

PARENT INFORMATION SHEET & INFORMED CONSENT FORM**A trial to look for the minimum effective low dose of ATG that could preserve insulin production in young people newly diagnosed with type 1 diabetes**

Thank you for taking the time to read this information. Your child is being invited to take part in a research trial called **MELD-ATG** because they have recently been diagnosed with Type 1 diabetes (T1D).

Before you and your child decide whether they would like to take part, we would like you to understand why this research is being done and what it would involve for your child. Please take time to read this information, and discuss it with others, if you wish. If there is anything that is not clear, or if you would like more information, please ask us.

- **Section 1** informs you of the purpose of this trial and what will happen to your child if they take part
- **Section 2** gives you more detailed information about the conduct of the trial
- A **Consent Form** is included at the end



Section 1: Purpose of the trial and what will happen

1.1 What is the purpose of the trial?

People develop Type 1 diabetes (T1D) because their immune system, the part of the body which helps fight infections, mistakenly attacks and destroys the insulin-producing cells in the pancreas (beta cells). When the immune system destroys these cells, the body's ability to produce insulin decreases, blood glucose levels run high, and T1D develops.

At the time of diagnosis of T1D, there are usually a small number of beta cells (10-20%) left in the pancreas, which still produce small amounts of insulin. We call this level of activity "beta cell function". Most people with T1D will eventually stop producing insulin themselves. This may occur rapidly in a few months, or more slowly over several years. However, the longer people with T1D can produce their own insulin, the better it is for the control of blood glucose levels and to avoid long-term complications.

Previous research has shown that a drug called **anti-thymocyte globulin (ATG)** may help prevent the immune system from attacking and destroying the insulin-producing beta cells. In the MELD-ATG trial, we are looking for the minimum effective low dose of **ATG** in young people newly diagnosed with T1D that:

- Can slow the decline of beta cell function and preserve the body's own insulin production
- Has manageable side effects

1.2 What is the drug being tested?

ATG is given as an infusion. It is made from a collection of proteins (antibodies), derived from rabbits and purified. It is already widely used in other medical conditions at much higher doses for example, in people receiving organ transplants to help prevent rejection by the immune system.

1.3 Why has your child been invited?

Your child has been invited to take part because they are aged between 5 and 25 years and have been diagnosed with T1D in the last 3 weeks. The early stage of T1D is when there is the best chance of ATG preserving the remaining functioning beta cells in the pancreas. We plan to include 114 people from several hospitals across the UK and Europe.

1.4 Does your child have to take part?

Participating in this trial is completely voluntary. If your child decides to participate you will be asked to sign an Informed Consent Form, but your child is still free to change their mind and leave the trial at any time without giving a reason. If your child chooses not to participate or to leave the trial, their future medical treatment and normal standard care will not be affected in any way. If you and your child believe that you need more time to consider your decision, please let the research team know.

The outbreak of Covid-19 has naturally made all of us anxious about our health. This trial has been delayed until we are all reassured that visits to hospital are quite safe and protection for staff, patients and families is in place.

ATG affects the immune system and this is the mechanism whereby it may prevent progression of type 1 diabetes. However, as we would not want to give the drug to anyone who has Covid-19, we will screen for the virus at the beginning of the trial. Similarly, if anyone comes in contact with the virus or develops symptoms, we will re-test and delay or cancel the administration of trial treatment. We all have the health and wellbeing of your child and your family as the main priority.

1.5 What would my child have to do?

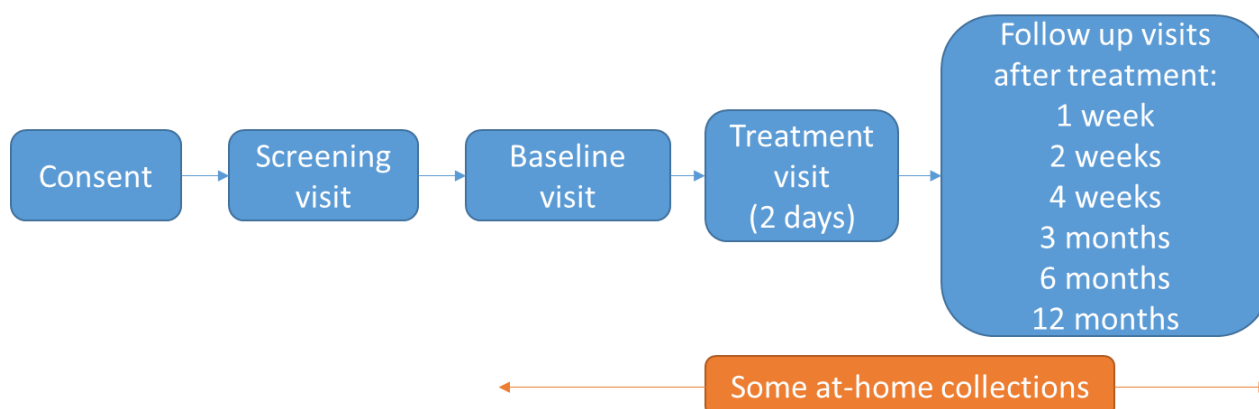
If your child decides to participate, they will need to:

- Continue to monitor their blood glucose and take their regular insulin, as advised by their diabetes care team
- Follow the visit, sample collection and home assessment schedules as instructed by their research team (summarised in this information sheet, pages 5 and 7)

- Tell their doctor or nurse if:
 - They feel unwell in any way while taking part
 - They need to start any new medications/vaccines prescribed by another healthcare professional
- Follow the contraception information in section 1.14 (page 9)

1.6 What will happen if your child takes part?

Your child will be asked to sign the Assent Form and you will be asked to sign the Parental Informed Consent Form. A copy of each will be given to you to keep. Participation will involve 8-10 hospital/clinic visits over about 13 months, and some at-home collections. Most visits take 1-4 hours, with one overnight stay for most participants when receiving trial treatment.



What will the hospital/clinic visits involve?



Medical history / changes in health

A nurse or doctor will talk to your child about their health (including their T1D).



Collection of blood samples

At every visit we would like to collect blood samples. The exact amount we take will vary from visit to visit. However, for example, the maximum amount of blood that would be taken at a single visit would be approximately 100 ml. Your child will usually have a small plastic cannula inserted into a vein (intravenous cannula) in their arm at each visit, which will be used to collect the blood. We can use a local anaesthetic spray/cream to numb their skin to make it more comfortable. The cannula will be removed before they go home.



Physical examination

Your child will have physical measurements taken, including height, weight, blood pressure and heart rate. On the two treatment days we will also measure their oxygen saturation, respiratory rate and temperature.



Medications and vaccinations review

A nurse or doctor will talk to your child about any medications they currently take or have taken until recently, and any recent or upcoming vaccines.



Pregnancy test

Female participants who may become pregnant will need to have regular urine pregnancy tests.



Family medical history / changes in family health

A nurse or doctor will talk to your child about their family's health (including if anyone has T1D).

**Mixed-meal tolerance test (MMTT)**

At four trial visits your child will have an assessment (mixed-meal tolerance test) to measure their pancreatic beta cell function:

- They will need to fast for 8 hours before this assessment (water is OK)
- They will be given a drink, similar to a milkshake
- Blood samples will be taken over a 2-hour period before, during and after the drink
- A nurse or doctor will advise them how they manage their insulin for this test

**Treatment allocation**

Your child will be allocated a treatment in a random way (by chance), much like flipping a coin. This treatment will be either:

- Active drug (a low dose of ATG); or
- Placebo (dummy drug)

Neither your child nor their research team will know which treatment they are given.























































**Overnight stay**

Most participants will have to stay overnight while having trial treatment.

**Trial treatment infusion**

Trial treatment is given as two separate intravenous infusions on two consecutive days, under strict medical supervision.

The table on the next page shows when these assessments happen.

Hospital/clinic visit schedule Trial assessments start after the Assent and Consent forms have been signed	Screening visit	Baseline visit	Treatment visit		Follow up visits after treatment					
	No more than 6 weeks from diagnosis	No more than 3 weeks from screening visit	Day 1 No more than 9 weeks after diagnosis No more than 1 week from baseline visit	Day 2	1 week	2 weeks	4 weeks	3 months	6 months	12 months
Arrive having fasted for 8 hours		Fasted						Fasted	Fasted	Fasted
Medical history/changes in health										
Family medical history/changes in family health										
Physical examination										
Medication and vaccines review										
Blood samples										
Pregnancy test (if applicable)										
Mixed meal tolerance test										
Random treatment allocation										
Overnight stay										
Trial treatment infusion										
Total duration of visit	2h	4h	2 days		1h	1h	1h	4h	4h	4h

1.7 Screening visit (duration 2 hours)

After the Assent and Consent Forms are signed, your child will have the screening assessments shown in the table on page 5. These will take place at the hospital/clinic and are to check that your child is eligible for the trial.

1.8 Baseline visit (duration 4 hours) - fasted

If your child is eligible to take part, they will have a baseline visit no more than 3 weeks after the screening visit. They should arrive fasted for 8 hours before the visit (drinking water is OK) because of the mixed meal tolerance test. They will have the baseline assessments shown in the table on page 5. If their baseline assessments were to show that they are not fit or well enough for trial treatment, their research team would explain why.

Covid-19:

As we would not want to give the drug to anyone who has Covid-19, we will be screening for the virus at the baseline visit. Similarly, if anyone comes in contact with the virus or develops symptoms, we will re-test and delay or cancel the administration of ATG.

1.9 Treatment visit (duration 2 days)

If your child is fit and well, they will have a treatment visit no more than 9 weeks from T1D diagnosis. Most participants will need an overnight stay for this visit, as there is no gap between treatment days 1 and 2. They will be able to eat and drink and give their insulin, as normal.

Treatment will be assigned in a random way (by chance), much like flipping a coin, by a central computer programme. This treatment will be either:

- Active drug (a low dose of ATG)
- Placebo (dummy drug)

Neither your child nor their research team will know which treatment they are given but overall 3 out of 4 people will get the active treatment.

❖ *Treatment day 1*

- A nurse or doctor will talk to your child about their health
- An intravenous cannula will be inserted, through which their trial treatment will be given
- Pre-treatment medications (an antihistamine, an anti-inflammatory and paracetamol) will be given. Some are given orally and others through the cannula. These medications are a precaution because some people can react to the trial treatment (see section 1.12, for possible side effects)
- Trial treatment infusion will take at least 12 hours
- Blood samples will be collected
- Vital signs (blood pressure, heart rate, oxygen saturation, respiratory rate, and temperature) will be checked throughout.

❖ *Treatment day 2*

















Your child will start their second trial treatment infusion at least 12 hours after completing the first. With the exception of the trial infusion which will only last 8 hrs, day 2 is the same as day 1, including pre-treatment medications, collecting blood samples, and measuring vital signs. Where possible, their intravenous cannula will be kept in place and used again on day 2. Your child will be able to go home after the infusion, once their research team agrees they are fit and well enough to do so.

1.10 Follow up visits

Your child will have 6 follow up visits at the hospital/clinic during the 12 months after finishing the trial treatment:

- 1 week after treatment (duration 1 hour)
- 2 weeks after treatment (duration 1 hour)

- Your child's doctor or nurse will also be in contact (e.g. by phone) between the 2- and 4-week visits to discuss any changes in their health
- 4 weeks after treatment (duration 1 hour)
- 3 months after treatment (duration 4 hours) – **fasted**
- 6 months after treatment (duration 4 hours) – **fasted**

At-home schedule	Screening visit	Baseline visit	Treatment visit		Follow up visits after treatment					
	No more than 6 weeks from diagnosis	No more than 3 weeks from screening visit	Day 1	Day 2	1 week	2 weeks	4 weeks	3 months	6 months	12 months
			No more than 9 weeks after diagnosis							
Dried blood spots		At hospital /clinic visit			<div></div> <p>Home collection will be monthly, starting 1–4 weeks after trial treatment</p> <p>Before and after a liquid meal</p>					
Urine & stool samples										
Trial diary										
CGM for 14 days										

- 12 months after treatment (duration 4 hours) – **fasted**

At each visit your child will have the follow up assessments shown in the table on page 5. For visits that are fasted, they will need to have fasted for 8 hours before (drinking water is OK).

1.11 Home collections

What does your child have to do at home?



Dried blood spots

Collection of dried blood spot samples (via a small finger prick) and blood glucose measurements, before and after a liquid meal (like the milkshake drink for the mixed-meal tolerance test). We will provide a short demonstration video, the liquid meals to take home, and written instructions.



Urine and stool samples

Collection of urine and stool samples at home within 1 week before or after the baseline, 3, 6- and 12-month follow up visits. Your child will be given sample pots, instructions, and pre-paid postage materials for sending the samples to their research team.



Trial diary

A short trial diary to complete at home following trial treatment. This will cover things like taking any medications and describing any possible side effects.



Continuous glucose monitoring (CGM)

Your child will use a CGM device for 14 days after each of the 3-, 6- and 12-month follow up visits, to measure blood glucose levels 24 hours a day. It uses a tiny sensor inserted just under the skin. The device transmits real-time blood glucose readings to a receiver and lets your child's authorised doctor review them. Your child will be given instructions on how to use the CGM device.

1.12 What are the side effects of the drug being tested?

As with all drugs, there is a risk that your child may experience some unwanted side effects. During this trial they will be closely monitored before, during and after treatment days to check for these. Many of the side effects are mild flu-like symptoms (fever, shivering, tiredness, runny nose, muscle/joint pain, and headaches), likely to last only a short time (1-7 days) and should completely resolve. We can give medications to make them more comfortable and recover from the side effects.

We expect that more than 1 in 10 MELD-ATG participants will experience one or some of the following:

- Flu-like symptoms, appearing either:
 - Immediately when having treatment. Your child will be closely monitored for any of these symptoms throughout the treatment visit, and only discharged home once the research team are satisfied they are fit and well enough
 - 5 to 15 days after treatment. Your child will be monitored for any of these symptoms at visits 1, 2 and 4 weeks after treatment, and by a phone call 3 weeks after treatment. Please also contact your child's research team immediately using the contact numbers at the end of this information sheet if you think they may be experiencing this side effect
- Infections
- Skin rash
- Mild effects on their nervous system e.g. tingling, pins and needles, weakness
- Aches and pains
- Changes in the cells in their blood, which are symptomless

If your child has any major concerns or is feeling very unwell, please contact their trial doctor immediately using the contact numbers at the end of this information sheet.

There may also be unknown risks resulting from possible interactions with other medication your child may be taking. Inform their study doctor about any medication they are taking.

1.13 What are the possible disadvantages and risks of taking part?

- **Additional hospital/clinic visits:** Where possible, trial visits will be booked to coincide with your child's normal hospital visits to minimise the number of trips.
- **Blood sampling:** Your child may experience some brief and/or minor discomfort when blood is taken or the cannula is inserted, and mild bruising or swelling can occur at the site. Occasionally, some people may become lightheaded during the procedure.
- **Fasting:** Your child will need to have fasted for 8 hours (drinking water is allowed) before four of the hospital/clinic visits and before their monthly at-home dried blood spot sample collection.
- **Side effects:** As described previously in section 1.12, your child may experience side effects from trial treatment.
- **Insurance:** You should discuss your child's participation in this trial with any insurance providers you have (e.g. travel insurance, protection insurance, life insurance, income protection, critical illness cover and private medical insurance) and seek advice if necessary, as failure to notify them may affect or invalidate the cover you have for your child.

- **Pregnancy and lifestyle:** Your child will need to follow the contraception guidance below in section 1.14. Trial medicines could harm an unborn baby, and pregnancy could affect the trial results due to the changes in the body. Your child should not participate in this trial if they are planning to become pregnant or father a child during the trial.

1.14 Contraception

Please share the following contraception information with your child and their partner if it is appropriate:

Women who are able to have a baby must use one of the following, highly effective forms of contraception for the entire duration of MELD-ATG trial participation:

- Oral contraceptive (either combined or progestogen alone)
- Contraceptive implant, injections or patches
- Vaginal ring
- Intrauterine device (IUD, coil or intrauterine system)
- True abstinence where this reflects their usual and preferred lifestyle

Men must do the following for the duration of trial participation:

- Use one of the following, reliable forms to contraception:
 - A condom and spermicide (chemical that kills sperm), even if female partner(s) is using another method of contraception
- Not donate sperm for the duration of the trial

If your child, or their partner, becomes pregnant during the trial, they should inform their trial doctor immediately. The outcome and progress of any pregnancy would be followed, and they would be asked questions about the pregnancy and baby, if appropriate.

1.15 What are the possible benefits of taking part?

Your child may improve their understanding, and therefore their management, of their T1D by taking part. However, there is no guarantee that they will benefit by taking part. Information collected may benefit people newly diagnosed with T1D in the future.

1.16 What happens when the trial stops?

At the end of your child's participation, they will continue with standard insulin therapy.

We will invite your child to take part in another study organised by the same research group (see section 2.1), which does not involve any drugs but collects information and samples for another 12 months. This is **optional** and your child will be given a separate information sheet and assent/consent form to consider at the end of MELD-ATG participation.

We would also like your child's permission to contact them in the future about other research projects that we think they might be suitable for.

1.17 Expenses & payment

Your child will not receive any payment for participating in this trial; but travel and parking costs will be reimbursed.

Section 2: Trial conduct

2.1 Who is organising and funding the trial?

MELD-ATG is coordinated by the University of Cambridge, UK, on behalf of the sponsor (University Hospital Leuven [UZ Leuven], Belgium).

The trial is part of a large research group called **INNODIA** (An innovative approach towards understanding and arresting Type 1 diabetes; www.innodia.eu). INNODIA brings together diabetes experts from across the UK and Europe, and aims to better understand the reasons why T1D develops and how it could be prevented.



MELD-ATG is funded by the Innovative Medicines Initiative 2 Joint Undertaking (grant agreement 115797). This receives support from the EU's Horizon 2020 research and innovation programme and European Federation of Pharmaceutical Industries and Associations (EFPIA), Juvenile Diabetes Research Foundation and the Leona M. and Harry B. Helmsley Charitable Trust.

2.2 What will happen to your child's samples?

We would like to use your child's blood, urine and stool samples to:

- Understand how the trial treatment, ATG, affects their body and their diabetes
- Contribute towards many other research studies into diabetes as part of the INNODIA research group (section 2.1). This is to help find new ways to predict and prevent the progression of T1D, including potential genetic associations. These research studies will have been approved by ethical committees.

For blood, urine and stool samples taken at each trial visit:

- Some will be sent to your child's local hospital laboratory for testing. These samples will be processed according to hospital procedures.
- Some will be sent immediately to the INNODIA research group laboratories across the UK and Europe for analysis.
- Others will be stored at your child's local hospital and then sent later to INNODIA laboratories for later analysis.

Samples sent to INNODIA laboratories will be labelled with a unique sample ID linked to your child's unique trial ID number. Only their local research team would be able to identify who provided the samples.

One of the blood samples your child provides will be used for genetic research by extracting the DNA from white blood cells and studying the genes that they have inherited from their parents. We will not provide the results of this genetic research to them or their doctors since we are not looking for specific genetic diseases, but only genes associated with diabetes and its complications.

Your child's white blood cells will also be used to study the body's immune responses and other blood samples will enable the measurement of diabetes-related antibodies and to discover new markers of disease progression. Your child's urine and stool samples may also provide new markers and new insights into how T1D works.

Your child's individual data/results will not be given to them.

At the end of the MELD-ATG trial, we would like to store your child's DNA samples and some of their blood, urine and stool samples in a central storage facility and make them available for INNODIA-

affiliated investigators for future research. All results would be stored centrally in a coded form to help future T1D investigators.

Samples may be stored for a minimum of 15 years.

2.3 What will happen to the results of the trial?

The results of the trial will be anonymous, and your child will not be identified in the information produced. When the results of this trial are available, they may be published in peer-reviewed medical journals and used for medical presentations and conferences. If you or your child would like to obtain a copy of the published results, please contact their research team directly.

Newsletters will be sent to your child during the trial to inform them how the trial is progressing, and at the end of the trial when the results become available.

The anonymous results will also be shared with the drug company that is providing the active drug (ATG) for this trial (Sanofi). Anonymous datasets from the trial may also be made available to other researchers in line with national and international data transparency initiatives.

2.4 Who has reviewed this trial?

All research within the NHS is reviewed by an independent group of people called a Research Ethics Committee, to protect your child's interests. This trial has been reviewed and given favourable opinion by [Name of Ethics Committee]. The Medicines and Healthcare Products Regulatory Agency (MHRA), who are responsible for regulating medicines in the UK, have also reviewed and approved this trial.

In addition, the INNODIA research group has established a Trial Steering Committee and an Independent Data Monitoring Committee who will oversee trial conduct. The Patient Advisory Committee from the INNODIA research group has supported the design of this information sheet and the trial design. This ensures that people with T1D are included in our research from start to finish.

2.5 What if your child decides they no longer wish to participate in the trial?

Your child is free to stop at any time without giving a reason and without affecting their future care or medical treatment. They will not be asked to have any further tests or give any further research samples for the trial. However, information already collected, and results from tests already performed on their samples, will continue to be used in the trial analysis.

In addition, the trial organisers, regulatory authority or trial doctors may decide to stop the trial at any time. If that happens, we will tell your child why and arrange for appropriate care and treatment for them.

2.6 What if there is a problem?

If your child has any concerns about any aspect of this trial, they should first speak to a member of their research team, who will do their best to answer their questions.

The Patient Advice and Liaison Service (PALS) at your child's hospital are available to provide further advice and support:

[Local site to insert PALS email address and/or telephone number]

In the event that something does go wrong and your child is harmed by taking part in the research and this is due to someone's negligence then your child may have grounds for a legal action for compensation against the sponsor (UZ Leuven, Belgium). The normal National Health Service (NHS) complaints mechanisms will still be available to your child (if appropriate). The sponsor (UZ Leuven) has obtained insurance which provides no-fault compensation i.e. for non-negligent harm, your child may be entitled to make a claim for this.

2.7 Will my child's taking part in this trial be kept confidential?

Your child's data will be processed in accordance with the European General Data Protection Regulation (GDPR). UZ Leuven (the sponsor) shall act as data controller for their data.

Your child is entitled to ask the trial team what data are being collected about them and what it is being used for in connection with the trial. This data relates to your child's current clinical circumstances, but also relates to their background, the results of examinations carried out within the context of care of their health in accordance with the current standards and the results of examinations required by the protocol.

How will we use information about your child?

We will need to use information from your child's medical records for this research trial.

This information will include your child's name and contact details. People will use this information to do the research or to check your child's records to make sure that the research is being done properly.

People who do not need to know who your child is will not be able to see their name or contact details.

Your child's identity will be replaced by an ID code in the trial.

We will keep all information about your child safe and secure.

Some of your child's coded information will be sent to the Sponsor in Belgium. They will only know your child's trial ID code and month/year of birth so they will not be able to identify them. The sponsor must follow both their own and our rules about keeping your child's information safe.

Some of your child's coded information may also be sent to the drug manufacturer. As above, they will only know your child's trial ID code and month/year of birth so they will not be able to identify them.

Once we have finished the trial, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that your child took part in the trial.

We will need to inform your child's GP of their participation in this trial so that any medical decisions made by their GP account for any treatment they are receiving as part of this trial. We will not inform them whether your child is allocated to active drug (ATG) or placebo.

What are my child's choices about how their information is used?

- Your child can stop being part of the trial at any time, without giving a reason, but we will keep information about them that we already have. After your child stops taking part, no further data will be taken, but we will use any data generated up to that point.
- We need to manage your child's records in specific ways for the research to be reliable. This means that we won't be able to let your child see or change the data we hold about them.
- If your child agrees to take part in this trial, they will have the option to take part in future research using their data saved from this trial, as part of the wider INNODIA research group (section 2.1).

Where can my child find out more about how their information is used?

Your child can find out more about how we use their information:

- At www.hra.nhs.uk/information-about-patients/
- At www.hra.nhs.uk/patientdataandresearch
- By asking one of the research team (see section 2.8)
- By contacting the Sponsor's Data Protection Officer (DPO – UZ Leuven, Herestraat 49, 3000 Leuven, Belgium; e-mail: dpo@uzleuven.be)

2.8 Further information and contact details

Your child's research team can be contacted on:

[Site level contact details for research team to be added by participating sites:

Name:

Email:

Phone:]

[Site level details of NHS Complaints (e.g. PALS) to be added by participating sites:

Email:

Phone:]

In the event of an emergency please contact:

[Site to complete emergency contact details]



A trial to look for the minimum effective low dose of ATG that could preserve insulin production in young people newly diagnosed with type 1 diabetes

INFORMED CONSENT FORM

Principal Investigator: _____ Participant Trial ID Number: _____

If you agree with each sentence below, please initial the box

INITIALS

1	I have read and understood the Parent Participant Information Sheet version ##, dated #### for the above trial and I confirm that the trial procedures and information have been explained to me. I have had the opportunity to ask questions and I am satisfied with the answers and explanations provided.	
2	I understand that my child's participation in this trial is voluntary and that they are free to withdraw at any time, without giving a reason and without their medical care or legal rights being affected.	
3	I understand that personal information about my child will be collected and used in accordance with this information sheet. This information will be kept in the strictest confidence and none of their personal data will be published.	
4	I understand that sections of my child's medical notes or information related directly to their participation in this trial may be looked at by responsible individuals from the sponsor, coordinator, regulatory authorities and research personnel where it is relevant to my child taking part in research and that they will keep my child's personal information confidential. I give permission for these individuals to have access to my child's records.	
5	I understand that my child's GP will be informed of their participation in this trial and sent details of the MELD-ATG trial.	
6	I have read and understood the compensation arrangements for this trial as specified in the information sheet.	
7	I have understood that the doctors in charge of this trial may close the trial or stop my child's participation in the trial at any time without my consent, if the need arises.	
8	I have read and understood my child's responsibilities for the trial including trial visits, sample collections and using appropriate contraception as listed in section 1.14.	
9	I understand that the trial requires DNA sampling & genetic testing. I understand that the results of this genetic research will not be provided to my child, or their doctor, because the research is not looking for specific genetic diseases, but only genes associated with diabetes and its complications.	

10	I agree that my child's coded data, blood, urine and stool samples collected as part of the MELD-ATG trial may be shared with other investigators across the UK and Europe to help find new ways to predict and prevent the progression of T1D, including potential genetic associations, as part of the INNODIA research group (innovative approach towards understanding and arresting Type 1 diabetes; www.innodia.eu). I understand that my child's individual data/results will not be given to them.	
11	I agree for my child's trial doctor, and the local MELD-ATG research team, to keep their contact details to keep them updated on progress of this trial.	
12	I agree that information held by the NHS and records maintained by the General Register Office may be used to keep in touch with my child and to follow up on their health status.	

Please initial YES or NO

OPTIONAL

YES NO

13	I agree for my child's trial doctor, and the local research team, to keep their contact details in order to contact them in the future about new studies or clinical trials affiliated with the INNODIA research group (www.innodia.eu).		
14	I agree that, at the end of the trial, my child's DNA and blood, urine and stool samples may be transferred to a central storage facility and made available to INNODIA-affiliated investigators for future research.		

I agree to my child participating in the MELD-ATG trial:

_____	_____	_____
Name of child participant	Signature	Date

_____	_____	_____
Name of parent/ Legal Guardian	Signature	Date

_____	_____	_____
Name of person taking consent	Signature	Date

Position of person taking consent

Time of consent (24hr clock) _____:_____

1 copy for the patient, 1 copy for the trial team, 1 copy to be retained in the hospital notes.