**Permission for Emergency OR Non-Emergency Single Patient Treatment with an Unapproved Test 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 Food and Drug Administration (FDA)-approved treatments available to you for treatment.

Read this document carefully. You may want to discuss your options with your doctors, family, friends, and others before deciding on whether to receive this treatment. Please ask questions about anything you do not understand.

## **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.
* Whether or not you get this treatment is completely voluntary and up to you.
* You can choose not to get this treatment or agree to get this treatment now and later change your mind without penalty or loss of benefits to which you are otherwise entitled.
* 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 you. The goal of this treatment is to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. ***[Describe the potential benefits of the treatment]***

## **What happens if I say yes, but I change my mind later?**

You can stop the experimental treatment at any time; it will not be held against you. If you stop treatment, information that was already collected may still be shared with the FDA. You may also be asked if you want to provide further information from your routine medical care.

## **Can from the experimental treatment be stopped without my OK?**

[Include only for Compassionate Use of a Device or Single Patient Expanded Access of a Drug where this is a possibility. Otherwise delete.] The person in charge of the experimental treatment or the sponsor can stop the treatment without your approval. Possible reasons for stopping the experimental treatment include [describe reasons why the subject may be withdrawn from the treatment, if appropriate.]

## **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 Institutional Review Board (IRB-an ethics committee that reviews this experimental treatment), representatives of this organization, the sponsor, and the Food and Drug Administration. In addition, your insurance company and/or the medical staff directly involved in your medical care may have access to your identity and information about your use of the experimental treatment. If the result of this treatment is published, your personal identifying information will not be used. Your information will not be used or distributed for future research studies.

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. [Insert the name of the institution] does not plan to pay for medical care for research-related injury. Contact the doctor for more information. [NOTE: HIPAA Authorization is not required because this does not meet the HIPAA definition of research.]

During your treatment, if we learn any new information about the risks or benefits of the investigational treatment, the doctor will let you know.

## **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 (804) 828-0868 or HRPP@vcu.edu.

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

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Printed name of patient

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Signature of patient, legally authorized representative, parent, or Date

guardian of child

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Printed name of legally authorized representative, parent, or guardian of child (if applicable)

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Signature of person obtaining consent Date

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Printed name of person obtaining consent