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2 (Complete Title of Study)
3

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

14 **Introduction**

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16 You are being asked to participate in a research project (Describe purpose of research project
17 in general non technical 8th grade reading terms.)
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19 This study is sponsored by (If applicable, enter name of sponsor -who is paying for the study.
20 Approximately (number) patients will participate in this study at Genesys Regional Medical
21 Center, Grand Blanc, MI. (or study is being done at multi-sites) A research physician may be
22 receiving financial support from the sponsor because of your participation in this study.
23

24 **Description of Procedures**

25 *(For non-randomized studies)*

26 Should you decide to participate, you will (Describe treatment program).
27

28 *(For randomized studies)*

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

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

34 Should you decide to participate, you will be assigned to one of (Enter number of treatment
35 groups) different treatment groups. The decision about which group you will be in will be
36 based on chance. Neither you nor your doctor will know which treatment you are receiving,
37 although this information is available in case of emergency.
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39 You will continue to receive treatment as described above unless you develop serious side
40 effects or the treatment does not help you. Your doctor also has the option of removing you
41 from the study if it is felt that this is in your best interest. If treatment is stopped, your doctor
42 will discuss other treatment options with you.
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44 Your response to treatment will be closely watched. (Describe tests, examinations and/or
45 procedures, which will be performed, testing intervals, and total time commitment).
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48 **Risks and Discomforts**

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Describe possible side effects of treatments and procedures. ([List all risks associated with this research study](#)) In addition, there is always the risk of very uncommon or previously unknown side effects. Rarely, complications of the treatment may result in death.

(The following paragraph should be included if appropriate, if not it should be deleted.)

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

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

Benefits

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

Alternatives

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

Rights and Responsibilities

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

95 **For studies involving a drug or device, which may become commercially available during**
96 **the study:** The drug ([Enter drug/device name](#)) will be provided to you free of charge as long as
97 it is experimental. Once the drug is approved, and is available through a regular pharmacy,
98 either you or your insurance company may be responsible for payment for the drug. A
99 description of this clinical trial will be available at www.clinicaltrials.gov as required by U.S.
100 Law.

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

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

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117 **Financial Responsibilities**

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

122

123 As explained under “Risks and Discomforts”, there is a possibility of side effects that may
124 occur as a result of your participation in this study. If research-related injuries occur as a result
125 of complications, treatment will be offered to you. Genesys Regional Medical Center will not
126 provide you with financial compensation or reimbursement for the cost of any research-related
127 injuries or complications. The institution or group providing medical care will charge you, your
128 insurance carrier, or other third party responsible for your healthcare costs.

129

130 **For Sponsored studies:**

131 If you become ill or are hurt while you are in this study, get the medical care that you need
132 right away. Let the research Doctor know what has happened as soon as possible. If the Doctor
133 thinks that you have become physically ill as a direct result of a study related procedure,
134 reasonable medical expenses will be reimbursed by the sponsor, if they are not covered by your
135 own insurance carrier. No other compensation will be available from the sponsor.

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138

139

Date:

140 **Legal Rights:**

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

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

146
147 I understand that by consenting to participate in this study, I will be responsible for following
148 instructions and informing study personnel of any side effects I may experience. I will also
149 express any concerns I may have about continuing to participate in this study. I understand that
150 I will be informed about any new information regarding the study that might affect my
151 willingness to continue participation.

152
153 I have had an opportunity to ask questions about the study and was given enough time to
154 consider my participation. I have received a copy of this form and agree to participate.

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158 _____
Participant's Signature

_____ Date

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162 _____
Investigator's Signature

_____ Date

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166 _____
Signature of Person Providing Information

_____ Date

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168 *Note: Delete all language – that does not apply to this study.*

169 *If it is not a sponsored study, delete any reference to a 'sponsor'.*

170 *If this research requires obtaining any Personal Health Information,*

171 *a HIPAA form must also be submitted along with this*

172 *Informed Consent form. Refer to www.genesys.org website -IRB forms*

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174 *Delete all blue/ink instructions, including this paragraph when*

175 *complete and submit to the IRB via www.irbnet.org*

176

177 *Date this Informed Consent in the "Footer" of this document.*

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