



## Waiver of Consent and Waiver of Documentation of Consent Form



I. PI and Waiver Request Type	
1.	PI Name: <b>Gyanendra Sharma</b>
2.	Protocol Title: <b>Impact of Anticoagulation on Resolution of Left Atrial and Left Atrial Appendage Thrombi</b>
3.	IRB Number: <b>1016768-1</b>
4.	Waiver Request Type: <input checked="" type="checkbox"/> Waiver of the Consent Process  <input type="checkbox"/> Waiver of Documentation of Consent

II. Waiver of the consent process	
1.	<input checked="" type="checkbox"/> Requesting a Waiver of the consent process  <input type="checkbox"/> 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, <b>all</b> of the following conditions must be met. Explain why your research meets each condition in the spaces provided.
	a. The research involves no more than minimal risk to the participants. <i>Explanation:</i> There are no risks to study subjects because no intervention will be performed. No personal health information (PHI) will be made available for disclosure. Dataset will be stored electronically with password-encrypted files and only accessible to team members of the study. Handling of sensitive PHI will strictly adhere to HIPAA regulations.
	b. The waiver will not adversely affect the rights and welfare of the participants. <i>Explanation:</i> see explanation as above
	c. The research could not practicably be carried out without the waiver. "Practicably" means there is no practical way to either implement a consent procedure or disclose all the elements of consent without jeopardizing the validity of the study. <i>Explanation:</i> There will be a large number of patients involved. No harm to the patient is anticipated.

	<p>d. Whenever appropriate, the participant will be provided with additional pertinent information after participation.</p> <p><i>If appropriate, explain how this will be done:</i> The study is a retrospective chart review. The patients will not be contacted.</p>
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III. Waiver of Documentation of the Consent Process	
1.	The Request for waiver meets one of the following conditions:
	<p><b>Condition 1</b>-The only record linking the participant and the research would be the consent document and the principal risk would be the potential harm resulting from a breach of confidentiality. This refers to instances where participants could be seriously harmed if it became known that they were participants in the research.  <i>Explanation:</i></p>
	OR
	<p><b>Condition 2</b>-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. This refers to procedures such as mail surveys or brief interviews over the telephone or at public events/venues that elicit non-sensitive information.  <i>Explanation:</i> This study is a retrospective chart review. The study will not require interaction with the patients.</p>

NAME OF PERSON COMPLETING THIS FORM and PRINCIPAL INVESTIGATOR ATTESTATION STATEMENT:		
<u>Hoyle Whiteside</u>		<u>1/23/17</u>
Printed or Typed Name of Person Completing This Form		Date
<u>(910) 512-7878</u>	<u>( )</u>	<u>hwhiteside@augusta.edu</u>
Phone number	Fax number	E-mail address (optional)
<u>Gyanendra Sharma</u>		<u>1/23/17</u>
Printed or Typed Name of Principal Investigator		Date
<p><b>"By electronically signing this package I, the Principal Investigator, attest to the accuracy of all statements in this form."</b></p>		