



**Date:** April 26, 2016  
**Principal Investigator:** Hitendra Patel

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**Protocol Number:** 1508054987  
**Protocol Title:** REVIEW OF EFFICACY AND SAFETY OF THE NEW ORAL ANTICOAGULANTS (NOACS) IN THE TREATMENT OF VENOUS THROMBOEMBOLISM IN GASTROINTESTINAL ONCOLOGY PATIENTS

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**Level of Review:** Exempt  
**Determination:** Approved

**Documents Reviewed Concurrently:**

- Data Collection Tools:** *NOAC Data Extraction Form August2015.docx*
- HSPP Forms/Correspondence:** *Appendix F\_signed 14August2015.pdf*
- HSPP Forms/Correspondence:** *Appendix F Waiver of Consent and Signatures or Alteration\_IRB edits 14August2015.doc*
- HSPP Forms/Correspondence:** *Appendix F Waiver of Consent and Signatures or Alteration.doc*
- HSPP Forms/Correspondence:** *F107 v2015-05-NOAC.doc*
- HSPP Forms/Correspondence:** *F203\_signed 14August2015.pdf*
- HSPP Forms/Correspondence:** *F203 7Aug2015\_IRB edits.doc*

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This submission meets the criteria for exemption under 45 CFR 46.101(b). This project has been reviewed and approved by an IRB Chair or designee.

- The University of Arizona maintains a Federalwide Assurance with the Office for Human Research Protections (FWA #00004218).
- All research procedures should be conducted according to the approved protocol and the policies and guidance of the IRB.
- Exempt projects do not have a continuing review requirement.
- Amendments to exempt projects that change the nature of the project should be submitted to the Human Subjects Protection Program (HSPP) for a new determination. See the Guidance on Exempt Research information on changes that affect the determination of exemption. Please contact the HSPP to consult on whether the proposed changes need further review.
- You should report any unanticipated problems involving risks to the participants or others to the IRB.
- All documents referenced in this submission have been reviewed and approved. Documents are filed with the HSPP Office. If subjects will be consented, the approved consent (s) are attached to the approval notification from the HSPP Office.