**OHR 31 7/8/15**

**IRB REVIEW OF WAIVER REQUEST FOR INCLUSION/EXCLUSION CRITERION**

**OFFICE OF HUMAN RESEARCH**

Instructions: Complete this form and submit directly to OHR or electronically as a scanned PDF document with PI signature to all of the following: Walter.Kraft@jefferson.edu, Kyle.Conner@jefferson.edu

IRB Control#:\_\_\_\_\_\_\_\_\_\_\_\_\_ PI: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Sponsor:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title of study:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Is study investigator-initiated?
2. If commercially sponsored, attached sponsor waiver approval document to this form.
3. Describe pertinent inclusion/exclusion criterion as written in protocol or OHR-2:
4. Please describe the rationale and circumstances regarding request for waiver of this inclusion/exclusion criterion.
5. Please assess any increased risk to subject associated with waiver:

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Principal Investigator Date

**For IRB use only**

Reviewer comments:

Request is \_\_\_\_\_ approved or \_\_\_\_\_ denied

Signature Date

Walter Kraft, M.D. Kyle Conner, M.A., CIP

Director, OHR Associate Director, OHR