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2 **Thomas Jefferson University**  
3 **Informed Consent Document for Human Subjects Research**  
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5 **Department:** Surgery

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7 **Principal Investigator:** Dr. Charles J. Yeo **Telephone:** 215-955-8643  
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9 **Co-Investigator(s):** Drs. Ernest Rosato, Karen Chojnacki, Bernadette Profeta, Adam Berger,  
10 Eugene Kennedy, Hwyla Arafat, Susan Lanza-Jacoby, Peter McCue, Patricia Sauter, Jonathan  
11 Brody, Agnesieszka Witkiewicz, Hallgeir Rui, Theresa Yeo, Michael Lisanti, Harish Lavu,  
12 Ronald Myers, Brian Carr, Thomas Kowalski, David Loren, Ms. Jennifer Brumbaugh and  
13 Sarah Charles **Telephone:** \_\_\_\_\_

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15 **Medical Study Title:** Jefferson Pancreas Tumor Registry (JPTR)

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17 **Lay Study Title:** A research study looking for factors that may cause pancreatic cancer  
18

19 **What Is Informed Consent?**  
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21 You are being asked to take part in a medical research study. Before you can make a  
22 knowledgeable decision about whether to participate, you should understand the possible risks  
23 and benefits related to this study. This process of learning and thinking about a study before you  
24 make a decision is known as *informed consent* and includes:

- 25
- 26 • Receiving detailed information about this research study;
  - 27 • Being asked to read, sign and date this consent form, once you understand the study and  
28 have decided to participate. If you don't understand something about the study or if you  
29 have questions, you should ask for an explanation before you sign this form;
  - 30 • Being given a copy of your signed and dated consent form to keep for your own records.

31 You should understand that your relationship with the study doctor is different than your  
32 relationship with your treating or personal doctor. Your treating doctor treats your specific health  
33 problem with the goal of making you better. The study doctor treats all subjects according to a  
34 research plan to obtain information about the experimental drug, device or procedure being  
35 studied and with the understanding that you may or may not benefit from your participation in  
36 the study. You should ask questions of the study doctor if you want to know more about this.

Subject Initials: \_\_\_\_\_

Date: \_\_\_\_\_

Thomas Jefferson University IRB

Approval Date 7-24-09

Expiration Date 5-13-10

Annual review due 6 weeks before expiration.

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**What is the purpose of this study?**

This is a research study. The Jefferson Pancreas Tumor Registry is attempting to collect information to determine if pancreas tumors tend to occur more frequently in families with a history of the disease and to determine environmental and occupational risk factors to which patients may be exposed. In this study, our aim is to gather information through the completion of the Jefferson Pancreas Tumor Registry questionnaire and to collect and analyze DNA samples that may find indicators or “biomarkers” of increased risk for pancreatic cancer. These samples may be obtained from patients undergoing pancreatic and other related cancer resections or from the patients’ family members (spouses and offspring) who wish to participate in the study.

**How many individuals will participate in the study and how long will the study last?**

We anticipate approximately 100- 200 patients to be entered in this study each year.  
The study is ongoing with total enrollment of about 300 subjects

**What will I have to do during the study?**

If you agree to participate in the Jefferson Pancreas Tumor Registry, you will be asked to give: 15 cc (3 tablespoons) of blood to the Registry for testing. In some instances these DNA samples will be screened for genes known to be associated with an increased risk of pancreatic cancer (these genes are called BRCA2, p16, PRSS1, hMLH1 and STK11). In some instances these DNA samples will be used to identify undiscovered genes associated with an increased risk of pancreatic cancer.

Blood (about three tablespoons) will be collected while you are under anesthesia prior to the surgery (if undergoing surgery) and stored using de-identified codes. Keys to the codes will be kept separate from samples. Additionally, we may collect blood samples prior to your leaving the hospital as well as at your follow-up office visit. If you are not undergoing surgery, these samples can be collected by your family doctor or clinic and mailed to us. If you agree to either of these tests, we will mail you a set of specific instructions to ensure that it is placed in the proper type of collection container and sent in the proper way. You will not be informed of the results of studies done on your blood. These samples are strictly for research purposes and not for clinical diagnostic testing. However, we may learn something in the future to suggest that you may benefit from gene testing. It is therefore possible that we may wish to contact you at

Subject Initials: \_\_\_\_\_  
Date: \_\_\_\_\_

76 a later time to make suggestions as to which gene test may be available to you from a  
77 clinical laboratory. If you do not wish to be contacted, circle no below. If you do want to  
78 be re-contacted, it is up to you to make sure that we have your current address in our  
79 files. There are no risks associated with agreeing or not agreeing to be contacted in the  
80 future. There may be benefits however, because the identification of undiscovered genes  
81 associated with an increased risk of pancreatic cancer could make you aware of your  
82 potential vulnerability to the disease and allow further testing or screening.

83 .  
84 I want to know the result of testing if it will have an effect on my family.

85  
86 Yes No (circle one).

87  
88 Sign your initials here: \_\_\_\_\_  
89

90  
91 **What are the risks or discomforts involved?**  
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93 There is very little risk or discomfort associated with participation in this study. There is a  
94 minimal risk of bruising and discomfort associated with blood drawing. If undergoing surgery,  
95 you will not suffer any discomfort while collecting the samples, since you will be under  
96 anesthesia as part of your surgical procedure. The tumor and tissue and fluid samples will also  
97 be collected at this time.

98 Samples that are collected during separate office visits will be no different than any of the  
99 routine blood draws.

100  
101 We will try to take as little of your time as possible in the completion of the questionnaire.  
102 It should take approximately 30 minutes to complete. All information will be kept strictly  
103 confidential and will be used only for research purposes; however, there is a small risk of loss of  
104 confidentiality. This will be minimized in two ways: 1) No individual identifiers will be used,  
105 and 2) Data will be analyzed and reported for scientific and/or educational purposes as group  
106 data only.

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108 **Are there alternatives to being in the study?**  
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110 The alternative to joining the study is to not participate in the Jefferson Pancreas Tumor Registry.  
111 If you decide not to participate, it will not affect your ability to receive medical care.

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114 **How will privacy and confidentiality (identity) be protected?**  
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Subject Initials: \_\_\_\_\_

Date: \_\_\_\_\_

116 There are federal regulations about protecting information about you. This information is called  
117 “protected health information” (PHI). PHI includes things that identify you personally like your  
118 name, address and social security number, etc., or any medical or mental health record, or test  
119 result, such as an X-ray, that may have this sort of information on it. According to federal and  
120 state regulations, you may see your health information at any time. However, in a research study,  
121 you may not see the health information related to the research until after the research is  
122 completed unless the study doctor decides otherwise.

123 By signing this consent form, you are allowing the research team to have access to your PHI.  
124 The research team includes the investigators listed on this consent form and other personnel  
125 involved in this specific study. Your PHI will also be shared, as necessary, with the University’s  
126 Division of Human Subjects Protections and the Institutional Review Board (a University  
127 committee that reviews, approves and monitors research involving human subjects).

128

129 All of the above entities are obligated by law to protect your PHI.

130

131 If the results of the research are published or presented, your identity will remain confidential.

132

133 The following information will be provided to the study sponsor and other entities noted above.

134

135

136 **Study Data for Analysis:**

137 - Blood samples, as well as tissue, pancreatic juice and bile collected during surgery.

138 - Medical records, including demographic data and clinical history will be accessed.

139 - JPTR questionnaire completed by the patient, family member or proxy respondent.

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141 Your PHI will be used/disclosed:

142

143 [ ] until the end of the research study

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145 [ X ] indefinitely.

146

147 You may quit the study and revoke permission to use and share your PHI at any time by  
148 contacting the principal investigator, in writing, at:

149 Dr. Charles J. Yeo, Dept of Surgery, Suite 620 College Bldg., Thomas Jefferson University, 1015

150 Walnut Street, Philadelphia, PA 19107

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152 If you quit the study further collection of your PHI will be stopped, but PHI that has already been  
153 collected may still be used.

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Subject Initials: \_\_\_\_\_

Date: \_\_\_\_\_

155 The results of clinical tests and procedures performed as part of this research may be included in  
156 your medical records. The information from this study may be published in scientific journals or  
157 presented at scientific meetings but you will not be personally identified in these publications and  
158 presentations.

159  
160 In the event that you experience a research-related injury, comprehensive medical and/or surgical  
161 care (including hospitalization) to the extent needed and available will be provided. However,  
162 Thomas Jefferson University cannot assure that this comprehensive medical and/or surgical care  
163 will be provided without charge. The costs will be billed to your insurance carrier but they may  
164 ultimately be your responsibility. A research-related injury is a physical injury or illness resulting  
165 to you as a direct result of the experiments, treatment(s) and/or procedure(s) used in this study  
166 that are different from the medical treatment you would have received if you had not participated  
167 in this study. No other financial compensation is available.

168  
169 **What if I am injured as a result of being in this study?**  
170 In the event that you experience a research-related injury, comprehensive medical and/or surgical  
171 care (including hospitalization) to the extent needed and available will be provided. However,  
172 Thomas Jefferson University cannot assure that this comprehensive medical and/or surgical care  
173 will be provided without charge. The costs will be billed to your insurance carrier but they may  
174 ultimately be your responsibility. A research-related injury is a physical injury or illness resulting  
175 to you as a direct result of the experiments, treatment(s) and/or procedure(s) used in this study  
176 that are different from the medical treatment you would have received if you had not participated  
177 in this study. No other financial compensation is available.

178  
179 **Will I benefit from being in this study?**  
180 You and your family may or may not benefit directly from your participation in this study.  
181 However, although you may not benefit directly from this research, there may be a benefit to  
182 society, in general, from a better understanding of the risk factors for pancreatic cancer and  
183 increased knowledge of the occurrence of pancreas tumors in families. Any information obtained  
184 from this research study, and which may be important to your health or disease progression, will  
185 be shared with you. Additional benefits from your participation in this study may include:

- 186 1) Identification of risk factors for pancreas cancer,  
187 2) Discovery of biomarkers that can be used in early detection of pancreas cancer and for  
188 screening high risk groups,  
189 3) Identification of genes that may aid in individualizing treatment of pancreas cancer, as  
190 well as identifying new treatment strategies.

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Subject Initials: \_\_\_\_\_

Date: \_\_\_\_\_

192 **Will I be paid for being in this study?**

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194 You will not be paid for joining this study. There are no plans or resources to reimburse you for  
195 any problems that you may experience by being in this study.

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198 **Who should I contact with questions or if I think I have a research-related injury?**

199

200 If you have any questions or concerns about this research, or if you experience a research-related  
201 injury, you may call the following numbers:.

202

Telephone number for questions about your rights as a research participant	The Institutional Review Board	215-503-8966
For questions, concerns or complaints about the research, or if you suspect a research-related injury	The Principal Investigator, Dr. Charles Yeo	215-955-8643
If you have difficulty contacting the study staff	Call the Institutional Review Board	215-503-0203

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206 **Will I be told about any new findings?**

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208 As the research progresses, any significant new finding(s), beneficial or otherwise, will be  
209 evaluated by the study director if it relates to the course of your treatment.

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211 **Are there costs related to being in this study?**

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213 **Standard Testing Procedures**

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215 There should be no costs to the subject associated with this protocol. If you elect to participate  
216 and are not a patient, there may be a minimal charge associated with the blood draw.

217 If you receive a bill that you think is wrong, please discuss it with the study doctor or research  
218 coordinator.

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220 **Voluntary Consent and Subject Withdrawal**

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Subject Initials: \_\_\_\_\_

Date: \_\_\_\_\_

222 You voluntarily consent to be in this research study. You have been told what being in this  
223 study will involve, including the possible risks and benefits.

224 You can agree to be in the study now and change your mind later. If you wish to stop, please  
225 tell us right away. If you leave the study early, Thomas Jefferson University may use any health  
226 information that it already has if the information is needed for this study or any follow-up  
227 activities.

228 If you decide not to participate in this investigation or withdraw your consent and discontinue  
229 participation in this study, it will not affect your ability to receive medical care at Thomas  
230 Jefferson University Hospital. If you withdraw from this study, you may continue treatment with  
231 your Jefferson doctor, or you may seek treatment from another doctor of your choice.

232 Your participation in this research study may be ended without your consent. Possible reasons  
233 for termination from the study include: not following study procedures as instructed, an event  
234 making your continued participation unsafe, or if the study has ended. There may be other  
235 reasons that end your participation without your consent.

Subject Initials: \_\_\_\_\_

Date: \_\_\_\_\_

236 **Non-Waiver of Legal Rights Statement**

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238 **By your agreement/your permission to participate/allow your child to participate in this**  
239 **study, and by signing this consent form, you are not waiving any of your/ your or your**  
240 **child’s legal rights.**

241

242 **In order to be in this research study, you must sign this consent/parental permission form.**

243

244 **You affirm that you have read this consent form. You have been told that you will receive a**  
245 **copy.**

246

**Signatures:**

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248

249 \_\_\_\_\_(Date)

250 Your Name *(please print or type)*

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253 \_\_\_\_\_(Date)

254 Your Signature

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261 \_\_\_\_\_(Date)

262 Name of Person Conducting Consent Interview

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265 \_\_\_\_\_(Date)

266 Signature of Person Conducting Consent Interview

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269 \_\_\_\_\_(Date)

270 Signature of Principal Investigator or

271 Co-Investigator

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\_\_\_\_\_(Date)

Witness Signature

*(Only required if subject understands and speaks English, but cannot read English, or if subject is blind or cannot physically sign the consent form—delete if inapplicable)*

As per University Counsel - Do not sign  
this consent form after 5-13-10

Subject Initials: \_\_\_\_\_

Date: \_\_\_\_\_