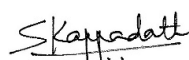

DATE: March 21, 2021

SUBJECT: Waiver of Informed Consent

Manuscript title: Disease Control and Failure Patterns of Unresectable Hepatocellular Carcinoma Following Transarterial Radioembolization with Yttrium-90 Microspheres

Invited Manuscript ID: 02664146

The Institutional Review Board Protocol number is DR09-0025. This was a retrospective review and waiver of informed consent was obtained.



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(Senior Author)

5.0 Request for Waiver of Consent/Authorization

A Waiver of Informed Consent and a Waiver of Authorization is requested because this is a retrospective data review that involves no diagnostic or therapeutic intervention, as well as no direct patient contact. It will be impracticable to obtain consent from patients because they are lost to follow up, no longer receiving treatment or deceased.

6.0 Data Confidentiality Plan

Identifiers (name, medical record number) will be collected but will be replaced by study numbers in the analytical file. The key linking these numbers will be retained in a locked file by the investigator. All identifiers will be destroyed after publication. The protected health information used in this study will not be reused or disclosed to any person or entity outside of the investigators nor will it be used for other research. No identifying information will be used in any publication from this study.

All study personnel have completed training in methods for maintaining the confidentiality of health information. Electronic records will be stored on password protected institution computers behind the institution firewall. Only the PI and research staff will have access to this study. Data will not be transferred to laptop computers that are removed from the institution. Complete confidentiality will be maintained during this retrospective evaluation, manuscript preparation and submission.

7.0 References