Humanitarian Use Device (HUD)

Patient Information

We have determined that you have [NAME OF CONDITION], which is a rare condition. We believe that [SPECIFY DEVICE] may help you because [INSERT REASONS]. There is currently no other treatment that we believe would be as helpful.

[SPECIFY NAME of DEVICE] is a Humanitarian Use Device (HUD). A HUD is a device that researchers can’t test in studies, because fewer than 8,000 people have the condition it’s used to treat.

**[FOR HUD approved indication]:** The U.S. Food and Drug Administration (FDA) has approved the use of HUDs for the clinical treatment of patients, even though HUDs don’t go through the same amount of testing that other products do. The FDA believes that HUDs are likely to be safe and will probably benefit patients.

**[For off label use of the HUD, include the following]**

Use of this HUD has not been approved by the FDA for your condition. This means….. [complete]

1. What are the procedures involved with receiving this device?

## What is usually done for patients who have this type of disease or condition?

Standard treatments for [NAME OF CONDITION] include [LIST STANDARD TREATMENTS]. We will be glad to talk to you about your other treatment options.

## What are the risks of being treated with this device?

1. **What are the possible benefits of being treated with this device?**
2. Will you be paid for receiving the device?

You will not get any money for taking part in receiving this device for your clinical care

1. **Will receiving this device cost you any money?**

The device will be provided free of charge to you.

**OR**

Your insurance plan may or may not pay for treatment with this device. If your insurance plan does not pay for this treatment, you will be billed for the cost of the device and all related doctor and hospital costs, including any treatments that are given to help you control any side effects. You will have to pay for any costs not covered by your health plan. You may be responsible for any co-payments or deductibles. You may wish to ask your insurance company for an estimate of what these costs might be or if pre-approval is required.

You will be responsible for the cost of travel to come to UVA Health facilities to receive this device and for any required follow up visits for your clinical care.