**Human Subjects Research**

**Assessment Form**

**Do not use abbreviations in this form- the form will be returned to be amended before it will be considered.**

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| --- |
| **Project Title:**       |
| **Project Leader’s Name:**       |
| **Date:**       |
| **KP Mailing Address:**      **Phone #:**      **Email:**       |

The purpose of this form is to determine if a given project is human subjects research which requires review and oversight by the Institutional Review Board (IRB) in accordance to federal regulations and institutional policies. Projects that do not meet both the definition of research and human subjects are not required to be submitted for review to have a formal determination made. However; there are serious consequences for conducting human subjects research without the appropriate oversight and therefore, anyone is encouraged to complete and submit this form to have the assessment made. For additional information regarding quality improvement vs human subjects research, please visit:

**http://www.hhs.gov/ohrp/policy/faq/quality-improvement-activities/**

The following questions are designed to assist the IRB in making a determination on whether or not a project is human subjects research. The call-out boxes in this form are designed to provide insight on how the assessment will be made. Please answer all of the questions that apply.

1. **Please provide a complete description of your project.**

1. **Is the activity a systematic investigation designed to develop or contribute to generalizable knowledge?**

[ ] [ ] Yes [ ]  No

Comments:

If the answer to this question is ‘Yes’, then this project is likely to be considered a ‘*systematic investigation’*.

1. **Is the activity being conducted only to comply with KP requirements for quality measures to benefit patients?**

[ ] Yes [ ]  No

Comments:

If the answer to this question is ‘NO’, then this project is likely to be considered a ‘*systematic investigation’*.

1. **How will this project differ from the routine (standard of) care and normal clinic operations?**

If the project deviates significantly from routine standards of care, it is possible that there may be increased risks to the participants and therefore require IRB review and oversight.

1. **Does the project pose any additional risks (physical risks &/or risks of confidentiality breach) or burdens (extra appointments or visits, longer appointments, additional surveys) on the patients beyond routine care?**

[ ]  Yes [ ]  No

If ‘Yes’, please comment:

If the project poses any additional burdens to the participants, it is possible that it **may be necessary to have additional oversigh**t of the project to look out for the best interests of the participants.

1. **Does the project involve obtaining information about living individuals?**

**[ ]** [ ]  Yes [ ]  No

Comments:

If the answer is ‘YES’, it is possible that the project may involve ‘human subjects’ as defined by the regulations.

1. **If YES to Question 5,** **Does the project involve either:**
2. **Obtaining information by intervening or interacting with an individual? OR**
3. **Collecting identifiable private information?**

**[ ]** [ ]  Yes [ ]  No

Comments:

If the answer is ‘YES’, it is possible that the project may involve ‘human subjects’ as defined by the 45 CFR 46 regulations.

**Project Leader Name Date**

**Submit this completed form to** **Isabel.M.Sanchez@kp.org**

**For questions, please contact: Isabel “Marcela” Sanchez at (626) 405--6124 or Daria Galindo at (626) 405-5972**