Parental agreement to investigation or treatment of a child: routine procedures under general anaesthetic for the whole course of leukaemia treatment

Key messages for patients
- Please read your admission letter carefully. It is important to follow the instructions we give you about your child not eating or drinking or we may have to postpone or cancel the procedure(s).
- Please read this information carefully, you and your health professional will sign it to document your consent.
- It is important that you bring the consent form with you when you are admitted for surgery. You will have an opportunity to ask any questions from the surgeon or anaesthetist when you are admitted. You may sign the consent form either before you come or when your child is admitted.
- Please bring with you any medications and it’s packaging your child uses (including inhalers, injections, creams, eye drops, patches, insulin and herbal remedies), a current repeat prescription from your GP, any cards about your treatment and any information that you have been given relevant to your care in hospital, such as x rays or test results.
- Laxatives and painkillers may be required after your hospital stay; please ensure you have appropriate supplies at home.
- Your child must take their medications as normal on the day of the procedure unless you have been specifically told that they should not take a drug or drugs before or on the day by a member of the medical team. If your child has diabetes please ask for specific individual advice to be given on the medication at the pre-operative assessment appointment.
- Please call your clinical nurse specialist on telephone number 01223 216485 if you have any questions or concerns about this procedure or your appointment.

After the procedure we will file the consent form in your child’s medical notes and you may take this information leaflet home with you.

Important things you need to know
Patient choice is an important part of your care. You have the right to change your mind at any time, even after you have given consent and the procedure has started (as long as it is safe and practical to do so). If you are having an anaesthetic you will have the opportunity to discuss this with the anaesthetist, unless the urgency of your treatment prevents this.

We will also only carry out the procedure on your consent form unless, in the opinion of the health professional responsible for your care, a further procedure is needed in order to save your life or prevent serious harm to your health. However, there may be procedures you do not wish us to carry out and these can be recorded on the consent form. We are unable to guarantee that a particular person will perform the procedure. However the person undertaking the procedure will have the relevant experience.

All information we hold about you is stored according to the Data Protection Act 1998.
What is leukaemia?

Leukaemia is a type of blood cancer. Leukaemia cells are made in the bone marrow (the blood ‘factory’, where all blood cells are made) and are sometimes also found in the cerebrospinal fluid (CSF), which is the fluid surrounding the brain and spine. This is why we must look in both the bone marrow and CSF regularly to make sure the treatment is working. We also give medicines into the CSF (called intrathecal chemotherapy) to treat cells found in this area, even if there are no cells found there.

Intended benefits

- Lumbar puncture (to obtain samples of cerebrospinal fluid - CSF)
- Intrathecal chemotherapy (part of leukaemia treatment)
- Bone marrow aspirate and trephine (to sample the bone marrow using a smaller or larger needle).

Who will perform my procedure?

This procedure will be performed by experienced doctors from the Paediatric Oncology and Haematology Unit.

On the day before the planned procedure:

- Your child will need to have blood taken the day before the procedure (we will organise who does it for you). This is to make sure that their blood count is ok for both the procedure and the anaesthetic, and to let us order additional blood or platelets if needed.
- Please check with the Paediatric Day Unit (PDU) the afternoon before the procedure to see if we will be able to go ahead as planned (this will depend on the blood test results).
- Please also let us know if your child has a cold or other infectious illness.

On the day of the procedure

- Please remove any nail-varnish and/or make-up because they could hide important signs during the anaesthetic.
- This procedure will usually be carried out under a general anaesthetic. We explain about the different types of anaesthesia or sedation we may use at the end of this leaflet. It is very important that your child does not eat anything for six hours before the general anaesthetic. Your child may drink water (not milk) but must not drink anything for three hours before the anaesthetic.
- Immediately before the procedure, your child will be weighed and have their temperature, pulse, blood-pressure and oxygen levels checked.
- You will also see a doctor and an anaesthetist (who is the doctor who will give the anaesthetic) to make sure your child is fit for both the procedure and the anaesthetic. It is important to tell our staff if your child has a cough/cold or any other minor illness on the day, because this might affect the anaesthetic. You will also be asked about any allergies, previous anaesthetics, loose teeth and when your child last ate or drank.
Patient Information

- Most children who have this procedure will need to stay in hospital for the day. Your doctor will discuss the length of stay with you.
- Please ask us any questions you have about the procedure or anaesthetic at any time.

During the procedure

- **The anaesthetic**
  Your child will be asleep and will not be aware or feel anything during the procedure. The anaesthetic will be given via a mask (using gas), or into a vein.

- **Lumbar puncture and intrathecal chemotherapy**
  During a lumbar puncture a small needle is inserted into your child’s back to remove a sample of CSF, which is a clear liquid that surrounds the spine and brain. This sample is sent to the laboratory for testing. If required, medicines can then be injected through the same needle. The needle is then removed, and a small plaster put on the area. This plaster must be removed later the same day.

- **Bone marrow aspirate**
  During this procedure, a needle is inserted into the back of the hip bone to sample the bone marrow. This sample is sent to the laboratory for testing. A small plaster will then be put on the area, which must be removed later that day.

  Very occasionally an extra bone marrow sample may be taken, from the same place as the first, but with a slightly bigger needle (this is called a trephine). This is sent to a different laboratory for testing, and the results can take a week to come back.

After the procedure

After the procedure, your child will stay in the treatment room until the anaesthetist is happy that they have woken up enough to go back to the ward area. They may sleep for a while afterwards and might need to have some extra oxygen using a face mask.

- **Eating and drinking.** After this procedure, your child can eat and drink as normal.

- **Getting about after the procedure.** After a lumbar puncture, if possible, your child should lie flat for an hour, because this will help to prevent headaches in the first few hours.

- **Leaving hospital.** Once your child is awake, has had something to eat and drink, and the nurses and you are happy, you will be discharged home (provided no further treatment is needed that day).
Special measures after the procedure: Your child may have slight bruising around the sites of both a lumbar puncture and bone marrow aspirate/trephination, and this area might be a little tender. Taking Calpol (a type of paracetamol) can help this, so if your child is sore please ask a member of staff for some.

We will give you further information about any special measures you need to take after the procedure. We will also give you information about things to watch out for that might be early signs of problems (eg infection).

Check-ups and results: Before you leave hospital, we will give you a follow up appointment.

Significant, unavoidable or frequently occurring risks of this procedure

- There is a small chance of bruising around or bleeding from procedure sites. If there is bleeding, press on the area until it stops. Paracetamol can be given if there is any pain.
- It is also possible for these sites to become infected, as with any break in the skin. This is more of a risk if your child has neutropenia (low neutrophils). Removing the plaster later the same day can reduce this risk. Please watch for signs of infection, which are redness, pain or swelling.
- Serious complications with anaesthetics are very rare. Any increased risk due to your child’s personal health and circumstances will be discussed with you on the day of the procedure. The anaesthetist will care for all aspects of your child’s health and safety over the period of their procedure and immediately after.

Alternative procedures that are available

As treatment progresses, some children decide that they would prefer to have their procedures carried out under a local anaesthetic. This means that they can be awake while the procedure is carried out. We will talk to you about this if you would like to know more.

Information and support

Additional information will be given to you in the form of patient information leaflets. Please speak to a member of staff if you have any questions or anxieties.

- PDU (Day Unit) 01223 217234 or 257157
- Ward C2 01223 217231 or 217534

Further information

Training doctors and other health professionals is essential for the continuation of the health service and improving the quality of care. Your child’s treatment may provide an important opportunity for such training, where necessary under the careful supervision of a senior doctor. When new doctors join the team and during their training, they will

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always be supervised by a senior doctor.

Anaesthesia

Anaesthesia means ‘loss of sensation’. There are three types of anaesthesia: general, regional and local. **The type of anaesthesia chosen by your anaesthetist depends on the nature of your surgery as well as your health and fitness.** Sometimes different types of anaesthesia are used together.

**Before your operation**

Before your operation you will meet an anaesthetist who will discuss with you the most appropriate type of anaesthetic for your operation, and pain relief after your surgery. To inform this decision, he/she will need to know about:

- your general health, including previous and current health problems
- whether you or anyone in your family has had problems with anaesthetics
- any medicines or drugs you use
- whether you smoke
- whether you have had any abnormal reactions to any drugs or have any other allergies
- your teeth, whether you wear dentures, or have caps or crowns.

Your anaesthetist may need to listen to your heart and lungs, ask you to open your mouth and move your neck and will review your test results.

**Pre-medication**

You may be prescribed a ‘premed’ prior to your operation. This is a drug or combination of drugs which may be used to make you sleepy and relaxed before surgery, provide pain relief, reduce the risk of you being sick, or have effects specific for the procedure that you are going to have or for any medical conditions that you may have. **Not all patients will be given a premed or will require one and the anaesthetist will often use drugs in the operating theatre to produce the same effects.**

**Moving to the operating room or theatre**

You will usually change into a gown before your operation and we will take you to the operating suite. When you arrive in the theatre or anaesthetic room and **before starting your anaesthesia, the medical team will perform a check of your name, personal details and confirm the operation you are expecting.**

Once that is complete, monitoring devices may be attached to you, such as a blood pressure cuff, heart monitor (ECG) and a monitor to check your oxygen levels (a pulse oximeter). An intravenous line (drip) may be inserted. If a regional anaesthetic is going to be performed, this may be performed at this stage. If you are to have a general anaesthetic, you may be asked to breathe oxygen through a face mask.

It is common practice nowadays to allow a parent into the anaesthetic room with
children; as the child goes unconscious, the parent will be asked to leave.

**General anaesthesia**

During general anaesthesia you are put into a state of unconsciousness and you will be unaware of anything during the time of your operation. Your anaesthetist achieves this by giving you a combination of drugs.

While you are unconscious and unaware your anaesthetist remains with you at all times. He or she monitors your condition and administers the right amount of anaesthetic drugs to maintain you at the correct level of unconsciousness for the period of the surgery. Your anaesthetist will be monitoring such factors as heart rate, blood pressure, heart rhythm, body temperature and breathing. He or she will also constantly watch your need for fluid or blood replacement.

**Regional anaesthesia**

Regional anaesthesia includes epidurals, spinals, caudals or local anaesthetic blocks of the nerves to the limbs or other areas of the body. Local anaesthetic is injected near to nerves, numbing the relevant area and possibly making the affected part of the body difficult or impossible to move for a period of time. Regional anaesthesia may be performed as the sole anaesthetic for your operation, with or without sedation, or with a general anaesthetic. Regional anaesthesia may also be used to provide pain relief after your surgery for hours or even days. Your anaesthetist will discuss the procedure, benefits and risks with you and, if you are to have a general anaesthetic as well, whether the regional anaesthesia will be performed before you are given the general anaesthetic.

**Local anaesthesia**

In local anaesthesia the local anaesthetic drug is injected into the skin and tissues at the site of the operation. The area of numbness will be restricted. Some sensation of pressure may be present, but there should be no pain. Local anaesthesia is used for minor operations such as stitching a cut, but may also be injected around the surgical site to help with pain relief. Usually a local anaesthetic will be given by the doctor doing the operation.

**Sedation**

Sedation is the use of small amounts of anaesthetic or similar drugs to produce a ‘sleepy-like’ state. Sedation may be used as well as a local or regional anaesthetic. The anaesthesia prevents you from feeling pain and the sedation makes you drowsy. Sedation also makes you physically and mentally relaxed during an investigation or procedure which may be unpleasant or painful (such as an endoscopy) but where your co-operation is needed. You may remember a little about what happened but often you will remember nothing. Sedation may be used by other professionals as well as anaesthetists.

**What will I feel like afterwards?**

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How you will feel will depend on the type of anaesthetic and operation you have had, how much pain relieving medicine you need and your general health.

Most people will feel fine after their operation. Some people may feel dizzy, sick or have general aches and pains. Others may experience some blurred vision, drowsiness, a sore throat, headache or breathing difficulties.

You may have fewer of these effects after local or regional anaesthesia although when the effects of the anaesthesia wear off you may need pain relieving medicines.

What are the risks of anaesthesia?

In modern anaesthesia, serious problems are uncommon. Risks cannot be removed completely, but modern equipment, training and drugs have made it a much safer procedure in recent years. The risk to you as an individual will depend on whether you have any other illness, personal factors (such as smoking or being overweight) or surgery which is complicated, long or performed in an emergency.

Very common (1 in 10 people) and common side effects (1 in 100 people)

- Feeling sick and vomiting after surgery
- Sore throat
- Dizziness, blurred vision
- Headache
- Bladder problems
- Damage to lips or tongue (usually minor)
- Itching
- Aches, pains and backache
- Pain during injection of drugs
- Bruising and soreness
- Confusion or memory loss

Uncommon side effects and complications (1 in 1000 people)

- Chest infection
- Muscle pains
- Slow breathing (depressed respiration)
- Damage to teeth
- An existing medical condition getting worse
- Awareness (becoming conscious during your operation)

Rare (1 in 10,000 people) and very rare (1 in 100,000 people) complications

- Damage to the eyes
- Heart attack or stroke
- Serious allergy to drugs
- Nerve damage
- Death
- Equipment failure

Deaths caused by anaesthesia are very rare. There are probably about five deaths for
every million anaesthetics in the UK.

For more information about anaesthesia, please visit the Royal College of Anaesthetists’ website: [www.rcoa.ac.uk](http://www.rcoa.ac.uk)

**Glossary of terms**

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>ALL</td>
<td>Acute lymphoblastic leukaemia</td>
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<tr>
<td>AML</td>
<td>Acute myeloid leukaemia</td>
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<tr>
<td>Anaesthetist</td>
<td>The doctor who will give the anaesthetic for the procedure and monitor your child’s condition during procedures and in recovery</td>
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<tr>
<td>Bone marrow</td>
<td>The blood ‘factory’ where the blood cells are made</td>
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<tr>
<td>Bone marrow aspirate</td>
<td>A small amount of bone marrow taken with a needle and syringe</td>
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<tr>
<td>Central line</td>
<td>A tube through which blood can be taken and medicines given</td>
</tr>
<tr>
<td>Chemotherapy</td>
<td>Drug treatment for leukaemia or other forms of cancer</td>
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<tr>
<td>CNS</td>
<td>Central nervous system, the brain and spine</td>
</tr>
<tr>
<td>CSF</td>
<td>Cerebrospinal fluid, the fluid around the brain and spine</td>
</tr>
<tr>
<td>General anaesthetic</td>
<td>A special sleep, which will mean your child will be not be aware or feel anything during the procedure</td>
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<tr>
<td>Intrathecal</td>
<td>Medicines given into the CSF</td>
</tr>
<tr>
<td>Intravenous</td>
<td>Medicines given into the veins or blood stream</td>
</tr>
<tr>
<td>Lumbar puncture</td>
<td>A needle is inserted into the lower back and fluid is taken off</td>
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<tr>
<td>Oncology</td>
<td>Care of people with cancer</td>
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<tr>
<td>Neutropenia</td>
<td>Low neutrophils, meaning your child is at risk of infection</td>
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<tr>
<td>Neutrophil</td>
<td>A type of white cell, which fights infection</td>
</tr>
<tr>
<td>Paediatric</td>
<td>Children’s</td>
</tr>
<tr>
<td>Remission</td>
<td>There is no leukaemia seen in the bone marrow</td>
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<tr>
<td>Trephine</td>
<td>An extra bone marrow sample taken with a slightly larger needle. This is only taken occasionally and is sent to a different laboratory for testing. It is a different way of looking at the bone marrow, and it takes a week for the results to be ready</td>
</tr>
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Information about important questions on the consent form

1  Creutzfeldt Jakob Disease (‘CJD’)

We must take special measures with hospital instruments if there is a possibility you have been at risk of CJD or variant CJD disease. We therefore ask all patients undergoing any surgical procedure if they have been told that they are at increased risk of either of these forms of CJD. This helps prevent the spread of CJD to the wider public. A positive answer will not stop your procedure taking place, but enables us to plan your operation to minimise any risk of transmission to other patients.

2  Photography, Audio or Visual Recordings

As a leading teaching hospital we take great pride in our research and staff training. We ask for your permission to use images and recordings for your diagnosis and treatment; they will form part of your medical record. We also ask for your permission to use these images for audit and in training medical and other healthcare staff and UK medical students; you do not have to agree and if you prefer not to, this will not affect the care and treatment we provide. We will ask for your separate written permission to use any images or recordings in publications or research.

3  Students in training

Training doctors and other health professionals is essential to the NHS. Your treatment may provide an important opportunity for such training, where necessary under the careful supervision of a registered professional. You may, however, prefer not to take part in the formal training of medical and other students without this affecting your care and treatment.

4  Use of Tissue

As a leading biomedical research centre and teaching hospital, we may be able to use tissue not needed for your treatment or diagnosis to carry out research, for quality control or to train medical staff for the future. Any such research, or storage or disposal of tissue, will be carried out in accordance with ethical, legal and professional standards. In order to carry out such research we need your consent. Any research will only be carried out if it has received ethical approval from a Research Ethics Committee. You do not have to agree and if you prefer not to, this will not in any way affect the care and treatment we provide. The leaflet ‘Donating tissue or cells for research’ gives more detailed information. Please ask for a copy.

If you wish to withdraw your consent on the use of tissue (including blood) for research, please contact our Patient Advice and Liaison Service (PALS), on 01223 216756.
Same sex bays and bathrooms are offered in all wards except critical care and theatre recovery areas where the use of high-tech equipment and/or specialist one to one care is required.

We are now a smoke-free site: smoking will not be allowed anywhere on the hospital site.

For advice and support in quitting, contact your GP or the free NHS stop smoking helpline on 0800 169 0 169.

Other formats:

If you would like this information in another language, large print or audio, please ask the department where you are being treated, to contact the patient information team: patient.info@addenbrookes.nhs.uk.

Please note: We do not currently hold many leaflets in other languages; written translation requests are funded and agreed by the department who has authored the leaflet.
Routine procedures during Leukaemia treatment:
Lumbar Punctures / Intrathecal Chemotherapy/
Bone Marrow Aspirates (+/- trephine)

A Patient's side  left / right or N/A

Consultant or other responsible health professional

Name and job title:

☐ Any special needs of the patient (e.g. help with communication)?

Please use 'Procedure completed' stamp here on completion: Not applicable

B Statement of health professional (details of treatment, risks and benefits)

1 I confirm I am a health professional with an appropriate knowledge of the proposed procedure, as specified in the hospital's consent policy. I have explained the procedure to the patient. In particular, I have explained:

a) the intended benefits of the procedure (please state)

• Lumbar puncture (to obtain samples of cerebrospinal fluid - CSF)
• Intrathecal chemotherapy (part of leukaemia treatment)
• Bone marrow aspirate and trephine (to sample the bone marrow using a smaller or larger needle).

b) the possible risks involved. Addenbrooke’s always ensures any risks are minimised. However all procedures carry some risk and I have set out below any significant, unavoidable or frequently occurring risks including those specific to the patient

• Bruising around or bleeding from procedure sites.
• Infection around the procedure sites to become infected.
• Serious complications with anaesthetics are very rare.

c) what the treatment or procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient:
Consent Form

Routine procedures during Leukaemia treatment: Lumbar Punctures / Intrathecal Chemotherapy/ Bone Marrow Aspirates (+/- trephine)

d) any extra procedures that might become necessary during the procedure such as:

☐ Blood transfusion  ☐ Other procedure (please state)

2 The following information leaflet has been provided:
   • Information sheet for parents of children with leukaemia
   • Leukaemia protocol parent information document

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or ☐ I have offered the patient information about the procedure but this has been declined.

3 This procedure will involve:

☐ General and/or regional anaesthesia  ☐ Local anaesthesia  ☐ Sedation  ☐ None

Signed (Health professional): .......................................................... Date: D _ D / M M / Y Y Y Y

Name (PRINT): .............................................................................. Time (24hr): H _ H : M _ M

Designation: .................................................................................. Contact/bleep no: PDU (Day Unit): 01223 217234 or 257157

Ward C2: 01223 217231 or 217534

C Consent of patient / person with parental responsibility

I confirm that the risks, benefits and alternatives of this procedure have been discussed with me and that my questions have been answered to my satisfaction and understanding.

Important: please read the patient information about this procedure and then put a tick in the relevant boxes for the following questions:

1 Creutzfeldt Jakob disease (CJD)
Have you ever been notified that you are at risk of CJD or variant CJD for public health purposes? If yes, please inform your health professional.

☐ Yes  ☐ No

2 Photography, Audio or Visual Recording
a) I agree to the use of any of the above type of recordings for the purpose of diagnosis and treatment.

☐ Yes  ☐ No

b) I agree to unidentified versions of any of the above recordings being used for audit and medical teaching in a healthcare setting.

☐ Yes  ☐ No

3 Students in training
I agree to the involvement of medical and other students as part of their formal training.

☐ Yes  ☐ No
Consent Form

Routine procedures during Leukaemia treatment: Lumbar Punctures / Intrathecal Chemotherapy/ Bone Marrow Aspirates (+/- trephine)

4 Use of Tissue
   a) I agree that tissue (including blood) not needed for my own diagnosis or treatment can be used and stored for ethically approved research which may include ethically approved genetic research.

   b) Where additional clinical information is needed for the purposes of ethically approved research, I agree that relevant sections of my medical record may be looked at by researchers or by relevant regulatory authorities. I give permission for these individuals to have access to my records.

I have listed below any procedures that I do not wish to be carried out without further discussion.

I have read and understood the Patient Information about this procedure and the above additional information. I agree to the procedure or treatment.

Signed (Patient): ................................................................. Date: __/__/YYYY
Name of patient (PRINT): .................................................................

If signing for a child or young person; delete if not applicable.
I confirm I am a person with parental responsibility for the patient named on this form.
Signed: ................................................................. Date: __/__/YYYY
Relationship to patient:

If the patient is unable to sign but has indicated his/her consent, a witness should sign below.
Signed (Witness): ................................................................. Date: __/__/YYYY
Name of witness (PRINT): .................................................................
Address: .................................................................
Routine procedures during Leukaemia treatment: Lumbar Punctures / Intrathecal Chemotherapy / Bone Marrow Aspirates (+/- trephine)

D Confirmation of consent

Confirmation of consent (where the treatment/procedure has been discussed in advance)
On behalf of the team treating the patient, I have confirmed with the patient that she/he has no further questions and wishes the treatment/procedure to go ahead.

Signed (Health professional): .................................................. Date: ..........M.M.Y.Y.Y.Y.

Name (PRINT): ................................................................. Job title: .................................................................

Please initial to confirm all sections have been completed:

E Interpreter's statement (if appropriate)

I have interpreted the information to the best of my ability, and in a way in which I believe the patient can understand:

Signed (Interpreter): .................................................. Date: ..........M.M.Y.Y.Y.Y.

Name (PRINT): .................................................................

Or, please note the language line reference ID number:

F Withdrawal of patient consent

☐ The patient has withdrawn consent (ask patient to sign and date here)

Signed (Patient): .................................................. Date: ..........M.M.Y.Y.Y.Y.

Signed (Health professional): .................................................. Date: ..........M.M.Y.Y.Y.Y.

Name (PRINT): ................................................................. Job title: .................................................................

Patient safety – at the heart of all we do

Addenbrooke's Hospital | Rosie Hospital

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