[Choose one title. Delete the Other:]

**Informed Consent for Emergency Treatment with an Unapproved Article** [OR]**Compassionate Use of an Unapproved Medical Device**

**INSTRUCTIONS:**

* **[BLUE]** highlighted text provide instructions to guide you in constructing this consent document.
* **[RED]** highlighted text must also appear when obtaining consent from surrogates on behalf of adults who lack decision-making capacity. Be sure to change the text to **[black]** in the document you use to obtain Surrogate Consent.
* **Delete all instructional text and scenarios that are not applicable** to the treatment.
* The document should be written in lay language, preferably at a 6th to 8th grade reading level.

Dr. [Name of physician] is offering to treat you (Words ”I” and “you” refer to the person you are representing as a surrogate) with [name of unapproved drug, device or biologic,] because you have a serious condition called [state what the serious condition is] and there are no standard acceptable treatment options available.

This consent form is designed to provide you with information regarding the [name of unapproved drug, device or biologic and name of the sponsor or funding source, if any, or manufacturer of the drug, device or biologic] that will be used in the emergency treatment that will be performed. Please take your time reviewing this information.

**What should I know about this experimental treatment?**

* This treatment has not been approved by the 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.
* 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 does not affect any benefits you are otherwise qualified to receive.
* Feel free to ask all the questions you want before you decide.

**What can I expect if I get this experimental treatment?**

[Provide information about the drug, device or biologic. Then explain what the treatment is and the procedures that will be followed in the treatment so the patient knows what to expect…first this will happen, then this, etc.]

**How long will this experimental treatment last?**

We expect that the experimental treatment will last [specify in hours, days, months, weeks, years, or until a certain event occurs. Be sure to add information about any necessary follow-up.]

**Is there any way this experimental treatment could be bad for me?**

This treatment may hurt you [In lay terms describe the risks of harm 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 applicable, add] 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.

**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.]

**Are their costs to me to take part in this experimental treatment?**

[Explain in lay language what the cost to participation will be, if any.] [Here is some sample text….] 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.

**Who might financially benefit from use of this experimental treatment?**

[If the doctor or the institution have a material financial stake or interest in this experimental treatment, disclose that here. Material interest is defined as material of $10,000 or more in securities or other assets valued at the date of disclosure, or in relative cumulative salary or other income, regardless of when it is earned or expected to be earned or as otherwise determined by the institution.]

**What if I am injured taking part in this experimental treatment?**

[For Patients Seeking Treatment Under A Single-Patient-Treatment, Emergency Use Or Compassionate Use (Also Known As Early Or Expanded Access) Protocol Involving More Than Minimal Risk Shall Contain The Following Information:] Patients seeking treatment under [fill in name of the single patient treatment, emergency use or compassionate use protocol] will be exposed to certain risks of personal injury in addition to those associated with standard forms of therapy, which include: [provide a complete description if not provided elsewhere in the consent form, or refer reader to appropriate section of form]. In addition, it is possible that during the course of this treatment, new adverse effects of [fill in name of drug, device, procedure, etc.] that result in personal injury may be discovered. The University will make appropriate referrals for medical and/or dental treatment for patients who sustain personal injuries or illnesses as a direct consequence of the treatment. The patient’s health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid or CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. No financial compensation will be provided by the University and no other type of assistance is available from the University. However, by signing this form, you are not giving up any legal rights to seek further compensation.

**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 IRB, authorized representatives of this organization, and the Food and Drug Administration. [NOTE: HIPAA Authorization is not required because this does not meet the HIPAA definition of research.]

**Who can I talk to?**

If you have any questions about taking part or if you feel you may have suffered an injury related to your participation in this experimental treatment, you can contact the doctor: [(Provide Doctor’s name, Institution/Department, address & contact number]

If you have questions, concerns, problems, information or input about the research or would like to know your rights as a research subject, you can contact the Rutgers IRB or the Rutgers Human Subjects Protection Program via phone at (973) 972-3608 or (732) 235-2866 or (732) 235-9806 OR via email [irboffice@research.rutgers.edu](mailto:irboffice@research.rutgers.edu), or you can write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

|  |
| --- |
| **CONSENT TO EXPERIMENTAL TREATMENT**  **Patient Consent**  By signing this form, you agree to take part in the experimental treatment.  Patient’s Name (Printed):  Patient’s Signature: Date:  **Physician Obtaining Consent**  To the best of my ability, I have explained and discussed the full contents of the project including all of the information contained in this consent form. All questions of the participant have been accurately answered.  Name of Physician Obtaining Consent (Printed):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature: Date: |

[If Surrogate Consent applies, delete the ‘Consent to Take Part in Experimental Treatment’ signature block and use instead the ‘Surrogate Consent to Take Part in Experimental Treatment’ signature block found below.]

|  |
| --- |
| **SURROGATE CONSENT TO EXPERIMENTAL TREATMENT**  I am the surrogate of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (name of patient) and I consent for them to take part in the experimental treatment.  Name of Surrogate (Print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Patient Assent\***  If documentation of assent of the adult (the patient) represented by a surrogate is by having the patient sign the Surrogate Consent form, add the following signature line:  Patient Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Physician or Person Obtaining Consent from the Surrogate and Assent of the Patient**:  [Initial the scenario that applies]  \_\_\_\_ The patient’s assent is documented by requesting the patient sign this Surrogate Consent form.  \_\_\_\_ The patient’s assent is documented by requesting the patient sign a separate assent form.  \_\_\_\_ The patient’s verbal assent was obtained.  \_\_\_\_ Assent will not be obtained because the patient’s capacity to understand is so limited that they cannot be reasonably consulted.  I have explained and discussed the full contents of the project including all of the information contained in this consent form. All questions of the patient and those of their legally authorized representative have been accurately answered.  Person Obtaining Consent Name (Print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature: \_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_  **Witness to Consent Process**  I have observed the consent process which included a description of the purposes and procedures of this experimental treatment and an opportunity for questions and answers about it. I attest that I am not the patient, their guardian or authorized representative, or the physician providing the experimental treatment and can attest that the requirements for informed consent to the treatment have been satisfied.  Name of Witness (Print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_  *[\*Assent is an affirmative agreement by an individual not capable of giving legally valid consent, such as an adult represented by a surrogate for decision-making purposes.]* |