Permission for Treatment with an Unapproved Article

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 (FDA).
- This treatment is considered experimental.
- FDA considers treatment with unapproved drugs to be research. ***[delete for uses of devices]***
- 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 unknown ways. These may be minor or so severe as to cause death.

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

Getting this treatment may lead to added costs to you. In general, you and your insurance company will be charged for the costs of care that you would usually be responsible to pay. Insurance may not pay for this treatment because it is experimental.

Can this experimental treatment help me?

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

What happens to the information collected?

To the extent allowed by law, we limit your personally identifiable information to people who have to review it. We cannot promise complete secrecy. The Food and Drug Administration, IRB and other representatives of this organization may inspect and copy your information.

What if I am injured because of this treatment?

[Include for research involving more than minimal risk. Otherwise delete]. If you need medical care because of taking part in this research study, contact the investigator and medical care will be made available. Generally, this care will be billed to you, your insurance, or other third party. ***[Insert the name of the institution]*** has no program to pay for medical care for research-related injury. ***[Describe any compensation available for research related injury].***

Who can answer my questions?

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

This research is being overseen by an Institutional Review Board ("IRB"). You may talk to them at 918-561-1400 or chsirb@okstate.edu if have questions about your rights or any unresolved question, concern, or complaint.

Your signature documents your permission for you or the individual named below to receive this experimental treatment.

Printed name of subject	
Signature of subject or subject's legally authorized representative	Date
Printed name of above person	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	