AUGUSTA UNIVERSITY

Waiver of Consent and Waiver of Documentation of Consent Form
2018 Regulations

I. PI and Waiver Request Type	
1.	PI Name: **John Erikson Yap**
2.	Protocol Title: **The Safety of Endoscopy among Patients on Antiangiogenic Agents in a Non-Specialized Hospital for Cancer Treatment: A retrospective study**
3.	IRB Number: **1494636-1**
4.	Waiver Request Type: ☒ Waiver of the Consent Process (complete section II) ☐ Waiver of Documentation of Consent (complete section III) ☐ Waiver of the Consent Process in research involving public benefit and service programs conducted by or subject to the approval of state or local officials (complete section IV)

II. Waiver of the consent process	
1.	☒ Requesting a Waiver of the consent process ☐ Requesting Alteration of the consent process. Specify the elements of consent that will not be fully disclosed:
2.	In order for the IRB to grant this waiver, **all** of the following conditions must be met. Explain why your research meets each condition in the spaces provided.
	i. The research involves no more than minimal risk to the subjects *Explanation:* The research design is a retrospective chart review of patients who have been treated at Augusta University with Endoscopic procedures who also have concurrently been treated with Anti-Vascular Endothelial Growth Factor Medications.The research involves no more than minimal risks as no active participation or active interventions are planned. Risks of patient protected health information data safety remains and all institutional requirements and recommendations will be followed.

	ii. The research could not practicably be carried out without the requested waiver or alternation *Explanation:* There is an unknown number of patients that meet the inclusion criteria for the study. It would additionally be impossible to achieve consent for all these patients as they have already been treated.
	iii. . If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format *Explanation:* This research does involve collection of PHI such as demographic information, social and medical history, and treatments provided. However all data will be de-identified and de-linked prior to storage and analysis.
	iv. The waiver or alteration will not adversely affect the rights and welfare of the subjects *If appropriate, explain how this will be done:*
	v. When appropriate, the subject or legally authorized representatives will be provided with additional pertinent information after participation.

III. Waiver of Documentation of the Consent Process	
1.	The Request for waiver meets one of the following conditions:
	Condition 1-The only record linking the subject and the research would be the informed consent form and the principal risk would be the potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; *(For example: where participants could be seriously harmed if it became known that they were participants in the research.)* *Explanation:*
	OR
	Condition 2- That the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context. *(For example: procedures such as mail surveys or brief interviews over the telephone or at public events/venues that elicit non-sensitive information).* *Explanation:*
	OR

	Condition 3- If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained. *Explanation:*

IV. Waiver of the consent process in research involving public benefit and service programs conducted by or subject to the approval of state or local officials	
1.	☐ Requesting a Waiver of the consent process ☐ Requesting Alteration of the consent process. Specify the elements of consent that will not be fully disclosed:
2.	In order for the IRB to grant this waiver, **all** of the following conditions must be met. Explain why your research meets each condition in the spaces provided.
	i.
	ii. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine { Select all that apply.}: ☐ Public benefit or service programs; ☐ Procedures for obtaining benefits or services under those programs; ☐ Possible changes in or alternatives to those programs or procedures; OR ☐ Possible changes in methods or levels of payment for benefits or services under those programs;
	iii. The research could not practicably be carried out without the waiver or alteration. *Explanation:*

NAME OF PERSON COMPLETING THIS FORM and PRINCIPAL INVESTIGATOR ATTESTATION STATEMENT:

Mohammad Umair Azam 9/11/19

Printed or Typed Name of Person Completing This Form **Date**

I will conduct the study identified above in the manner described in this application, the protocol, and any additional materials included in this, or subsequent, submissions. I will submit any proposed changes to the research to the AU Institutional Review Board prior to implementation, to evaluate whether the research remains exempt.

John Erikson Yap 9/11/2019

Printed or Typed Name of Principal Investigator **Date**

By electronically signing this package I, the Principal Investigator, attest to the accuracy of all statements in this form.