INFORMOVANÝ SOUHLAS

First name and surname:	**Insurance ID #:**
Patient's guardian (name and surname):	

Denomination of the health care intervention (or interventions):

DONATION OF BLOOD OR BLOOD COMPONENTS FOR AUTOTRANSFUSION

Goal, nature, presumed benefit, effects and possible risks of the health care intervention:

Donation of blood or blood components for autotransfusion is a procedure when a pre-defined quantity of whole blood or using a special device (separator) a specific blood component (red blood cells, blood plasma or platelets) is taken from the patient. Autotransfusion is transfusion of blood or blood components coming from the patient-recipient's blood stream. Therefore, the donor is also the recipient at the same time. Preparation for autotransfusion also includes laboratory tests on the taken blood, including the ABO test (blood type), test for presence of irregular antibodies against red blood cells, tests for hepatitis (jaundice) B and C, syphilis and HIV (AIDS virus). In case of adverse test results, the referring doctor is informed and the blood taken from the patient may be disposed of. Blood and blood components taken for treatment of any other patients, so they will be disposed of if not used.

Preparation: we recommend to eat a low fat meal (eg. bread, jam, honey, fruit, etc.) and drink at least 0.5 litres (eg. soda, still water, juice, etc.) in the morning.

Advantages of autotransfusion: prevention of transmission of infectious diseases from donor to recipient, exclusion of possible alloimmunization (creation of antibodies against red blood cells, white blood cells or platelets in connection with the transfusion, and the graft versus host disease is excluded too. Further, a considerable reduction in occurrence of febrile (feverish) responses for other reasons than bacterial contamination.

Drawbacks of autotransfusion: limitation by diagnosis – donations for autotransfusion are only suitable for certain types of operations and only under certain health conditions on the patient's part. The donation must be done in adequate advance before the planned surgery (not less than 1 week). In case of delay of the surgery, the expiry date of the transfusion preparation (i.e. the end of its life time) may come, as the storage life of the preparation is limited.

Risks of donation of whole blood for autotransfusion: some are connected with possible occurrence of systemic disease in the patient, use of medications, there is a risk of induction of anaemia due to blood donation, and some circulatory complications. In connection with venepuncture (puncture of a vein), bruising at the site of the puncture can occur, or rarely injury to the tissues.

Risks of taking blood components by machine: only one specific blood component is taken each time, while the other components are returned to the patient's blood flow. As anti-coagulating solution is added to the blood components that are returned to the patient's blood flow, which reduces the calcium levels in the body, some predisposed (prone) persons may experience the feeling of pins and needles in the tongue, lips and/or fingertips, and rarely cramps if the reduction of calcium is dramatic. We prevent these unwanted reactions by giving the patient calcium, dissolved in water, before or during the donation. Rarely, a systemic response (fainting, collapse condition) can occur during or after the donation, most often due to transient decrease in blood pressure, and therefore normal saline solution is applied into a vein to compensate for the taken volume of red blood cells. The puncture into the vein can lead to bruising at the site of the jab, or rarely to injury to the tissues. In case of the patient's

INFORMOVANÝ SOUHLAS

First name and surname:	**Insurance ID #:**

predisposition (inborn or acquired), allergic or even anaphylactic reaction (severe systemic allergic response) to the solutions and/or disinfectants used.

The hazard of administration of autotransfusion consists in possible incidence of bacterially toxic or allergic reaction. In case of lack of autologous transfusion preparations (autotransfusion) or in case of their disposal due to inadequate laboratory results or for other reasons, allogeneic transfusion preparations can be given (i.e. those prepared from other donors' blood).

Other options, their appropriateness, benefits and hazards:

Administration of an allogeneic transfusion preparation (i.e. one prepared from other donor's blood).

Benefits: the donation needn't be planned before the surgery, so it can also be used in unplanned surgeries; the patient does not take the risks connected with the reaction to donation; also suitable in patients that are contraindicated (not suitable) for donation for autotransfusion, e.g. because of systemic diseases.

Risks: general risks of transfusion, such as haemolytic post-transfusion reaction (disintegration of red blood cells in the recipient's blood stream), non-haemolytic post-transfusion reactions (chills, fever, urticaria), allergy or even anaphylaxis (severe general allergic reaction), alloimmunization in HLA and in group systems of erythrocytes (generation of antibodies connected with transfusion), transmission of infection from donor to recipient, sepsis due to incidental bacterial contamination, metabolic imbalance on massive transfusion, acute damage of the lungs connected with transfusion (TRALI), post-transfusion purpura (severe acute decrease of the level of blood platelets in the recipient's blood flow connected with presence of antibodies against blood platelets), graft versus host disease (reaction of the donor's immunity system against the recipient), circulatory overload, iron overload.

The course of the health care intervention will be as it follows:

Taking of blood or blood components for autotransfusion is performed before the planned surgery on the basis of the referral by the attending doctor (usually a surgeon or anaesthetist). Before blood is taken, the patient is examined by a doctor of the blood transfusion department, who will – considering the patient's history, clinical state and laboratory results – decide whether the patient is able to undergo the donation for autotransfusion at the moment. If need be, he/she will decide on examination of the blood count before the donation.

Course of the donation:

Donation of whole blood: after disinfection of the skin at the elbow crease, venepuncture (puncture of a vein) will be performed, using a disposable blood sampling set (including a disposable needle) and 450 ml blood will be taken for autotransfusion and a sample of blood for investigation for the blood type and signs of clinically important infections (HIV 1,2; hepatitis type B and C; syphilis). As the material used is disposable, there is no risk of transmission of infection. The procedure takes approximately 8-15 minutes.

Taking blood components by machine: after disinfection of the skin at the elbow crease, venipuncture (puncture of a vein) will be performed, and blood will be taken using a special apparatus (separator of blood elements). The set used, which includes a disposable needle, is only used once, so that the risk of transmission of infection will be excluded. During the procedure, only a certain element of blood (red blood cells, blood platelets or plasma) is taken from the blood flow while the other elements of blood will be returned into the patient's blood

INFORMOVANÝ SOUHLAS

First name and surname:	**Insurance ID #:**

circulation. As prevention of a decrease of calcium level, the patient will be given a beverage with calcium dissolved. The donation takes approximately 30-90 minutes, considering the patient's clinical state and blood count values.

Limitations and recommendations concerning:

It is necessary to stay in the sitting or lying position under supervision at the department and only leave it after the definitive treatment of the site of the puncture and check-up by a health professional, and motor vehicles must not be driven within at least 30 minutes following the procedure.

The dressing/adhesive plaster at the site of the puncture should be left at the place for that day.

On the day of the procedure (before as well as after) you should not fast, you should take care of your fluid intake, take your regular medicines and avoid alcoholic beverages.

On the day of the procedure, regimen of rest is recommended (avoiding increased physical activity), and the arm from which blood was taken should not be used to lift and/or carry objects.

Further necessary treatment:

As ordered by the attending doctor.

Thereby I declare that the doctor who informed me personally explained to me everything that constitutes the content matter of this written Informed Consent, and that I had the chance to ask questions, which were properly answered. I declare that I fully understand the said information and explanation, and I give my explicit consent to this health care intervention to be performed:

If the patient is **a minor or a person with limited legal capacity** and he/she is adequately mature in the mental and volitional aspects:

I declare that I was informed to the above extent.

If such information was not provided to the patient, the reason why it was not provided will be specified here:

In Prague on

.....	.....
Patient's / Guardian's signature	*Doctor's name, surname and signature*

.....

signature of minor Patient / Patient with limited legal capacity

If the Patient / Guardian cannot sign due to the health state:

The reason why the Patient / Guardian is not able to sign:

The way the Patient / Guardian manifested his/her will:

.....

Witness's name, surname and signature