorders                  |
| Respiratory Tract Diseases                  | Respiratory Hypersensitivity           |
| Respiratory Tract Diseases                  | Respiratory System Abnormalities       |
| Respiratory Tract Diseases                  | Respiratory Tract Fistula              |
| Respiratory Tract Diseases                  | Respiratory Tract Infections           |
| Respiratory Tract Diseases                  | Respiratory Tract Neoplasms            |
| Respiratory Tract Diseases                  | Thoracic Diseases                      |
| Respiratory Tract Diseases                  | Tracheal Diseases                      |
| Skin and Connective Tissue Diseases         | Connective Tissue Diseases             |
| Skin and Connective Tissue Diseases         | Skin Diseases                          |
| Stomatognathic Diseases                     | Ankyloglossia                          |
| Stomatognathic Diseases                     | Jaw Diseases                           |
| Stomatognathic Diseases                     | Mouth Diseases                         |
| Stomatognathic Diseases                     | Pharyngeal Diseases                    |
| Stomatognathic Diseases                     | Stomatognathic System Abnormalities    |
| Stomatognathic Diseases                     | Temporomandibular Joint Disorders      |
| Stomatognathic Diseases                     | Tooth Diseases                         |
| Vaccines                                    | Vaccines                               |
| Virus Diseases                              | Arbovirus Infections                   |
| Virus Diseases                              | Bronchiolitis, Viral                   |
| Virus Diseases                              | Central Nervous System Viral Diseases  |
| Virus Diseases                              | Coinfection                            |
| Virus Diseases                              | DNA Virus Infections                   |
| Virus Diseases                              | Encephalitis, Viral                    |
| Virus Diseases                              | Eye Infections, Viral                  |
| Virus Diseases                              | Fatigue Syndrome, Chronic              |
| Virus Diseases                              | Hepatitis, Viral, Human                |
| Virus Diseases                              | Opportunistic Infections               |
| Virus Diseases                              | Pneumonia, Viral                       |
| Virus Diseases                              | RNA Virus Infections                   |
| Virus Diseases                              | Sexually Transmitted Diseases          |
| Virus Diseases                              | Skin Diseases, Viral                   |
| Virus Diseases                              | Slow Virus Diseases                    |
| Virus Diseases                              | Tumor Virus Infections                 |
| Virus Diseases                              | Viremia                                |
| Virus Diseases                              | Zoonoses                               |
| Women's Health                              | Women's Health                         |
| Wounds and Injuries                         | Abdominal Injuries                     |
| Wounds and Injuries                         | Amputation, Traumatic                  |



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| Wounds and Injuries   | Arm Injuries  |
| Wounds and Injuries   | Asphyxia  |
| Wounds and Injuries   | Athletic Injuries                                     |
| Wounds and Injuries   | Back Injuries   |
| Wounds and Injuries   | Barotrauma  |
| Wounds and Injuries   | Battered Child Syndrome                               |
| Wounds and Injuries   | Birth Injuries  |
| Wounds and Injuries   | Bites and Stings                                      |
| Wounds and Injuries   | Burns   |
| Wounds and Injuries   | Cold Injury   |
| Wounds and Injuries   | Contrecoup Injury                                     |
| Wounds and Injuries   | Crush Injuries  |
| Wounds and Injuries   | Drowning  |
| Wounds and Injuries   | Electric Injuries                                     |
| Wounds and Injuries   | Esophageal Perforation                                |
| Wounds and Injuries   | Extravasation of Diagnostic and Therapeutic Materials |
| Wounds and Injuries   | Foreign Bodies  |
| Wounds and Injuries   | Fractures, Bone                                       |
| Wounds and Injuries   | Fractures, Cartilage                                  |
| Wounds and Injuries   | Frostbite   |
| Wounds and Injuries   | Hand Injuries   |
| Wounds and Injuries   | Heat Stress Disorders                                 |
| Wounds and Injuries   | Hip Injuries  |
| Wounds and Injuries   | Joint Dislocations                                    |
| Wounds and Injuries   | Lacerations   |
| Wounds and Injuries   | Leg Injuries  |
| Wounds and Injuries   | Microtrauma, Physical                                 |
| Wounds and Injuries   | Multiple Trauma                                       |
| Wounds and Injuries   | Nasal Septal Perforation                              |
| Wounds and Injuries   | Neck Injuries   |
| Wounds and Injuries   | Occupational Injuries                                 |
| Wounds and Injuries   | Radiation Injuries                                    |
| Wounds and Injuries   | Retropneumoperitoneum                                 |
| Wounds and Injuries   | Rupture   |
| Wounds and Injuries   | Self Mutilation                                       |
| Wounds and Injuries   | Shock, Traumatic                                      |
| Wounds and Injuries   | Shoulder Injuries                                     |
| Wounds and Injuries   | Soft Tissue Injuries                                  |
| Wounds and Injuries   | Spinal Cord Injuries                                  |
| Wounds and Injuries   | Sprains and Strains                                   |
| Wounds and Injuries   | Surgical Wound  |
| Wounds and Injuries   | Tendon Injuries                                       |
| Wounds and Injuries   | Thoracic Injuries                                     |
| Wounds and Injuries   | Tooth Injuries  |
| Wounds and Injuries   | Trauma, Nervous System                                |
| Wounds and Injuries   | Tympanic Membrane Perforation                         |
| Wounds and Injuries   | Vascular System Injuries                              |
| Wounds and Injuries   | War-Related Injuries                                  |
| Wounds and Injuries   | Wounds, Nonpenetrating                                |
| Wounds and Injuries   | Wounds, Penetrating                                   |
| <b>Other Areas of Expertise</b>   |   |
|   |   |
| <b>Study Phase Capabilities</b>   |   |
| Phase I; Phase II; Phase III; Phase IV  |   |
| <b>Other Facility Details</b>   |   |
| Do you have Affiliated Research Sites or Satellite Sites/Clinics? A Satellite Site is a secondary location where the investigator sees clinical trial subjects, usually this is the same investigator who sees subjects at the primary site location. | No  |



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| What study types does your Facility have experience with?   | Industry; Investigator Initiated; Academic   |
| Is your Facility affiliated with a government agency or part of a government funded health service? | Yes  |
| <b>Patient Population</b>   |  |
| Patient Population Demographics   | Pediatrics - Less than or equal to 17; Adults - Ages 18-64; Geriatrics - Greater than or equal to 65 |
| <b>Patient Population Comments</b>  |  |

**IRB/ERB/ETHICS COMMITTEE**

|  |                              |
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| <b>General Questions</b>   |                              |
| What is the average time (in days) to start a study once you have received the regulatory package?   | Greater than 120             |
| Does your facility perform IRB/ERB/Ethics Committee submissions?   | Yes                          |
| Does your facility have a dedicated department or group to perform IRB/ERB/Ethics Committee submissions?   | Yes                          |
| Department Contact Name  | Center for Clinical Research |
| Department Contact Phone Number  | +81-836-22-2428              |
| Department Contact Email Address   | ychiken@yamaguchi-u.ac.jp    |
| Is your facility able to initiate study activities prior to IRB/ERB/Ethics Committee protocol approval?  | Yes                          |
| What types of IRB/ERB/Ethics Committee does your Facility use?   | Local                        |
| Does your institution and/or local regulation mandate the distribution of safety reports [e.g., Development Safety Update Report (DSUR), suspected unexpected serious adverse reaction (SUSAR)] to a local Review only IRB/ERB/Ethics Committee? | Yes                          |
| Are there any other steps that the Sponsor should be aware of for your IRB/ERB/Ethics Committee review and submission?   | No                           |
| Other Steps Explain  |                              |

**OTHER REVIEW BOARDS**

|   |    |
|---|----|
| Does your facility have Other Review Boards that need to approve the study prior to IRB/ERB/Ethics Committee submission? For example, scientific, radiation safety committees, or others. | No |
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**Local Lab**

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| Is your Facility using a Local Lab?                                    | Yes  |
| <b>Local Lab: Yamaguchi University Hospital Division of Laboratory</b> |  |
| Lab Name   | Yamaguchi University Hospital Division of Laboratory   |
| Lab Contact First Name   |  |
| Lab Contact Last Name  |  |
| Address  | 1-1-1, Minami-kogushi, Ube, Yamaguchi, Japan, 755-8505   |
| Phone Number   | +81-836-22-2582  |
| Fax Number   |  |
| Email Address  |  |
| Local Lab Accreditation  | CAP; ISO; Others   |
| Other Local Lab Accreditation  | Japanese Association of Medical Technologists and Japanese Committee for Clinical Laboratory Standards |

**CONSENT & TRAINING**

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| <b>Consent</b>  |     |
| Does your Facility have a written SOP/Policy/Procedure for: Informed Consent?                       | Yes |
| Does your Facility have a written SOP/Policy/Procedure for: Minor Assent for Pediatric Populations? | Yes |
| Does your Facility have a written SOP/Policy/Procedure for: Other Vulnerable Populations?           | Yes |





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| Will your Facility require language translations for consents?   | Yes   |
| Select the required languages  | Japanese  |
| If located in the US, has your Facility used or are you able to use the informed consent short form?   | Not Applicable  |
| <b>Training</b>  |   |
| Does your Facility have a training program for the research staff?   | Yes   |
| Does the course content include GCP?   | Yes   |
| Does your Facility use an external program to conduct research training?   | Yes   |
| Please provide program course name.  | Training in clinical reserch(including GCP) sponsored by MEXT, Training in clinical reserch(including GCP) sponsored by Japanese Society of Hospital Pharmacists, Training in clinical reserch(including GCP) sponsored by MHLW, PMDA GCP Training course |
| Do you have a process or program in place to retrain research staff when a protocol is amended?  | Yes   |
| Does the study staff that prepares or transports dangerous goods have training that meets the IATA International Air Transport Association (US) or other countries hazardous training requirements for shipping dangerous goods? | Yes   |

**FACILITY & EQUIPMENT**

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| <b>Facility Capabilities</b>  |   |
| Can your Facility support patient visits on weekends?   | Yes   |
| Can your Facility support in-patient admissions for research studies?   | Yes   |
| Does your study staff have sufficient English knowledge to understand communications in English?  | No  |
| Does your Facility have access to translators and translation support for trial conduct (e.g. consent, trial specific instruction)?   | No  |
| Does the Facility have storage space for Study-Related materials (e.g. Lab Kits, Patient Materials, etc.)?  | Yes   |
| Does your Facility have the ability to collect and store PK/PD specimens?   | Yes   |
| Does your Facility have the ability to collect PK/PD samples beyond normal business hours?  | Yes   |
| Does your Facility typically allow the collection of Pharmacogenomic (PGX) samples for research purposes?   | Yes   |
| <b>Equipment</b>  |   |
| Identify the Diagnostic Equipment available at or near the Facility to support Research studies?  | Computerized Tomography Scan; Dual-Energy X-ray Absorptiometry or Bone Densitometry; Magnetic Resonance Imaging; Fluoroscopy; X-Radiation; Magnetic Resonance Angiography; Magnetic Resonance Spectroscopy; Mammography; Nuclear Medicine (e.g. Bone scan, Thyroid scan, Thallium cardiac stress test); Electrocardiogram |
| <b>General Equipment</b>  |   |
| Does your Facility have an SOP or process that ensures routine calibration and maintenance of general equipment? Examples of general equipment include: scale, pulse oximeter, stadiometer, sphygmomanometer, etc.? | Yes   |
| Does your Facility have the necessary equipment to treat medical emergencies (ie. code cart)?   | Yes   |
| <b>Equipment Available At The Facility To Support Research Studies</b>  |   |
| Identify the equipment available at the Facility to support Research studies?   | Refrigerated Centrifuge; Centrifuge; Refrigerator (2 to 8 Degrees C); Freezer (-20 to -30 Degrees C); Freezer (-70 to -80 Degrees C)  |
| <b>Equipment Capabilities: Refrigerator (2 to 8 Degrees C)</b>  |   |





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| Do you have the ability to generate a temperature monitoring log for this equipment?   | Yes  |
| Does this equipment provide Min/Max Temperature Monitoring?  | Yes  |
| How frequently can temperature measurement occur? Check the most frequent measurement your equipment can support.  | Hourly   |
| Does this equipment have back-up power?  | Yes  |
| Does this equipment have a temperature alarm?  | Yes  |
| Do you have an SOP which supports calibration of this equipment?   | Yes  |
| <b>Equipment Capabilities: Freezer (-20 to -30 Degrees C)</b>  |  |
| Do you have the ability to generate a temperature monitoring log for this equipment?   | Yes  |
| Does this equipment provide Min/Max Temperature Monitoring?  | Yes  |
| How frequently can temperature measurement occur? Check the most frequent measurement your equipment can support.  | Hourly   |
| Does this equipment have back-up power?  | Yes  |
| Does this equipment have a temperature alarm?  | Yes  |
| Do you have an SOP which supports calibration of this equipment?   | Yes  |
| <b>Equipment Capabilities: Refrigerator (-70 to -80 Degrees C)</b>   |  |
| Do you have the ability to generate a temperature monitoring log for this equipment?   | Yes  |
| Does this equipment provide Min/Max Temperature Monitoring?  | Yes  |
| How frequently can temperature measurement occur? Check the most frequent measurement your equipment can support.  | Hourly   |
| Does this equipment have back-up power?  | Yes  |
| Does this equipment have a temperature alarm?  | Yes  |
| Do you have an SOP which supports calibration of this equipment?   | Yes  |
| <b>Computer Capabilities</b>   |  |
| Does your Facility have computers which are dedicated to research studies?   | Yes  |
| What type of computer operating system(s) does your institution use to support studies?  | Windows (Windows XP, Windows 7, Windows 8, etc.) |
| What type of internet access does your Facility have?  | Cable or DSL; Wi-Fi                              |
| Does your Facility limit or prohibit access and use of external web-based tools or sites for clinical research? (e.g. web portals to submit documents to sponsors or CROs) | No   |
| Does the Facility have access to local IT support?   | Yes  |

**INVESTIGATIONAL PRODUCT & CONTROLLED SUBSTANCES**

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|---|--|
| <b>Investigational Product Shipping Details</b>   |  |
| IP Recipient Name   | Yamaguchi University Hospital<br>Department of Pharmacy            |
| Address   | 1-1-1, Minami-kogushi, Ube,<br>Yamaguchi, Japan, 755-8505          |
| Email Address:  | di-info@yamaguchi-u.ac.jp  |
| Phone Number:   | +81-836-22-2668  |
| Fax Number:   |  |
| <b>Investigational Product Storage Location</b>   |  |
| IP Storage Location Name  | Yamaguchi University Hospital<br>Department of Pharmacy            |
| Address   | 1-1-1, Minami-kogushi, Ube,<br>Yamaguchi, Japan, 755-8505          |
| Email Address:  | di-info@yamaguchi-u.ac.jp  |
| Phone Number:   | +81-836-22-2668  |
| Fax Number:   |  |
| <b>Investigational Product Storage Equipment</b>  |  |
| Identify the Investigational Product Storage Equipment at your Facility   | Refrigerator (2 to 8 Degrees C);<br>Freezer (-20 to -30 Degrees C) |
| <b>Equipment Capabilities: Refrigerator (2 to 8 Degrees C)</b>  |  |
| Do you have the ability to generate a temperature monitoring log for this equipment?                              | Yes  |
| Does this equipment provide Min/Max Temperature Monitoring?   | Yes  |
| How frequently can temperature measurement occur? Check the most frequent measurement your equipment can support. | Daily  |
| Does this equipment have back-up power?   | Yes  |
| Does this equipment have a temperature alarm?   | Yes  |



|   |  |             |
|---|--|-------------|
| Do you have an SOP which supports calibration of this equipment?  | Yes  |             |
| <b>Equipment Capabilities: Freezer (-20 to -30 Degrees C)</b>   |  |             |
| Do you have the ability to generate a temperature monitoring log for this equipment?  | Yes  |             |
| Does this equipment have Min/Max Temperature Monitoring?  | Yes  |             |
| How frequently can temperature measurement occur? Check the most frequent measurement your equipment can support.   | Daily  |             |
| Does this equipment have back-up power?   | Yes  |             |
| Does this equipment have a temperature alarm?   | Yes  |             |
| Do you have an SOP which supports calibration of this equipment?  | Yes  |             |
| <b>Investigational Product Storage And Handling</b>   |  |             |
| Is the Investigational Product Storage Room secured with controlled access?   | Yes  |             |
| Do you have the ability to generate a temperature monitoring log for this Investigational Product Storage Room?   | Yes  |             |
| Does the Investigational Product Storage Room provide Min/Max temperature monitoring?   | Yes  |             |
| Does the Investigational Product Storage Room have back-up power?   | Yes  |             |
| Does the Investigational Product Storage Room have a temperature alarm?   | Yes  |             |
| Do you have an SOP which supports calibration of the temperature monitoring equipment?  | Yes  |             |
| Does your Facility have the ability to manage on-site or off-site destruction of Investigational Product?   | Yes  |             |
| Does your Facility have a written SOP/Policy/Procedure for destruction of Investigational Product?  | Yes  |             |
| Do you provide your Satellite Site(s) with a dedicated inventory of Investigational Product?  | Not Applicable   |             |
| Does your Facility have a written SOP/Policy/Procedure to ensure that Investigational Product is appropriately maintained during transportation to Satellite Site(s)? | Not Applicable   |             |
| Describe additional Investigational Product Storage & Handling Capabilities   |  |             |
| <b>Preparation and Administration Of Investigational Product</b>  |  |             |
| Identify the Investigational Product preparation capabilities at your Facility  | Extemporaneous Preparation; Vertical laminar flow hood (chemo/hazardous drugs) |             |
| Is your Facility capable of administering infusions?  | Yes  |             |
| Is your Facility adequately staffed to support studies with both blinded and un-blinded Investigational Product?  | Yes  |             |
| <b>Controlled Substances</b>  |  |             |
| Does the Facility have the required licenses or registrations to receive, store, dispense and return controlled substances as required by local law?                  | Yes  |             |
| Is the storage area for controlled substances securely constructed with restricted access in accordance with local law?   | Yes  |             |
| Does the Facility have the ability to handle radio-labelled Investigational Product?  | Yes  |             |
| Does your Facility have the ability to manage on-site or off-site destruction of controlled substances when appropriate?  | Yes  |             |
| <b>Attachments</b>  |  |             |
| Document Type   | Document Name  | Description |
| No Records  |  |             |

**SOURCE DOCUMENTATION**

|  |                   |
|--|-------------------|
| <b>Source Documents</b>  |                   |
| What type of source documents will be used?  | Paper; Electronic |
| Does your Facility have secure storage for patient records?                                    | Yes               |
| Does your Facility have patient record archiving on-site?                                      | Yes               |
| Provide Location name and address of any offsite archives                                      |                   |
| <b>Electronic Medical Records (EMR)/Electronic Health Records (EHR)</b>                        |                   |
| Do you have Electronic Health Records (EHR)/ Electronic Medical Records (EMR)?                 | Yes               |
| What EMR/EHR system do you use?  | In-house system   |
| For Facilities with satellite sites, where is the monitor required to access source documents? |                   |
| Please list any access limitations/requirements for the Electronic Medical Records.            |                   |
| <b>Monitoring</b>  |                   |



|   |  |
|---|--|
| Check all equipment that will be available to Monitors:                             | Phone; Fax; Copy Machines; Internet Access                   |
| What Electronic Data Capture (EDC) systems has your staff used for clinical trials? | Oracle Inform; Medidata Rave; Oracle RDC Remote Data Capture |

**ADDITIONAL LOCATIONS**

| Additional Locations   |              |         |              |            |                |
|--|--------------|---------|--------------|------------|----------------|
| Add any addresses you wish to be available in the Study Site Profile. These addresses will be available for selection in the following sections of the Study Site Profile -<br>Additional Study Locations - These addresses can be added to your FDA Form 1572, if applicable. |              |         |              |            |                |
| Location Name  | Contact Name | Address | Phone Number | Fax Number | E-mail Address |
| No Records   |              |         |              |            |                |

**ADDITIONAL INFORMATION & ATTACHMENTS**

| Additional Information   |               |                      |
|--|---------------|----------------------|
| Please provide additional information not captured in other sections of the Facility Profile that you feel is important for Sponsors to know about your Facility. Please reference the section name if applicable. |               |                      |
|  |               |                      |
| Facility Attachments   |               |                      |
| Document Type  | Document Name | Document Description |
| No Records   |               |                      |

**ORGANIZATION AFFILIATIONS**

| Organization Affiliations  |                               |                                 |             |
|--|-------------------------------|---------------------------------|-------------|
| The Organization (s) that requested Affiliation with your Facility/Department are listed below with Affiliation Status |                               |                                 |             |
| Organization Name and Address  | Organization Affiliation Type | Organization Affiliation Status | Status Date |
| No Records   |                               |                                 |             |