

【English Version】

Comprehensive Consent Regarding Medical Care, Personal Information, and Research Use (Draft)

(For Website Publication)

Fukuda Hospital, Aikukai Social Medical Corporation (hereinafter referred to as “the Hospital”), places the highest priority on providing safe and high-quality medical care to our patients. In relation to medical treatment, examinations, education, research, and related activities, we kindly request your comprehensive consent within a specified scope in advance.

When receiving medical care at our Hospital, we ask for your understanding of the following matters. Unless you expressly indicate otherwise, we will consider that you have given your consent.

1. Medical Care and Treatment

At our Hospital, medical services including medical examinations, diagnostic tests, procedures, medications, injections, blood transfusions, surgeries,

anesthesia, and labor and delivery management are performed based on medical evidence and medical safety standards.

In providing medical care, treatment policies and attending physicians may be determined at the Hospital's discretion, taking into consideration the patient's condition, urgency, and available medical resources. In cases where it is medically determined to be necessary for patient safety, such as significant bleeding, blood transfusion may be administered with priority given to patient safety, regardless of prior consent.

When medically necessary, in addition to photographing the affected areas of the patient, we may also record, photograph, audio-record, and store examinations, medical procedures, and the patient's condition or movements (such as walking) using cameras or other devices.

For highly invasive procedures or special examinations and treatments, separate explanations will be provided and individual consent will be obtained.

2. Clinical Education (Training of Healthcare Professionals)

Our Hospital conducts education and training for physicians, nurses, midwives, residents, and medical students for the purpose of improving the quality of medical care and fostering the next generation of healthcare professionals.

Accordingly, under the supervision of attending physicians or clinical instructors, residents, medical students, nursing students, and others may participate in medical care.

We will ensure that full consideration is given to patient safety and privacy, and that the quality and safety of medical care are not compromised.

3. Request for Female Physicians in Medical Care

At our hospital, we make every effort to accommodate patients' requests to be examined and treated by female physicians.

However, not only in obstetrics but across all departments, there may be situations where we are unable to meet such requests due to factors including physician availability, specialization, urgency, and the overall medical care system.

In obstetric care, in particular, the condition of the mother and fetus may change rapidly, requiring prompt and appropriate medical intervention.

Therefore, as our hospital prioritizes medical safety above all, we may not always be able to accommodate requests for female physicians—even when such requests are made not only by the patient but also by a spouse, partner, or other third parties—for the following reasons. We kindly ask for your understanding in advance.

- In emergencies or sudden changes in condition
- During nighttime, holidays, or labor and delivery
- When no female physician is available
- When considering physicians' expertise, experience, and staffing arrangements
- When accommodating the request may affect the care of other patients

Furthermore, particularly in obstetric care, to ensure sufficient understanding of medical safety and the impact on the medical care system, we ask both the patient and their partner or accompanying person to sign a separate confirmation document.

Please note that treatment by a female physician cannot be guaranteed.

4. Importance of Prenatal Checkups

Regular prenatal checkups during pregnancy are essential to protect the health of both the mother and the fetus.

If a patient does not attend prenatal checkups that the Hospital has determined to be medically necessary, or if the number of visits is extremely limited, it may become difficult to ensure the safety of the mother and fetus.

In such cases, from the perspective of medical safety and maternal and child welfare, the Hospital may review the scope of medical care provided and, when necessary, coordinate with relevant institutions.

5. Decisions Regarding Continuation of Medical Care and Provision of Services

If sufficient understanding and cooperation regarding the Hospital's medical safety policies and medical care system cannot be obtained, the Hospital may, at its discretion, limit the scope of medical services, review the continuation of care, or refer the patient to another medical institution.

6. Handling of Personal Information

The Hospital manages patients' personal information appropriately in accordance with the Act on the Protection of Personal Information and other relevant laws and regulations.

Within the scope necessary for medical care, personal information may be used or shared in the following circumstances:

1. Medical treatment and healthcare services
2. Medical insurance administration and accounting
3. Medical safety and quality improvement
4. Research and academic activities
5. Hospital administration and operations
6. Public relations and medical service information
7. Compliance with laws and regulations

For further details, please refer to the Hospital's Personal Information Protection Policy (Privacy Policy).

7. Use of Medical Information and Specimens for Research

At our Hospital, for the purpose of improving the quality of medical care and advancing medical science, information and specimens obtained through clinical practice may be used for research and educational purposes.

The information and specimens that may be used include:

- Medical records (electronic medical record data, treatment details, test results, etc.)
- Medical imaging data (ultrasound, X-ray, CT, MRI, etc.)
- Specimens (blood, urine, placenta, umbilical cord blood, amniotic fluid, etc.)
- Perinatal clinical data (pregnancy course, delivery status, neonatal information, etc.)

Such information and specimens will be appropriately processed to prevent identification of individuals and may be used for the following purposes:

(1) Academic research and quality improvement

Joint research with universities and research institutions, conference

presentations, academic publications, case reports, statistical analyses related to perinatal medicine, and evaluations aimed at improving medical quality.

(2) Clinical data analysis and development of new medical technologies

Analysis using existing clinical data, examination of new diagnostic, therapeutic, and preventive methods, medical data analysis utilizing AI (artificial intelligence), and medical digital transformation (DX).

(3) Collaboration with external institutions

Information sharing with universities, research institutions, and academic societies; participation in multicenter studies; reporting to public authorities when required by law.

When information and specimens are used for research or educational purposes, they will be managed appropriately in accordance with the Act on the Protection of Personal Information and related laws, with sufficient measures taken to ensure that individuals cannot be identified.

Patients may refuse or withdraw consent for the use of their information and specimens for research purposes.

Such refusal or withdrawal will not result in any disadvantage in medical care.

8. Photography and Video Recording Within the Hospital

In order to ensure the safety of patients and newborns, protect privacy, and maintain medical safety, photography and video recording within the Hospital are permitted in principle, provided that no third parties other than family members or Hospital staff are captured in the images.

The following conditions and prohibitions must be strictly observed:

(1) Recording of Ultrasound Images During Prenatal Checkups

Photography or video recording of a patient's own ultrasound images during prenatal checkups must not interfere with medical care or medical procedures.

(2) Recording During Delivery

Photography and video recording during delivery in the LDR room must prioritize the safety of the mother and newborn and the smooth performance of

medical procedures, and must follow the instructions of Hospital staff.

Recording in the operating room is not permitted.

(3) Recording in the NICU and GCU

Photography and video recording in the NICU (Neonatal Intensive Care Unit) and GCU (Growing Care Unit) must follow staff instructions from the perspectives of neonatal safety, infection prevention, and privacy protection.

(4) Prohibited Activities

The following activities are strictly prohibited:

- Video recording outside the areas described in (1)–(3) and outside the patient's own hospital room
- Recording in areas where unspecified persons gather, such as waiting rooms
- Recording in the operating room
- Recording other patients, healthcare professionals, or hospital facilities without permission
- Recording that interferes with medical procedures

- Recording that does not comply with staff instructions

Even if care is taken not to capture third parties or staff, recording in waiting areas is prohibited out of consideration for others who may feel uncomfortable.

(5) Other Matters

Regardless of the above, the Hospital may permit or prohibit photography and video recording at its discretion.

(6) Response to Violations of the Photography and Recording Policy

If conduct in violation of the above policy is observed, the Hospital may request cessation of recording and, if necessary, require deletion of data, review the provision of medical care, request departure from the premises, or consult relevant authorities.

9. Cooperation with Relevant Institutions

If the Hospital determines that it is difficult to ensure the safety of outpatients or inpatients, or if circumstances arise that significantly interfere with the provision of medical care, the Hospital may, in accordance with applicable laws and

regulations, cooperate and share information as necessary with administrative authorities, other medical institutions, and relevant organizations.

10. Comprehensive Consent and Patient Cooperation

This Comprehensive Consent sets forth fundamental matters necessary for the Hospital to provide safe and appropriate medical care to patients.

Patients may review the contents of this Comprehensive Consent and express their intentions regarding it. If you wish to do so, please inform the reception desk or a member of our staff.

However, if a patient's request concerns matters that affect the core structure of the Hospital's medical care system or medical safety policies, it may become difficult for the Hospital to provide safe and appropriate medical care. In such cases, at the Hospital's discretion, we may review the scope of medical services, reconsider the continuation of care, or refer the patient to another medical institution.

The Hospital values mutual cooperation between patients and healthcare professionals in order to provide safe and high-quality medical care.

Accordingly, we ask for patients' understanding and cooperation with respect to the "Responsibilities of Patients."

Please refer to the Hospital website for details regarding the "Responsibilities of Patients."

11. Inquiries

If you have any questions regarding this Comprehensive Consent, please contact:

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*This document has been translated using ChatGPT.

If you notice any errors or inaccuracies, please contact us.