Hospital Logo

PARTICIPANT 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. You are being invited to take part in a research trial called **MELD-ATG** because you have recently been diagnosed with Type 1 diabetes (T1D).

Before you decide whether you would like to take part, we would like you to understand why this research is being done and what it would involve for you. 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 you if you 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 **m**inimum **e**ffective **l**ow **d**ose 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 have I been invited?

You have been invited to take part because you 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 Do I have to take part?

Participating in this trial is completely voluntary. If you decide to participate you will be asked to sign an Informed Consent Form, but you are still free to change your mind and leave the trial at any time without giving a reason. If you chose not to participate or to leave the trial, your future medical treatment and normal standard care will not be affected in any way. If you 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 effects 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 you and your family as the main priority.

1.5 What would I have to do?

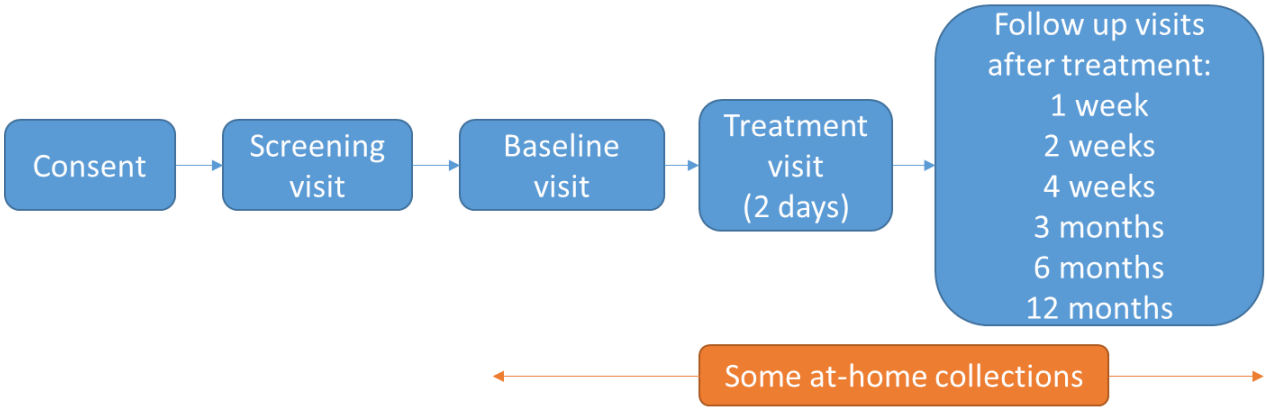
If you decide to participate, you will need to**:**

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

- Tell your doctor or nurse if:
  - You feel unwell in any way while taking part
  - You 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 I take part?

You will be asked to sign the Informed Consent Form and you will be given a copy 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 you about your health (including your 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. You will usually have a small plastic cannula inserted into a vein (intravenous cannula) in your arm at each visit, which will be used to collect the blood. We can use a local anaesthetic spray/cream to numb your skin to make it more comfortable. The cannula will be removed before you go home.

Physical examination
You will have physical measurements taken, including height, weight, blood pressure and heart rate. On the two treatment days we will also measure your oxygen saturation, respiratory rate and temperature.

Medications and vaccinations review
A nurse or doctor will talk to you about any medications you 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 you about your family's health (including if anyone has T1D).

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

- You will need to fast for 8 hours before this assessment (water is OK)

- You 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 you how you manage your insulin for this test

Treatment allocation
You 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 you nor your research team will know which treatment you 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 you have signed the consent form	**Screening visit** No more than 6 weeks from diagnosis	**Baseline visit** No more than 3 weeks from screening visit	**Treatment visit** **Day 1** **Day 2** No more than 9 weeks after diagnosis No more than 1 week from baseline visit		**Follow up visits after treatment** **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 signing the Consent Form, you 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 you are eligible for the trial.

1.8 Baseline visit (duration 4 hours) - fasted

If you are eligible to take part, you will have a baseline visit no more than 3 weeks after the screening visit. Please arrive fasted for 8 hours before the visit (drinking water is OK) because of the mixed meal tolerance test. You will have the baseline assessments shown in the table on page 5. If your baseline assessments were to show that you are not fit or well enough for trial treatment, your 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 you are fit and well, you 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. You will be able to eat and drink and give your 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 you nor your research team will know which treatment you are given but overall 3 out of 4 people will get the active treatment.

❖ *Treatment day 1*

- A nurse or doctor will talk to you about your health
- An intravenous cannula will be inserted, through which your 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*

You will start your 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, your intravenous cannula will be kept in place and used again on day 2. You will be able to go home after the infusion, once your research team agrees you are fit and well enough to do so.

1.10 Follow up visits

You 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 doctor or nurse will also be in contact (e.g. by phone) between the 2- and 4-week visits to discuss any changes in your health*
- 4 weeks after treatment (duration 1 hour)
- 3 months after treatment (duration 4 hours) – **fasted**
- 6 months after treatment (duration 4 hours) – **fasted**
- 12 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			Home collection will be monthly, starting 1–4 weeks after trial treatment Before and after a liquid meal					
Urine & stool samples										
Trial diary										
CGM for 14 days										

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

1.11 Home collections

What do I 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. You will be given sample pots, instructions, and pre-paid postage materials for sending the samples to your 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)
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 authorised doctor review them. You 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 you may experience some unwanted side effects. During this trial you 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 you 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. You will be closely monitored for any of these symptoms throughout the treatment visit, and only discharged home once the research team are satisfied you are fit and well enough
    - 5 to 15 days after treatment. You 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 research team immediately using the contact numbers at the end of this information sheet if you think you may be experiencing this side effect
- Infections
- Skin rash
- Mild effects on your nervous system e.g. tingling, pins and needles, weakness
- Aches and pains
- Changes in the cells in your blood, which are symptomless

If you have any major concerns or are feeling very unwell, please contact your 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 you may be taking. Inform your study doctor about any medication you 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 normal hospital visits to minimise the number of trips.
- **Blood sampling:** You 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:** You will need to have fasted for 8 hours (drinking water is allowed) before four of the hospital/clinic visits and before your monthly at-home dried blood spot sample collection.
- **Side effects:** As described previously in section 1.12, you may experience side effects from trial treatment.
- **Insurance:** You should discuss your 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 your cover.

- **Pregnancy and lifestyle:** You 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. You should not participate in this trial if you are planning to become pregnant or father a child during the trial.

1.14 Contraception

Please share the following contraception information with your 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 your 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 you, or your partner, become pregnant during the trial, you should inform your trial doctor immediately. The outcome and progress of any pregnancy would be followed, and you would be asked questions about the pregnancy and baby, if appropriate.

1.15 What are the possible benefits of taking part?

You may improve your understanding, and therefore your management, of your T1D by taking part. However, there is no guarantee that you 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 participation, you will continue with standard insulin therapy.

We will invite you 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 you will be given a separate information sheet and consent form to consider at the end of MELD-ATG participation.

We would also like your permission to contact you in the future about other research projects that we think you might be suitable for.

1.17 Expenses & payment

You 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 **inno**vative approach towards understanding and arresting Type 1 **dia**betes; 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 my samples?

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

- Understand how the trial treatment, ATG, affects your body and your 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 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 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 unique trial ID number. Only your local research team would be able to identify who provided the samples.

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

Your 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 urine and stool samples may also provide new markers and new insights into how T1D works.

Your individual data/results will not be given to you.

At the end of the MELD-ATG trial, we would like to store your DNA samples and some of your 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 you 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 would like to obtain a copy of the published results, please contact your research team directly.

Newsletters will be sent to you during the trial to inform you 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 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 I decide I no longer wish to participate in the trial?

You are free to stop at any time without giving a reason and without affecting your future care or medical treatment. You 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 your 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 you why and arrange for appropriate care and treatment for you.

2.6 What if there is a problem?

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

The Patient Advice and Liaison Service (PALS) at your 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 you are harmed by taking part in the research and this is due to someone's negligence then you 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 you (if appropriate). The sponsor (UZ Leuven) has obtained insurance which provides no-fault compensation i.e. for non-negligent harm, you may be entitled to make a claim for this.

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

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

You are entitled to ask the trial team what data are being collected about you and what it is being used for in connection with the trial. This data relates to your current clinical circumstances, but also relates to your background, the results of examinations carried out within the context of care of your

health in accordance with the current standards and the results of examinations required by the protocol.

How will we use information about you?
We will need to use information from your medical records for this research trial.

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

People who do not need to know who you are will not be able to see your name or contact details. Your identity will be replaced by an ID code in the trial.

We will keep all information about you safe and secure.

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

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

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 you took part in the trial.

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

What are your choices about how your information is used?

- You can stop being part of the trial at any time, without giving a reason, but we will keep information about you that we already have. After you stop taking part, no further data will be taken, but we will use any data generated up to that point.

- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

- If you agree to take part in this trial, you will have the option to take part in future research using your data saved from this trial, as part of the wider INNODIA research group (section 2.1).

Where can you find out more about how your information is used?
You can find out more about how we use your 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 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]

TO BE PRINTED ON HEADED PAPER

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 Adult 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 participation in this trial is voluntary and that I am free to withdraw at any time, without giving a reason and without my medical care or legal rights being affected.	
3	I understand that personal information about me will be collected and used in accordance with this information sheet. This information will be kept in the strictest confidence and none of my personal data will be published.	
4	I understand that sections of my medical notes or information related directly to my 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 taking part in research and that they will keep my personal information confidential. I give permission for these individuals to have access to my records.	
5	I understand that my GP will be informed of my 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 participation in the trial at any time without my consent, if the need arises.	
8	I have read and understood my 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 me, or my 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 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 (**inno**vative approach towards understanding and arresting Type 1 **dia**betes; www.innodia.eu). I understand that my individual data/results will not be given to me.	
11	I agree for my trial doctor, and the local MELD-ATG research team, to keep my contact details to keep me 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 me and to follow up on my health status.	

OPTIONAL

Please initial YES or NO

		YES	**NO**
13	I agree for my trial doctor, and the local research team, to keep my contact details in order to contact me 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 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 participate in the MELD-ATG trial:

_____	_____	_____
Name of participant	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.