＜帝王切開分娩についての説明用紙＞

§ Record of informed consent to condition, intervention, and therapy program

Important notice: Our anesthesiologist requests removal of all makeups including manicures and pedicures. Failure to do so may result in cancellation of the procedure.

When there are some therapeutic options, we will show you currently available options of interventions/therapy. And your attending doctor will recommend you one that seems suitable to you.

Every intervention/therapy (or examination) has therapeutic effects and side effects as well as varied degrees of safety or risk. Please understand advantages and disadvantages of each option and select one that seems most suitable to you by yourself.

If we recommend you therapy which may have a side effect, please understand that we thought that the expected merits of the therapy would outweigh possible demerits of side effects in the context of your condition.

To confirm what was explained and the program of intervention/therapy/ examination, please sign the informed consent form. (Even after that, we would be glad to talk with you about modification of your therapy program for a change in condition or other reasons.)

・If you have any questions, please don't hesitate to ask your attending doctor or nurses.

・Please take a copy of written information.

Department of Obstetrics & Gynecology
Aiiku Hospital, Maternal & Child Health Center
2015.7

§ Informed consent to Cesarean Delivery

Department of Obstetrics & Gynecology
Aiiku Hospital, Maternal & Child Health Center

１． Disease / Condition

(_____days _____weeks of gestation;　Today / Scheduled date of surgery) _____

２． Methods of procedure / treatment

① Cesarean delivery (abdominal Cesarean section)

Planned incisional wound: Skin incision (Transverse)

Uterine incision ①Lower transverse incision (usual Cesarean section)

Cesarean section is an operation in which abdomen is opened with skin incision and the uterus is opened to bring out the baby.

In the case of the first abdominal operation, the baby is born usually in about five minutes after the start of operation.　The total operation time is about one hour.

In atypical cases such as preterm birth or fetal malpresentation, the uterus may have to be opened vertically.

Once you go through Cesarean section, you would basically undergo Cesarean section in following deliveries as well.

In cases of preterm birth, nitroglycerin (Millisrol^{R}) may be used in order to temporarily soften the uterine wall so that the baby is delivered gently (use of the drug for expulsion is not covered by health insurance).

- **The alternative to Cesarean section: vaginal delivery**
- **Advantages and disadvantages when Cesarean section is not selected:**

② Possible concomitant operation：

Always notified during the procedure.

３． Side effects and complications which may be caused by the procedure/treatment

- **Bleeding**: Larger volume of bleeding is associated with Cesarean delivery compared with vaginal delivery. If excessive bleeding should occur to the life-threatening level, blood transfusion may be performed, though at less than 1% frequency.　(Information about blood transfusion and blood preparations is given in a separate sheet). On very rare occasions, postoperative bleeding may require another laparotomy or hysterectomy for the purpose of hemostasis.
- **Infection**: Particularly in emergent Cesarean section cases, intrauterine infection or wound infection may develop.　And wound infection may cause wound disaggregation.　Some antibiotic is administered during and after operation to prevent postoperative infection.

- **Damage to other organs**: On very rare occasions, bladder, urinary duct, or bowel may be injured. In that case we will repair the injury during operation but postoperative rest period may become longer.
- **Thrombosis/embolism**: Blood clotting is apt to occur during pregnancy. If thrombus should develop in the vein, the venous thrombosis may lead to serious pulmonary embolism (so-called economy-class syndrome). For prevention of thrombosis, massage device is placed on legs from during operation. In addition, antithrombotic therapy is administered to patients at high risk for thrombosis. The antithrombotic therapy, which uses a drug to prevent blood clotting, may cause difficulty in hemostasis leading to postoperative rebleeding or hematoma which require treatment such as another laparotomy.
- **Drug allergy**: All drugs including anesthetics may cause allergic reaction which on very rare occasions leads to shock symptoms. If you have a history of drug allergy or asthma, please report to us.
- **Other postoperative complications**: Intestinal paresis (ileus) or intraperitoneal adhesion may occur. To prevent them, early postoperative ambulation is important.
- At incision of the uterus, surgical knife or other instruments may injure the fetus. But usually the injury is very mild and it heals spontaneously without special treatment scarcely leaving any scarring.
- If hemostasis is difficult due to placenta previa or placenta accreta (the placenta invading the uterine myometrium and hardly detachable), atonic bleeding, or uterine rupture, hysterectomy may be conducted out of necessity.
- Currently in Japan, maternal mortality is about 5/100,000 people. It is reported that, while mortality rate from vaginal delivery is 2.7/100,000 people, maternal death rate from Cesarean section is 10 /100,000 people, about four times as high. However, simple comparison between the two types of delivery is inappropriate because patients who receive Cesarean section select that because they have high risk with vaginal delivery for some reason or other.
- Treatment of complications of operation is covered by health insurance.
- If hospitalization of the newborn is extended with the mother's extended hospital stay, 18,000 Yen per day is charged for hospitalization with care of the newborn unless the newborn has any abnormality.

４． Particular risks/prevention of complications for you

☐ You have normal risks, not particularly high.
☐ Anticoagulant therapy will be conducted to prevent thrombosis.
☐ Since you have high risk of massive bleeding, we will prepare for (autologous/allogeneic) blood transfusion.
☐ As you have high risk of placenta accrete, hysterectomy may be performed.
☐ :
☐ Special nutritional management: Necessary / Not necessary

Information and Consent Form about Anesthesia (for Surgery/Treatment)

Department of Anesthesiology, Aiiku Hospital

Method of anesthesia (planned)

□ General anesthesia

General anesthesia is means with which the patient is made asleep with medication.

It includes various kinds including from mild one which causes vaguely sleepy feeling to deep one which causes deep sleep followed by complete mechanical ventilation. Your anesthesiologist selects the safest method for each patient.

In cases of deep general anesthesia where breathing is completely controlled, air is sent mechanically through an instrument (through which a tube is inserted into the trachea or a mask is put into the mouth) inserted by the anesthesiologist to enable ventilation, that is artificial respiration.

(Possible complications/adverse reactions)

Nausea/vomiting, Hoarse voice for a few days (following tube insertion through the trachea), Tooth damage, Pneumonia, Pulmonary atelectasis (partial collapse of the lung), Pneumothorax (perforation of the lung), Lung edema, Heart failure, Malignant hyperpyrexia (unusually high fever, very rare)

□ Spinal anesthesia

Spinal anesthesia is a means to temporarily immobilize the lower body, without making the patient sleepy.

The procedure consists of insertion of a needle through the space of the backbone (lumbar spine) and injection of medicine(s) into the spinal subarachnoid space around the spinal cord. Soon after injection, the lower body from the navel downward becomes virtually immovable (it becomes movable again a few hours after the surgery).

The immovable part of the body feels no pain, though there is sensation of being touched.

(Possible complications/adverse reactions)

Headache (it heals in about a week in most cases), Hypotension, Nausea/vomiting, Temporary decrease in sensation/muscle weakness in the lower extremity, Nerve injury (on very rare occasions, paralysis may persist long),

Epidural hematoma (accumulation of blood), Epidural abscess (collection of pus)

☐ Epidural anesthesia

Epidural anesthesia is used in many cases to alleviate postoperative pain.

In some cases, operation may be performed only with epidural anesthesia (when the anesthesiologist judges that the procedure is safest).

For epidural anesthesia, a needle is inserted through the space of the backbone (spine) and a very thin tube named catheter is inserted into the epidural space near the spinal cord. Medicine(s) is injected through the catheter to eliminate the pain.

The catheter is left there for several days after operation. You can sleep on your back even with the indwelling catheter.

(Possible complications/adverse reactions)

Headache (it heals in about a week in most cases), Hypotension, Nausea/vomiting,
Temporary decrease in sensation/muscle weakness in the lower extremity,
Nerve injury (on very rare occasions, paralysis may persist long),
Epidural hematoma (accumulation of blood), Epidural abscess (collection of pus)

☐ Other methods of anesthesia:

Finally,

If an unexpected complication/adverse reaction should develop in association with anesthesia or allergy, we would provide the best possible therapy.

◎ As described above, I have given you information about your condition as well as Cesarean delivery and anesthesia. I also gave information about other selectable methods if any as well as their advantages or side effects.

Date:_____ time:_____ Doctor who gave information:__ 

◎ I was given information as above, asked questions if any, and understood what was informed.
I thus give consent to receive Cesarean section and accompanying treatment (anesthesia, prevention of complications, etc.).

Date:_____ Patient's signature：_____

Family member's signature：_____(Patient's_____)

Informed Consent: Husband's Attendance at C-section

C-section is one of surgeries to be performed in a clean environment and the operating room is in principle off-limits to visitors. Considering the operation is for childbirth, however, we allow the husband/partner to attend C-section when some conditions are met. For the sake of safety of the mother and child, we would appreciate your understanding and cooperation for the precautions shown below:

- The husband is led to the operating room after completion of anesthesia, disinfection of the operative field, and other arrangements. In the operating room, please keep sitting on the designated chair near the parturient's head. Please don't stand up from the chair or move around in the room as such actions would affect operation or anesthesia.
- Please put a protecting gown and cap on. The operation needs clean manipulation. Never touch the linen in the operative field or peer into the operative field as such actions will increase the risk of infection. Also avoid talking to the surgeons or the anesthetists during operation in order that they can concentrate on the procedure.
- The husband may hold the parturient's hand. As the medical procedures have a priority, however, attendance may have to be discontinued out of necessity if the husband's attendance is judged to affect the operation/anesthesia.
- In cases of high risk such as placenta previa, husband's attendance may not be allowed at the surgeon's or anesthetist's discretion. Depending on conditions, the husband's attendance would be judged to be discontinued after his entry into the room. That is for the sake of safety of the mother and child, so please understand.
- The husband will welcome the birth of baby together with his wife. After the examination by the neonatologist, the husband leaves the room together with his baby.
- Please don't bring a camera, video camera, cell phone/smartphone, etc. into the room and refrain from taking pictures or recording during operation.
- For the sake of safe medical procedure, please follow instructions of the hospital staff in the operation room. If the above precautions are not followed, we may have to ask you to leave the room.

Dept. of Ob-gyn, Aiiku Hospital Nov. 2008

Revised: June 2015

Letter of Consent

To: Director, Aiiku Hospital

We agree with the above statements and intent, and we request husband's attendance during C-section.

Date:_____

Parturient:_____

Husband/partner:_____

Blood transfusion therapy　Record of informed consent

Aiiku Hospital, Maternal & Child Health Center

This document is to explain about transfusion therapy to the patient who needs or may come to need a transfusion (including patients whose autologous blood are pooled).

Transfusion therapy is a therapy to supplement blood components (red blood cells, platelets, protein components, coagulation factors, etc.) when they decrease in number or function.

While blood transfusion has become remarkably safe recent years, it will be difficult to completely exclude side effects or complications associated with it. Non-use of blood transfusion, on the other hand, may lead to a threat to life or serious residual disabilities. When we judge a blood transfusion necessary, we explain it to a patient and the family. However, in case of emergency, the explanation will be performed after the transfusion therapy.

● You need transfusion therapy for the following reasons:

・Massive bleeding (at delivery / operation / _____)
・Decrease in coagulation factors (massive bleeding / abnormal blood clotting due to hypertension disorders of pregnancy / congenital clotting factor deficiency / _____)
・Thrombocytopenia ・Others _____

● When blood transfusion is not given, it may lead to (_____)

● Planned volume of blood transfusion and type of blood preparation to be used:

・Red blood cells _____ units ・Fresh frozen plasma _____ units
・Platelets _____ units ・Others (_____) _____ units

● For each type of blood preparation, expected effects of blood transfusion and risk with non-use are as follows：

・Red blood cells

Red blood cells carry oxygen taken up at the lung all through the body. Depletion of red blood cells causes lack of oxygen and dysfunction of organs, and prolongation of such condition may leave disorders in the body system.

・Fresh frozen plasma

Plasma is the light yellow fluid which remains after cellular components such as red blood cells, leukocytes, and platelets are removed from the blood. Plasma contains various proteins and blood coagulation factors in it. In some pathological conditions, such as massive bleeding, blood coagulation factors are consumed excessively, which makes bleeding less controllable. Fresh frozen plasma is given on such occasions or when such conditions may arise.

・Platelets

Platelets cooperate with blood coagulation factors to close bleeding wounds or prevent leakage of blood by reinforcing the vascular wall. Lack of platelets due to massive bleeding or diseases such as thrombocytopenia may cause bleeding without any injuries or less controllable bleeding from a wound. Platelet preparation is used to treat such conditions. In patients who do not have sufficient platelets inherently, a platelet preparation will be given in advance of the delivery.

● Side effects, complications, and risk associated with transfusion therapy

*Figures in parentheses denote approximate incidences when blood from five donors is transfused (quoted from a report of the Informed Consent Subcommittee, The Japan Society of Blood Transfusion)

・Post-transfusion infections
- Hepatitis C and B (1/ 1,000,000)
- HIV (＜1/ 10,000,000)
- Other infections〔Yersinia, malaria, HTLV-1 virus, parvovirus, Creutzfeldt-Jakob disease, and others〕 (from unknown incidence to ＜1/ 1,000,000)

In addition to hepatitis screening and HIV antigen/antibody screening conducted in blood donors, nucleic-acid amplification testing to detect trace amounts of viruses have shortened the negative test period in the early phase infection (window period). As a result, the incidences of posttransfusion infections decreased fairly but it is impossible to completely eliminate them. Infections with unknown pathogenic agents may also arise.

・Allogeneic response
- Hives, fever (1/ 10 - 1/ 100)
- Anaphylactic shock (1/ 10,000): with breathing difficulty, erythema, and blood pressure fall
- Hemolysis (1/ 1,000 of mild cases to 1/ 10,000 of severe cases)

※Immune reaction caused by anyone else's components taken into the body.

・Graft-versus-host disease〔GVHD〕

The complication has not been confirmed in Japan since 2000 as irradiated blood became widely used. It is a complication in which any donor leukocytes contained in a transfusion preparation attack and destroy the patient's body tissues. Irradiation inactivates those leukocytes. Fever, erythema, hepatic disorder, diarrhea, pancytopenia, and bone marrow aplasia develop after one to two weeks, and the condition follows fatal course. Once developed, there is no effective therapy for it at present. Transfusion of blood from relatives is avoided because it increases the risk of this complication.

・Transfusion-related acute lung injury〔TRALI〕 (309 cases, including suspected cases were reported since 2004 to 2012 in Japan.)

It is breathing difficulty accompanied by lung edema which develops during or within 6 hours after blood transfusion. This condition is presumed to develop as antigen-antibody reaction, in which anti-leukocyte antibodies in blood preparations damage the peripheral blood vessels of the lung, though the detailed mechanism is unknown. Once developed, respiratory management with a respirator is necessary to control the condition.

● To avoid blood transfusion

When a bleeding necessitating blood transfusion is expected and there is sufficient time, the patient's own blood may be withdrawn and pooled. By the own blood transfusion, the side effects and the complications mentioned in the previous section are logically avoided. However, blood cannot be withdrawn in cases with, for example, anemia, and the withdrawing during pregnancy would be harmful for both the mothers and the fetuses. The preserved blood cannot be used in cases of bacterial contamination or clotting, which occur on rare occasions.

● Therapies, alternative to transfusion therapy

Usually alternative therapies, if available, are used before considering the blood transfusion therapy.
Examples of alternative therapies: Fluid replacement therapy, vasopressor therapy, anti-inflammatory treatment with corticosteroid, iron preparation.

● Care after blood transfusion

Tests to see liver functions, anemia, and post-transfusion infections are conducted one and three months after transfusion.

● Emergency response

Please understand that the minimum necessary volume of blood may be transfused at a doctor's discretion when blood transfusion seems urgently necessary. In emergency situations, we do not have time enough to obtain prior consent from the patient or the family. In such cases, your retrospective approval would be requested.

● Retention of Records and Disclosure of Information

Date:_____

Patient's signature_____

Aiiku Hospital retains the records of your name and address, the preparation's name and lot No. (production number), and the date of administration for twenty years. If any events should occur requiring action to prevent occurrence or expansion of health hazards due to the use of blood transfusion, we may present the records to the preparation's manufacturer and/or Japanese administrative agencies.

Plasma preparations therapy　Record of informed consent

Aiiku Hospital, Maternal & Child Health Center

Plasma preparations are products prepared from plasma component, blood residue after removal of cell components. The preparations are used only when their benefits are thought to overweigh risks.

● Types of plasma preparations

・Dried and concentrated human anti-thrombin

Deficiency of anti-thrombin makes the body prone to develop clots to cause embolism or other disorders, thus threatening life. Anti-thrombin preparations work to normalize the regulating mechanism of clot formation or resolution.

・Fibrinogen preparations

In some conditions such as massive bleeding, sepsis, and systemic thromboembolism, the coagulation factors are consumed extensively and the clotting system falls into malfunction. The condition is called disseminated intravascular coagulation (DIC). Fibrinogen, which is one of the coagulation factors, usually decreases after acute DIC develops. In that condition, only fibrinogen preparations can resolve the bleeding tendency. Please understand that the Japanese health insurance does not cover the fibrinogen preparations therapy in acute DIC cases.

・Albumin preparations

The main function of albumin is to maintain the osmotic value level within the plasma and thus to prevent water in plasma from permeating out of vessels. In some conditions such as massive bleeding, plasma protein level drops to a low level, which brings in pulmonary edema, pleural effusion, and ascites. Albumin preparations are used to improve those symptoms.

・Immunoglobulin preparations

Immunoglobulin preparations are known to have an effect of improving or preventing infections. They are also effective in regulating immunity and improving Kawasaki disease, idiopathic thrombocytopenic purpura, Guillain-Barre syndrome, and chronic inflammatory demyelinating polyradiculoneuropathy.

※Anti-D human immunoglobulin is used when blood type incompatibility is expected between the fetus with Rh (+) and the mother with Rh (-).

・Fibrinogen preparations (factor XIII with fibrinogen, fibrinogen combination products, etc.)

An adhesive made of coagulation factor in blood, which is applied to operative wound (not to be administered intravenously). The agent prevents leakage of blood, fluid, or gas from the site of surgical suture or juncture.

・Other plasma preparations may be used to compensate for deficiencies in respective blood components and improve the clinical condition (such as an adhesive patch to stop bleeding on the surface of an organ).

● Adverse effects

・Infection

The preparations are made from blood which has been checked for viruses and heat-treated to inactivate viruses. No viral infections such as HIV infection or hepatitis due to those preparations have so far been confirmed. However, as they are made from blood, possibility of infection cannot be completely excluded.

Also undeniable is a risk of infection with unknown pathogens such as abnormal prions --presumably causative of the new type of Creutzfeldt-Jakob disease--which cannot be removed with the current technique.

Since it is difficult to completely inactivate or remove viruses such as human parvovirus B19 (pathogen for infectious erythema), we will cautiously follow the course after administration.

・Allergic reaction

Hives, anaphylactic reaction, fever, decrease in blood pressure, difficulty in breathing, etc.

● Emergency procedures

On life-threatening occasions, we will place utmost priority on life saving. Please understand that information in this leaflet may be given after administration of a plasma preparation in those cases.

● Possible risks associated with non-use of plasma preparations

・Pulmonary embolism (respiratory arrest) due to blood clot or embolism, multi organ failure;
・Respiration failure due to pulmonary edema;
・Excess strain on the cardiovascular system due to decreased circulating plasma volume; etc.

--All of the above conditions may threaten life.

● Retention of Records and Disclosure of Information

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Doctor who gave the information: 

Nurse/midwife in charge:_____

Date:_____

We have been fully informed about the necessity and risks of the transfusion and plasma preparations therapies. We have understood and consent to the therapies, related treatments and tests.

Date:_____

Patient's signature_____

(Family member's signature_____,

patient's_____)