



MedStar Health Research Institute-Georgetown University Oncology Institutional Review Board

Date: 11/21/2016

To: [Metin Ozdemirli](#)

From: [Harley Gould](#)
Institutional Review Board

IRB#: [2016-0699](#)

Title: Primary Mucosa-associated Lymphoid Tissue (MALT)
Lymphoma of the liver: a report of two cases

Action: Non-Human Subject Research

Attachments being reviewed:

Document	Version
Primary Mucosa-associated Lymphoid Tissue (MALT) Lymphoma of the Liver: a report of 2 cases.	0.01

Your above mentioned project does not require review and approval by the Georgetown University Institutional Review Board (GU IRB), as it does not meet the definition of human subjects research as defined in the Georgetown University policies and procedures and the Common Rule (Title 45 Code of Federal Regulations Part 46).

A human subject is "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information" [45 CFR 46.102(f)].

You are using de-identified (coded) bio-specimens from ---. You and your research team/ staff do not have access to any identifiable information or to any other means that might enable you to link the bio-specimens to the individual subjects. This research project does not involve human subjects as no identifiable private

information will be obtained.

You must submit your project to be reviewed by the GU IRB if any project changes occur that will involve the following:

- obtaining data about living individuals for research purposes through intervention or interaction with them;
- obtaining individually identifiable private information for research purposes (45 CFR 46.102(d),(f))
- receiving a direct HHS award to support such research, even if all of the human subjects activities will be performed by agents or employees of another institution.

No further IRB review is required for your project at this time. Please contact the IRB office at 202-687-1506 if you have any questions.

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