Patient Explainer: Consent Forms

Dealing with TB is hard enough. Understanding a consent form doesn't have to be.

Note On Use

- This is an open source template. Adapt it to your local context as you see fit, though we do request that in your version you retain the acknowledgement section and attribute the original template to The BETTER Project.
- The parts highlighted in blue throughout the text need to be customised before this can be shared with patients.
- Before sharing, remove highlights, delete this Note on Use section, and update the table of contents below by clicking inside the table and then clicking "Update Table" or the refresh icon that pops up.

Table of Contents

Note On Use	1
Table of Contents	1
1. What Do These Words Mean?	3
2. You Have a Right to…	4
3. The What and Why of this Compassionate Use Program	4
4. Who Will Pay For It?	5
5. What is the Process If You Agree to the CU?	5
6. Can the CU Treatment Help You?	5
7. Is There Any Way This CU Treatment Could Be Bad For You?	6
8. Why Might Your Doctor Stop the CU Treatment?	6
9. What information will be needed from you and how will it be protected?	7
10. Data Protection Information and Rights	7
11. Who Can You Contact in Case of Questions?	8

Why This Explainer?
Treatment consent forms are often lengthy and hard to understand. This document explains your *Compassionate Use Informed Consent Form (CU ICF)* in a simple way.

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What The Explainer is Not: This is not a consent form. This is not medical advice. This is not a contract or a legal document.

1. What Do These Words Mean?

Compassionate Use (CU): CU helps people with serious and/or life-threatening illnesses get experimental, new medicines, when:

- Existing treatment options are limited or no other treatments are working, and
- Timely treatment is important.

These new medicines are not yet fully studied or approved, but most countries have CU programs that allow patients to get medicines that could be helpful, especially for diseases like TB. CU may also be called “pre-approval access” or “expanded access programme.”

Informed Consent Form (ICF): A document that gives people the information (benefits, risks etc.) they need to decide whether they want to get a certain test or treatment. Records their permission for said test/treatment through their signature/thumb print.

Investigational New Drug (IND): Unapproved medicine, meaning a new experimental medicine/treatment which is still under study/being tested and has not been approved by drug regulatory agencies for general use and sale in any country.

Drug Regulatory Agency: Government bodies (for example, Food and Drug Administration of USA or the Drug Administration of Vietnam) that:

- Oversee how new medicines are developed, approved, manufactured, and sold in a given country/region.
- Establish required standards for safety, efficacy, and quality for medicines so that they are safe for the public.

Approved Drug: A medicine that has been fully studied and approved by drug regulatory agencies for general use and sale.

You/Your: You/your, both in this explainer and the CU ICF, refer to the patient.

Healthcare Provider: Any person including a doctor, nurse, health worker who is providing medical ca

Healthcare Proxy: Some patients are children, or adults whom the law does not recognise as capable of legally recognised permission (consent), for example persons with certain mental disabilities. Another person has to consent on behalf of said patients, with their assent where possible. This person—usually a parent or spouse (but could also be another family member/relative or a court appointed social worker)—is the patient’s healthcare proxy.

Assent: Even if the law does not recognize a patient as capable of giving consent, it is important to confirm their willingness, where possible, before giving permission on their behalf. Them expressing they are willing to get treated/tested is what is called assent.

Cumulative Toxicity: Long-term side effects or harm from a medicine that builds up in a patient’s body over time.

Pseudonym: Using a secret code name instead of the patient’s actual name to protect their identity and information.

2. You Have a Right to…

- Decide whether you want this *Compassionate Use (CU)* treatment or not.*
- Ask your doctor/*healthcare provider* about this treatment, its risks, and why it's being offered to you.
- Know the process of the CU, including information about what tests are needed, where it will be provided, follow-up visits.
- Give your permission to be part of the CU programme and also take back your permission at any time in the programme. You can leave the programme whenever you want. This will not affect your regular care outside of the programme.
- Ask your doctor/healthcare provider to explain the consent form to you before you sign it.
- Ask the doctor/healthcare provider for information about the rest of the medications you are being given and any other tests you will need to go through.
- A signed copy of your consent form.
- Privacy and your personal information being protected and used only with your permission, and only for the purposes you agreed to.
- You have the right to know what type of personal information is shared, and your doctor can show you the CU Report Forms that are shared. Information/data shared (for example, your age, your weight, the description of your side effects, the treatment response) is used to understand if the medicine is working, and if it continues to be safe.

For a healthcare proxy: role includes supporting the patient in decision-making and signing the ICF on their behalf. How can a proxy support a patient's decision-making?

As a healthcare proxy you can ask the doctor/health staff to explain the CU process to your patient in a way that is suited to the patient's level of understanding. For instance, a 12-year-old may be able to understand the basics of CU, if explained in simple terms. But for a 3-year-old the focus is on explaining that they're sick and that their doctor is trying to make them better.

Wherever possible, include both the healthcare proxy's consent and the patient's *assent*. Talk to your patient with the doctor/healthcare provider and address patient concerns before you sign the consent form on their behalf. Where assent is not possible, for example, the patient is a 1-year-old, the healthcare proxy must do what's best for the patient in consultation with their healthcare providers.

3. The What and Why of this Compassionate Use Program

- The medicine(s), [Name of drug/drugs], being offered as part of this CU programme is an investigational new drug (IND)/medicine, meaning its effects are still under study and it is not yet approved for sale.
- Your existing treatment options are limited or your current treatment is not working. Because timely treatment is critical, [Name of drug/drugs] is being offered to you through [Name of the Drug Company]'s CU programme because of its potential benefits.
- This programme is the only way to access this medicine, since it is a new drug and not yet approved for or available in the market in any country.
- All required permissions for CU have been taken before offering you this medicine.
- This is not a clinical trial/research study, meaning, you do not have to participate in an experimental study to get the new medicine.

- Participation in this CU programme is completely voluntary. It is your choice. If you choose to not participate, please know that this will not affect your regular care outside this programme.

4. Who Will Pay For It?

The new medicine is free. But you or the clinic may still have to cover regular doctor visits and standard TB tests. Please talk to your doctor/health provider if you are worried about these costs.

5. What is the Process If You Agree to the CU?

- You will be asked to take [Name of drug/drugs] along with your standard TB medication, as directed by your doctor/healthcare provider.
- Your doctor will tell you when you have to take [Name of drug/drugs], in combination with which other TB medicines, for how long, and where you can receive the treatment (for example, at home or a health center/hospital).
- For the duration of the CU programme, in addition to your regular tests, your doctor may also prescribe certain other follow-up visits and tests. This is to see how the new medicine is working and to protect you from possible side effects.
- Your doctor may share necessary information, including test results, with [Name of the Drug Company] as part of the CU programme.
- But all such information will be shared with your privacy protected. More about this is explained in the information sections (9 & 10) below.

6. Can the CU Treatment Help You?

[Name of drug/drugs] is a new medicine that has only been formally studied for a short time. So there are still things we do not know about this medicine and no one can promise that this will help you. But here is what we can tell you, based on early studies:

- This medicine has shown potential for promising results.
- Presently, there is no evidence to suggest that this medicine is harmful in the long-term, meaning so far there is no indication of cumulative toxicity. But the medication has not been studied in the long-term, so this information is not fully known.
- This medicine may also not have been studied in combination with the other medicines your doctor is recommending. So we do not completely know the specifics of how the combination will work and what effects there might be.
- There may be some discomfort and side effects while you are on treatment (as there are with any treatment including your other anti-TB medicines).
- For your safety and well-being, your doctor will watch you closely through: a minimum of monthly visits, asking about your symptoms, testing your sputum/blood/other samples, and any other tests necessary.
- From what is known so far, your doctor considers this your best option.

7. Is There Any Way This CU Treatment Could Be Bad For You?

This medicine - like any other medicine - may have side-effects. What is different about this CU treatment is that unlike your other TB medication, this medicine has only been formally tested/studied for a short time.

From the evidence gathered so far, the following side effects are possible:

- [Mention side-effects in accessible language, this will change depending on the drug so we will have to customise it at a later stage].
- There may be other side effects we do not know of yet.

So, your doctor/healthcare provider will make sure that they watch closely for any side effects. But if you feel any distress or discomfort while on treatment, or get a physical injury, tell your doctor immediately. That way you and your doctor can see how to manage the side effects and make you as comfortable as possible.

We do not know how this medicine affects pregnancy or breastfeeding. It is important to let your doctor know, before you take the CU treatment, if you are pregnant or breastfeeding. If you are not pregnant but pregnancy is a possibility for you or your partner during CU, speak to your doctor to take needed precautions to avoid pregnancy until after your CU treatment is finished.

8. Why Might Your Doctor Stop the CU Treatment?

You can choose to join and leave the CU programme. But there are certain situations in which your doctor may have to stop [Name of the Drug] and ask you to stop the CU treatment.

What are these situations?

- If the medicine becomes unsafe for you or if it becomes too hard for you to take the pills exactly as prescribed.
- If the drug has only been studied for a fixed duration—say, 6 months—then it may be stopped at the end of six months for your safety.

If you are asked to stop the drug:

- You will be told why.
- At the time of stopping the CU drug, if you are yet to complete your anti-TB treatment, your doctor will be responsible for continuity of care.
- You will be asked to allow doctors and nurses to perform procedures, such as blood tests, and other tests similar to the ones that would have been performed at the end of your participation in the CU. Your doctor/nurse will tell you about these procedures.
- Your medical information may still be shared with the [Name of the Drug Company] and other relevant parties as specified below. But you can ask for the information to not be shared, with a few exceptions. More about your information gathering, sharing, and related rights follows below.

9. What information will be needed from you and how will it be protected?

Your doctor/nurse/health staff will have access to your information such as your name, email, medical records and other health-related information needed for providing care.

As part of this CU, to help monitor the performance (efficacy) and safety of the medicine, your doctor will need to share some key protected information/data including your health information such as [based on country context add examples of information like weight, height etc] with [Name of drug company]/relevant third parties.

But whenever your information is shared in this way with authorised parties, your privacy will be protected. **How?**

- Any information shared with [Name of Drug Company]/third parties will be shared in a coded, protected form. For example, if a patient's name is [Salam Farrag; Note for customizing form: Can contextualize name as per your country. For e.g., in Vietnam give a Vietnamese name as an example.], the codename (pseudonym) could be [SF05; change code according to name]. This will ensure you are not easily identifiable and that your information is protected. Only your doctor/nurse/health care provider will know [SF05; edit as per code change above] is actually [Ms Salam Farrag; replace Salam with whatever name you use above for uniformity].
- The [Name of Drug Company]/third parties identified in the ICF will have access to the coded (psuedonymized) health information collected till the end of the CU programme.
- Your information will be stored for a period as prescribed by national/international regulations.
- Parties handling your information will take all reasonable steps to protect it.
- The results of this CU may be published in journal articles or at conferences, but your identity will not be known.
- The consent form (CU ICF) will explain how your information will be processed along with a contact for the person processing your information.
- Signing the ICF would also mean that you are giving permission for your information to be collected and shared in the ways described in the ICF.

10. Data Protection Information and Rights

At any point in the CU, you may:

- Ask to look at your information/data or get a free of charge copy of your data.
- Refuse the processing of personal information/data in certain cases mentioned in your consent form.
- Ask for moving your information (data portability). For e.g., you can ask for a copy of your records to give to another doctor.
- Take back your permission* for processing your information. You do not have to give any justification for this. All you have to do is write to [Drug company] or tell your doctor that you are taking back your permission. **Taking back your permission will not affect your treatment.**

If you need to make a complaint you can write to the data protection authority that will be identified in your consent form.

** If you take back your permission, information(data) that has been gathered before that point may still be used to understand the effects of the new medicine. Your doctor/[Name of Drug Company] may stop information (data) collection at any point without your permission.*

There are certain cases where some of your rights may be limited. For example, if required for scientific research purposes or if limited by law.

11. Who Can You Contact in Case of Questions?

In case of any questions about the CU, any related side effects, or if you change your mind about participating in the CU programme, please contact your doctor. **Please do not make any changes to your treatment without consulting your doctor/healthcare provider.**