Kaiser Permanente
Institutional Review Board
Core Data Form

Project Title: [1259140-1] Appropriateness of Pharmacogenomic Testing in Patients with Metastatic Colorectal Cancer

Last edited by: Thomas Delate

Last edited on: June 14, 2018

[instructions for researcher]

I. Project Information

Please provide a brief, plain-language description of the study:

The purpose of the proposed study is to describe the uptake and implementation of guideline recommendations for *KRAS*, *NRAS* and *BRAF* pharmacogenomic testing among patients with metastatic colorectal cancer who are candidates for cetuximab or panitumumab therapy at KPCO and KPMA. Results from this study will provide information on if pharmacogenomic testing has been applied accurately in the oncology setting and identify if additional processes are needed to ensure appropriate use of such testing and its results.

Project Characteristics:

- ☐ Clinical Trial
- ☐ Coded / Linked Private Information or Specimens
- ☐ Protected Health Information
- ☐ Radiation or Radioactivity
- ☐ None of the above
- ☐ Hazardous Material
- ☐ De-Identified Biological Samples / Specimens
- ☐ Genetic Testing
- ☑ Data Only

Will you have direct oversight of research activities taking place off-site and involving non-KP research sites, non-KP personnel, or other KP regions? ☐ Yes ☑ No

Is this research part of a collaborative, Multi-Site project? ☐ Yes ☑ No

II. Funding Information

Funding Sources:

- ☐ Industry Sponsor
- ☐ Other Non-KP Grant / Contract
- ☐ Other
- ☐ Federal Grant / Contract
- ☑ Internal KP Funds
- ☐ Not Funded

If funded by an Industry Sponsor, please complete this section for each Industry Sponsor.

Name:	Funding ID:

If funded by an a Federal or Other Non-KP Grant, please complete this section for each Grant / Contract.

Grant Title:

Grant ID #:

Grant Sponsor:

Federally funded? ☐ Yes ☐ No

Region is prime recipient? ☐ Yes ☐ No

Funding Begins: **Funding Ends:**

If funded internally, not funded, or funded by some other means, please describe how this study is supported.

KPCO Pharmacy Dept.

III. External Sites N/A ☑

Please complete this section for each External Site.

IRB Name:

Contact Name: **Email:**

IV. Multi-site Studies N/A ☑

Are you requesting that this IRB...

...be IRB of record? ☐ Yes ☐ No

...cede to another IRB or region? ☐ Yes ☐ No ☐ N/A

V. Genetic Testing Information N/A ☑

What type of data is involved in the genetic research?

- ☐ De-identified Data without Consent
- ☐ De-identified Data with Prior Consent
- ☐ Identifiable Data without Consent
- ☐ Identifiable Data with Prior Consent

VI. Clinical Trial Information N/A ☑

Clinical Trial Type:

- ☐ Bio-medical
- ☐ Behavioral

Clinical Trial Phase:

- ☐ Phase I
- ☐ Phase I / II
- ☐ Phase II
- ☐ Phase II / III
- ☐ Phase III
- ☐ Phase IV
- ☐ None / Not Applicable

Study involves the following:

- ☐ Drugs, Biologics, and / or Nutritional Supplements
- ☐ Medical Devices
- ☐ None of the Above

VII. Drug, Biologic, or Nutritional Supplement Information N/A ☑

Please complete this section for each Drug, Biologic, or Nutritional Supplement.

Trade Name:

Generic Name:

Manufacturer:

Used according to FDA-approved labeling: ☐ Yes ☐ No ☐ N/A

Does an IND apply? ☐ Exempt ☐ Required ☐ N/A

If an IND is required for at least one Drug, Biologic, or Supplement, please complete the following:

Is KP the IND Holder? ☐ Yes ☐ No

IND Number:

Please explain why the IND Number is not available. If the IND Number is available, please enter "N/A."

VIII. Medical Device Information N/A ☑

Please complete this section for each Medical Device.

Device Name:

Manufacturer:

Device is HUD: ☐ Yes ☐ No

Exempt from IDE: ☐ Yes ☐ No

If approved or cleared, follows FDA Labeling: ☐ Yes ☐ No ☐ N/A

Device Risk:

- ☐ Study is Exempt from IDE
- ☐ FDA Non-Significant Risk Determination
- ☐ Sponsor Non-Significant Risk Determination
- ☐ Significant Risk Device (IDE/HDE)

If an IDE / HDE is required for at least one Device, please complete the following:

Is KP the IDE / HDE Holder? ☐ Yes ☐ No

IDE / HDE Number:

Please explain why the IDE or HDE Number is not available. If the IDE or HDE Number is available, please enter "N/A."

INSTRUCTIONS TO RESEARCHERS

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Thank you for completing the **Kaiser Permanente - IRB Core Data Form**.

Principal and Co-Investigator Attestation:
By signing this package in IRBNet, I attest that I have read and understand the Investigator Responsibilities (*Principal Investigator Statement of Assurance*), and I agree to adhere to them for the duration of the project.

If you have any questions or concerns about this application or any other IRB issue, please feel free to contact the IRB Office.

Based on your responses, the following additional documentation must be included with this package before submission. Upload additional documentation in the Designer.

Additional required documentation:
No additional documents are required for this project.

Please use this checklist to ensure that you have attached all the necessary documentation for complete IRB review.