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

1. This treatment has not been approved by Food and Drug Administration (FDA).
2. This treatment is considered experimental.
3. FDA considers treatment with unapproved drugs to be research. [delete for uses of devices]
4. Someone will explain this treatment to you.
5. You volunteer to get this treatment.
6. Whether or not you get this treatment is up to you.
7. You can choose not to get this treatment.
8. You can agree to get this treatment now and later change your mind.
9. If you do change your mind, contact your doctor right away.
10. Whatever you decide it will not be held against you.
11. Feel free to ask all the questions you want before you decide.

## How long will I get 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 the viewing of your personal information to people who have to review it. We cannot promise complete secrecy. The IRB, Temple University, Temple University Health System, Inc. and its affiliates, other representatives of these organizations, and the Food and Drug Administration may inspect and copy your information.

What if this research has additional findings about me that were not related to the research questions?

[DELETE THIS SECTION IF THERE ARE NO POSSIBLE INCIDENTAL FINDINGS THAT COULD COME ABOUT DUE TO THE RESEARCH]

[Include if incidental findings may be communicated to the participant] This *(provide imaging procedure (e.g. MRI))* is done for research purposes rather than for diagnosis. The *(provide procedure)* will not be routinely examined by health professionals for potential structural and functional clinical abnormalities. However, in the event an abnormality is detected by the investigators or the *(administer of the procedure* *(e.g. MRI technician)),* the *(named procedure)* will be further examined by a *(name appropriate clinician* (e.g. a radiologist)) and the investigator may encourage you to consult your physician. ***[add below language if applicable]***

[The blood, saliva, tissue that is obtained from you will be tested and/or stored for future use and potential laboratory, genomic and proteomic studies. The material will have your name, medical record number and other identifying information associated with it. Please indicate if you wish to be contacted in the future regarding any test results that may be obtained.]

[Include if incidental findings will not be communicated to the participant] The *(named procedure)* we collect are for research purposes only and we cannot provide a (*name* *appropriate clinician)* clinical interpretation of the results. However, if your healthcare provider would like to use the *(type of data e.g. scans)* for comparison with another clinical *(applicable types of data)* that has already been obtained or may be obtained in the future, they may request these *(type of data)* if they are still available.  ***[add the below language if applicable]***

[The blood, saliva, tissue that is obtained will be tested and/or stored for future use and potential genomic and proteomic studies. However, the material will be de-identified (will not have your name, medical record number or other identifying information associated with it. Therefore, we will not be able to contact you in the future regarding any test results that may be obtained.]

What if I am injured because of this treatment?

If you are injured as a result of taking part in this research, immediately notify the research team and they will arrange for you to get immediate medical care. There is no commitment by Temple University, Temple University Health System or its subsidiaries to provide monetary compensation or free medical care to you in the event of a research-related injury. If you have a research-related injury, please contact Dr. [NAME] at (xxx) xxx-xxxx during regular hours and at (xxx) xxx-xxxx after hours and on weekends and holidays

## 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 research has been reviewed and approved by an Institutional Review Board. You may talk to them at (215) 707-3390 or e-mail them at: irb@temple.edu for any questions about your rights or any unresolved question, concern, or complaint.

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