Dr. ***[Name of physician]*** proposes to administer treatment to you, your child (hereafter, "you" will be used to refer to "your child" within this document), or your designated proxy (wherein "you" will denote the individual you represent) using ***[Name of unapproved drug, device, or biologic]***. This is due to your diagnosis with a significant medical condition known as \_\_\_\_\_\_\_\_\_\_\_\_ for which there are no conventional treatments deemed satisfactory.

***Essential Information Regarding This Investigational Therapy***

* The US Food and Drug Administration has not sanctioned this therapy.
* The therapy is under investigation.
* A qualified individual will provide you with a detailed explanation of this therapy.
* Participation in receiving this therapy is entirely voluntary.
* The decision to undergo this therapy rests solely with you.
* You have the option to decline this therapy.
* You may consent to this therapy initially and reconsider your decision later.
* Should you decide to withdraw, it is imperative to notify your physician immediately.
* Your decision will not affect your medical care or your relationship with your healthcare provider.
* You are encouraged to ask any questions you might have prior to making your decision.

***Duration of the Investigational Therapy:***

The duration of the investigational therapy is anticipated to be \_\_\_\_\_\_\_\_ ***[hours/days/months/weeks/years, until a specific event].***

***Expected Outcomes from the Investigational Therapy:***

Upon receiving this investigational therapy, ***[Here, describe to the patient in straightforward language what they might experience, using accessible and easy-to-understand terms].***

***Potential Adverse Effects of the Investigational Therapy:***

***[Describe Risks Associated with the Treatment]***

The treatment presents potential risks that are currently unidentified. The impact of these risks can range from minor nuisances to extreme cases that could result in fatality.

For individuals who are pregnant or may become pregnant, there is a possibility that the treatment could adversely affect your unborn child or your pregnancy in unforeseeable ways. These effects could be trivial or critically severe, potentially leading to fatal outcomes.

Choosing this treatment may result in additional financial responsibilities for you. Both you and your insurance provider will be billed for medical services that typically fall under your financial obligation. Given the experimental nature of this treatment, there is a possibility that your insurance may not cover the associated costs.

***Potential Benefits from the Experimental Therapy***

It is not guaranteed that this therapy will provide benefits. The primary aim of this treatment is to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. ***[Here, succinctly describe the anticipated advantages or positive outcomes of the therapy].***

***Additional Information You Should Be Aware Of***

Measures will be taken to protect your privacy and limit access to your personal and medical information to those who require it for review purposes. However, absolute confidentiality cannot be guaranteed. Entities such as the Institutional Review Board (IRB), representatives from this organization, and the US Food and Drug Administration may have the authority to access and review your information. ***[It's important to note that HIPAA Authorization is not needed as this does not fall under the HIPAA definition of research.]***

In the event you experience injury or illness as a result of participating in this treatment, medical attention will be provided. Typically, the costs for such care will be your responsibility or billed to your insurance. Depending on the situation, you might receive care at no charge. For further details, please reach out to the investigator.

***Contacts for Inquiries***

Should you have any questions, concerns, or grievances, or if you believe the treatment has caused you harm, please communicate with your physician at \_\_\_\_\_\_\_\_\_\_\_\_ [Insert contact details here].

This treatment is monitored by an Institutional Review Board. For inquiries about your rights or to address any unresolved issues, concerns, or complaints, please contact them at (646) 217-0403 or via email at info@beyondbound.org

Your consent to participate in this experimental therapy is confirmed by your signature below.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of patient, legally authorized representative, Date

parent, or guardian of a child.

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Printed name of patient

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of individual obtaining consent Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name and signature of individual obtaining consent