

IRB MEMO

Research Integrity Office

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APPROVAL OF SUBMISSION

September 11, 2019

Dear Investigator:

On September 11, 2019, the IRB reviewed the following submission:

IRB ID:	STUDY00020406
Type of Review:	Initial Study
Title of Study:	Definitive treatment? A single institution experience of below knee amputations and analysis of risk factors for reoperation
Principal Investigator:	James Meeker
Funding:	None
IND, IDE, or HDE:	None
Documents Reviewed:	<ul style="list-style-type: none">• Protocol• HIPAA Waiver• PPQ

The IRB granted final approval on 9/11/2019. The study requires you to submit a check-in before 9/9/2022.

Review Category: Exempt Category #4

Copies of all approved documents are available in the study's **Final** Documents (far right column under the documents tab) list in the eIRB. Any additional documents that require an IRB signature (e.g. IIAs and IAAs) will be posted when signed. If this applies to your study, you will receive a notification when these additional signed documents are available.

Ongoing IRB submission requirements:

- Six to ten weeks before the eIRB system expiration date, submit a check-in..
- Any changes to the project must be submitted for IRB approval prior to implementation.
- Reportable New Information must be submitted per OHSU policy.
- Submit a check-in to close the study when your research is completed.

Guidelines for Study Conduct

In conducting this study, you are required to follow the guidelines in the document entitled, "[Roles and Responsibilities in the Conduct of Research and Administration of Sponsored Projects](#)," as well as all other applicable OHSU [IRB Policies and Procedures](#).

Requirements under HIPAA

If your study involves the collection, use, or disclosure of Protected Health Information (PHI), you must comply with all applicable requirements under HIPAA. See the [HIPAA and Research](#) website and the [Information Privacy and Security](#) website for more information.

IRB Compliance

The OHSU IRB (FWA00000161; IRB00000471) complies with 45 CFR Part 46, 21 CFR Parts 50 and 56, and other federal and Oregon laws and regulations, as applicable, as well as ICH-GCP codes 3.1-3.4, which outline Responsibilities, Composition, Functions, and Operations, Procedures, and Records of the IRB.

Sincerely,

The OHSU IRB Office