NOTIFICATION OF RETROSPECTIVE REVIEW APPROVAL

To:	S Robert Rozbruch, MD
From:	Edward C. Jones, MD, MA Rosemarie Gagliardi
Re:	Study# 2018-1843 High Tibial Osteotomy: Monolateral External fixation vs Internal fixation Expedited Review Category #5 - Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis)
Date:	10/10/2018

I am pleased to inform you that your Expedited Application was approved on 10/10/2018. This approval will expire on 10/9/2019. As the Principal Investigator of the study, you are responsible for fulfilling the following requirements of approval:

Inclusive dates of chart review: January 2007-September 2018 for 80 subjects.

1. Patient Privacy

To ensure that the privacy of patients is maintained throughout this research if any patient data from the medical record is collected and stored outside of the medical record a secured method for protecting the data should be used. Please contact Clinical Research Administration to discuss privacy strategies. At a minimum the following standards should be met:

- Subject privacy and confidentiality should be maintained through the storage of study data in a password-protected database or other password protected electronic file;
- Stored data can only be accessible to the principal investigator and other IRB-approved study personnel;
- Patients must be assigned a unique study number for identification in the study database and in cannot not be derived from or related to information about the individual.
- A key linking this unique study number to patient identifiers (i.e. name, medical record number, date of birth, registry number) should be maintained in a different password-protected database/file maintained by the PI.

Other Privacy Assurances

- Presentations and publications that result from this study cannot contain any individual identifiers other than unique study numbers.
- Private Health Information (PHI) collected as part of this study will not be reused or disclosed to any other person or entity, except as required by law or hospital policy.

2. Protocol Changes: The Principal Investigator is responsible for notifying the IRB, in writing, of any changes to this original approved protocol and any additions or deletions to the original list of investigators on the protocol. Changes in the above referenced research project cannot be initiated without prior IRB approval.

Thank you,

Edward C. Jones, MD MA
Rosemarie Gagliardi

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