

IRB Exempt Form (Attachment K)

Title of Study:

Retrospective Cohort Study of Hepatocellular Carcinoma Patients Using the Surveillance, Epidemiology, and End Results (SEER) Medicare Linked Database

Primary Investigator: Robert Wong, M.D.

Phone #/email address: 510-437-6531

Email: Rowong@alamedahealthsystem.org

1. Give a brief description of this study.

Retrospective observational cohort study of patients with hepatocellular carcinoma (HCC) using de-identified publically available data from the National Cancer Institute's Surveillance Epidemiology and End Results Registry (SEER) Medicare Linked Database. Our proposed study will evaluate long term trends in HCC incidence and outcomes, including race/ethnicity-specific differences in HCC incidence, HCC tumor stage at presentation, and overall HCC survival. We will also be evaluating cost-effectiveness of different treatment strategies as they relate to HCC after correcting for clinically relevant variables such as etiology of liver disease (e.g. HBV, HCV, NASH, alcoholic liver disease), as well as HCC tumor stage at presentation.

2. Which exempt category(ies) does this research fall within? (See categories described in Requirements for IRB Exempt Status, above.)

E. Research involving the collection or study of existing data, documents, records, pathological specimens or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

3. Will any subjects be contacted for purposes of the study? If so, please describe the contact process.

No

4. Will subjects be completely anonymous? If not, how will their identities be protected? How long and in what way will records be retained? Who will have access to study data?

Yes

5. Will there be any data collection forms used for study purposes? If so, please submit a copy of each.

No

CERTIFICATION OF EXEMPT STATUS

On the basis of the information presented, this research activity qualifies as exempt from review by the Alameda Health System Institutional Review Board

DENIAL OF EXEMPT STATUS

On the basis of the information presented here, this study does not qualify for exempt status, and a protocol should be presented to the Alameda Health System IRB for review by the:

- Expedited review
- Full IRB Committee review

Robert N. Cole _____ 4/3/18
Principal Reviewer, _____ Date

[Signature] _____ 4/3/18
Chairman, Alameda Health System _____ Date
Institutional Review Board