**Louisiana State University Health Sciences Center in New Orleans**

Permission for Non-Emergency Treatment with an Unapproved Drug, Biologic or Device

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| **INSTRUCTIONS:** * Use this consent template only when treating a patient with an unapproved drug, biologic or device in a non-emergency situation.
* Update the version date in the header each time you make a change.
* Placeholders and instructions are written in **blue text**.
* **Text in black** is suggested language. While not mandatory, we highly recommend using this language to maintain consistency across consent forms. This text is optimized for readability and grade-level comprehension.
* As much as possible, write in common, everyday language that can be understood by a participant with an 8th to 10th grade education, similar to the style used in popular news magazines and newspapers. Check the readability level of the document or a subset of the document in [Word](https://support.office.com/en-us/article/test-your-document-s-readability-85b4969e-e80a-4777-8dd3-f7fc3c8b3fd2#__toc342546555) or [StoryToolz](https://storytoolz.com/readability).
* Delete all **blue text** and this **text box** before finalizing the consent document.
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**TITLE:** Non-Emergency treatment with [name of drug, biologic or device]

**TREATING PHYSICIAN:**       [Name and credentials]

**DAYTIME PHONE #:**

**24-HOUR PHONE #:**

Dr. [Name of physician] is offering to treat [select one: you, your child or the person you are representing] with an experimental [select one: drug, biologic or device] called [name of unapproved drug, device, or biologic]. [If applicable, include this sentence: Throughout this document, the word “you” will refer to [select one: “your child” or “the person you are representing”.]] You are being offered an experimental treatment because you have a serious condition called [name of condition/disease] and there are no standard acceptable options.

What you should know about this experimental treatment

* This treatment has not been approved by US Food and Drug Administration.
* This treatment is considered experimental.
* 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?

If you agree to this treatment, the following procedures will be performed on you:

[Provide a concise description, in lay terms, of all procedures in chronological order and in enough detail to give a clear picture of what the patient will experience during the treatment.]

Can this experimental treatment be bad for me in any way?

The possible risks and/or discomforts associated with the treatment include:

[Using simple, short sentence, describe the risks involved with the treatment in language that is understandable to a lay person. The explanation of risks should be reasonable and should not minimize reported adverse effects. State whether side effects are temporary or permanent.]

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 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 confidentiality. Organizations that may inspect and copy your information include the LSUHSC-NO Institutional Review Board (IRB), the committee that is responsible for the protection of individuals participating in human research at LSUHSC and affiliated institutions; representatives of this organization; and the US Food and Drug Administration. [NOTE: HIPAA Authorization is not required because this does not meet the HIPAA definition of research.]

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.

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 treating physician for more information.

Who can I talk to?

If you have questions, suggestions, or concerns regarding this experimental treatment; or think the treatment has hurt you; or you want to stop the treatment: please talk to the treating physician whose contact information is provided at the top of this document.

If you have questions about your rights; or want to discuss problems, concerns or questions; or obtain information or offer input: you can contact the Chancellor of the LSU Health Sciences Center of New Orleans at (504) 568-4801.

Your Consent

The non-emergency treatment has been fully explained to me. I have had a chance to ask any questions I have about the treatment and procedures and I have been told that any additional questions I may have will be answered at any time by my physician. I also have been informed that this treatment is using an investigational drug, biologic or device (not yet approved for clinical treatment by the FDA).

By signing this document, I acknowledge or am aware that:

* I do not waive any of my legal rights by signing this consent document.
* I will receive a copy of the signed consent form and a copy will be placed in my medical records.

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| **Signature of Patient:***I agree to receive the experimental treatment.* |
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| Name of Patient |  |  |
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| Patient Signature |  | Date of Signature |
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| **Signature of Legally Authorized Representative (LAR):***I am a legally authorized representative of the patient named below. I agree for the patient to receive the experimental treatment.* |
|  |  | **Type of LAR (Check applicable box):**[ ] Court-appointed Guardian[ ] Health Care Proxy[ ] Durable Power of Attorney[ ] Family Member/Next-of-KinRelationship: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ] Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Name of Patient |  |
|  |  |
| Name of LAR |  |  |
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| Signature of LAR |  | Date of Signature |
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| **Signature of Treating Physician or Designee:***I have provided this patient and/or his/her legally authorized representative(s) with information about this treatment that I believe to be accurate and complete. The patient and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the treatment, including risks and benefits of its use.* |
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| Name of Treating Physician or Designee |  |  |
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| Signature of Physician or Designee |  | Date of Signature |
|  |  |  |
|  |  | Time of Signature |