

OR

Compassionate Use of an Unapproved Medical Device

Dr. _____ *[Name of physician]* is offering to treat you, your child (in which case the word “you” will refer to “your child” throughout this document), or your representative (in which case the word “you” will refer to the person you are representing) with _____ *[Name of unapproved drug, device, or biologic]* because you have a serious condition called _____ and there are no standard acceptable options.

What you should know about this experimental treatment

- This treatment has not been approved by Food and Drug Administration.
- This treatment is considered experimental and research. *[delete “and research” for uses of devices]*
- Someone will explain this treatment to you.
- You volunteer to get this treatment.
- Whether or not you get this treatment is up to you.
- You can choose not to get this treatment.
- You can agree to get this treatment now and later change your mind.
- If you do change your mind, contact your doctor right away.
- Whatever you decide it will not be held against you.
- Feel free to ask all the questions you want before you decide.

How long will this experimental treatment last?

We expect that the experimental treatment will last _____ *[hours/days/months/weeks/years, until a certain event]*.

What happens if I get this experimental treatment?

[Tell the patient what to expect using lay language and simple terms.]

Is there any way this experimental treatment could be bad for me?

[Describe the risks of the treatment]

This treatment may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

If you are or become pregnant, this treatment may hurt your baby or your pregnancy in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

Getting this treatment may lead to added costs to you. You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. Insurance may not pay for this treatment because it is considered experimental.

Can this experimental treatment help me?

We cannot promise that this treatment will benefit. The goal of this treatment is to _____ *[Describe the potential benefits of the treatment]*

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What else do I need to know?

Efforts will be made to limit your personal information, including medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB, representatives of this organization, and the Food and Drug Administration. ***[NOTE: HIPAA Authorization is not required because this does not meet the HIPAA definition of research.]***

If you are injured or made sick from taking part in this treatment, medical care will be provided. Generally, this care will be billed to you or your insurance. Depending on the circumstances, this care may be provided at no cost to you. Contact the investigator for more information.

Who can I talk to?

If you have questions, concerns, or complaints, or think the treatment has hurt you talk to your doctor at _____ ***[Insert contact information]***

This treatment is subject to oversight by an Institutional Review Board. If you have questions about your rights or any unresolved question, concern, or complaint, talk to them at (555) 555-1212 or irboffice@organization.org.

Your signature documents your permission to take part in this experimental treatment.

_____ Signature of patient, legally authorized representative, parent, or guardian of a child	_____ Date
_____ Printed name of patient	
_____ Signature of person obtaining consent	_____ Date
_____ Printed name of person obtaining consent	