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4
5 (Title of Study)
6

7 PATIENT CONSENT FOR RESEARCH
8

9 PLEASE READ THE FOLLOWING MATERIAL TO ENSURE THAT YOU ARE INFORMED OF THE
10 NATURE OF THIS MEDICAL RESEARCH STUDY AND HOW YOU WILL PARTICIPATE IN IT. SIGNING
11 THIS FORM WILL INDICATE THAT YOU HAVE BEEN SO INFORMED AND THAT YOU GIVE YOUR
12 CONSENT TO PARTICIPATE IN A FREE AND INFORMED MANNER. FEDERAL REGULATIONS
13 REQUIRE WRITTEN INFORMED CONSENT PRIOR TO PARTICIPATION IN THIS MEDICAL RESEARCH
14 STUDY.
15

16 **Introduction**
17

18 You are being asked to participate in a research project ([Describe purpose of research project in general non](#)
19 [technical terms.](#))
20

21 This study is sponsored by (Enter name of sponsor, if applicable). Approximately (number) patients will participate
22 in this study at several centers throughout the United States, including Genesys Regional Medical Center, Grand
23 Blanc, MI. A research physician may be receiving financial support from the sponsor because of your participation
24 in this study.
25

26 **Description of Procedures**
27

28 *(For non-randomized studies)*

29 Should you decide to participate, you will ([Describe treatment program](#)).
30

31 *(For randomized studies)*

32 Should you decide to participate, you will be assigned (like flipping a coin) to one of ([Enter number of treatment](#)
33 [groups](#)) different treatment groups. The decision about which group you will be in will be based on chance.
34

35 *(For randomized, double-blind studies)*

36 Should you decide to participate, you will be assigned to one of (Enter number of treatment groups) different
37 treatment groups. The decision about which group you will be in will be based on chance. Neither you nor your
38 doctor will know which treatment you are receiving, although this information is available in case of emergency.
39

40 You will continue to receive treatment as described above unless you develop serious side effects or the treatment
41 does not help you. Your doctor also has the option of removing you from the study if it is felt that this is in your best
42 interest. If treatment is stopped, your doctor will discuss other treatment options with you.
43

44 Your response to treatment will be closely watched. ([Describe tests, examinations and/or procedures, which will be](#)
45 [performed, testing intervals, and total time commitment](#)).
46

47 **Risks and Discomforts**
48

49 Describe possible side effects of treatments and procedures.

50 In addition, there is always the risk of very uncommon or previously unknown side effects. Rarely, complications of

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Date:

51 the treatment may result in death.

52 *(The following paragraph should be included if appropriate, if not it should be deleted.)* Because the medications
53 used in this study may affect an unborn baby, you should seriously evaluate any decision to proceed with
54 participating in the study. **If, after this evaluation, you decide to proceed with the study, you should not become**
55 **pregnant or father a baby while participating in this study, nor should you nurse a newborn while in this**
56 **study.** It is strongly recommended that you inquire about counseling and obtain more information about preventing
57 pregnancy prior to participating in the study. To exclude the possibility of pregnancy before enrollment into the
58 study, a pregnancy test will be performed on women of childbearing potential. Should you have any questions about
59 this, please consult your doctor before agreeing to participate. If you become pregnant or have reason to believe you
60 might be pregnant, please inform your doctor immediately. Once you are no longer receiving this study treatment,
61 discuss with your doctor when it might be safe to become pregnant.

62
63 While this information is not intended to alarm you, you should be aware of the risks of the treatment. Your doctor
64 is aware of the possible risks and has determined that the benefits potentially outweigh the possible risks. Therefore,
65 any potential risk, which you do not fully understand should be further discussed with (Enter physicians'/researchers'
66 names who are associated with the study), the investigator, by calling (810) (Enter telephone number). You will be
67 closely monitored to determine if any side effects occur. In addition, you should tell your doctor of any new or
68 unusual symptoms.

70 **Benefits**

71
72 It is not possible to predict whether any personal benefit will result from the treatments proposed in this
73 investigation. Possible benefits are (Describe possible benefits). Information from this study may also help other
74 patients in the future.

76 **Alternatives**

77
78 Alternative treatments, which may be considered, include (Describe alternative treatments, therapies.) Your doctor
79 can provide detailed information about your disease and the benefits of the various treatments available.

81 **Rights and Responsibilities**

82
83 If you choose to participate in this study, you may withdraw in the future by calling (Enter physician's or
84 researcher's name), the principal investigator at (810) (Enter telephone number). If you choose not to take part in this
85 study, or if you withdraw after you have started, you will not be penalized in any way. You will continue to be
86 provided with appropriate care. You will be informed of any new developments that may affect your willingness to
87 continue participating in this study.

88
89 **For studies involving a drug or device, which may become commercially available during the study:** The drug
90 (Enter drug/device name) will be provided to you free of charge as long as it is experimental. Once the drug is
91 approved, and is available through a regular pharmacy, either you or your insurance company may be responsible
92 for payment for the drug.

93
94 A record of your progress while on the study will be kept in a confidential file at Genesys Regional Medical Center.
95 Only those people who work on the study will have access to records that could directly or indirectly identify you.
96 Such access may include copying a portion of your medical records related to this research. The persons who may
97 have access include representatives from Federal and State agencies, including the FDA and other regulatory
98 agencies. (List all sponsor(s), agencies, monitoring companies, etc.) may have access to the subject's records. All of
99 the information collected will be combined with data collected from other participants for a final review. Your name
00 or any other personal identification will not be used in any published reports.

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Date:

01
02 In addition, as part of routine monitoring of research at Genesys Regional Medical Center, members and staff of the
03 Clinical Research Committee may review the records of your participation in this study. A representative of that
04 Committee for information may contact you about your experience with this study.

05
06 **Financial Responsibilities**

07
08 As explained above, there is a possibility of side effects that may occur as a result of your participation in this study.
09 If research-related side effects or complications do occur, treatment will be offered to you. Genesys Regional
10 Medical Center will not provide you with financial compensation or reimbursement for the cost of any research-
11 related side effects or injuries. The institution or group providing medical care will charge you, your insurance
12 carrier, or other third party responsible for your healthcare costs.

13
14 You will not be paid or receive any other form of compensation for participating in this study. Any test, procedure
15 or activity that occurs solely for the purpose of this research study may not be charged to your insurance company.
16 You or the study sponsor will be responsible for the cost. Please ask your doctor for further information.

17
18 **Sponsored studies:**

19 If you become ill or are hurt while you are in this study, get the medical care that you need right away. Let your
20 Doctor know what has happened as soon as possible. If the Doctor thinks that you have become physically ill as a
21 direct result of a study related procedure, reasonable medical expenses for the research-related illness or side effects
22 may be reimbursed by the sponsor, if they are not covered by your own insurance carrier. No other compensation
23 will be available from the sponsor.

24 **Legal Rights:**

25 The above section does not limit your right to seek legal help. You do not waive any legal rights by signing this
26 Consent Form.

27
28 Should you have any questions about your rights as a subject or should you sustain any side effects or complications
29 related to the research, you may contact the Genesys Institutional Review Board at (810) 606-7722.

30
31 I understand that by consenting to participate in this study, I will be responsible for following instructions and
32 informing study personnel of any side effects I may experience. I will also express any concerns I may have about
33 continuing to participate in this study. I understand that I will be informed about any new information regarding the
34 study that might affect my willingness to continue participation.

35
36 I have had an opportunity to ask questions about the study and was given enough time to consider my participation. I
37 have received a copy of this form and agree to participate.

38
39
40 _____
41 Participant's Signature

_____ Date

42
43
44 _____
45 Investigator's Signature

_____ Date

49 Signature of Person Providing Information

Date

50