**Emory Orthopaedics**

**Clinical Research Division**

**Standard Operating Procedure for Statistical Support for new studies or data analysis for completed projects.**

**Purpose:** To ensure that the statistical support we receive from BIOS consulting center at Rollins School of Public health is managed in an effective manner for the advancement of our research projects.

**Scope:** This policy and procedure will apply to all research studies requesting statistical analysis at the Emory Department of Orthopaedics.

**Procedure:**

1. During the development state of any retrospective and prospective study, the research coordinator in conjunction with the study principal investigator and study staff will meet to determine if statistical support is needed. It is mandatory to obtain statistical analysis for all prospective studies before submission to the Emory IRB. It is not mandatory but highly encouraged to obtain statistical support for retrospective studies before submission to Emory IRB.
2. The study staff should submit the study protocol and a brief explanation of the study objectives/goals to the designated BIOS personnel via email.
3. After revision of the information provided by the study staff, the BIOS personnel will arrange a meeting (via phone or in person) with the study team to discuss changes to the protocol, data collection methods, or any other relevant detail pertinent to the study conduction. For prospective studies with baseline and regularly scheduled longitudinal study visits a formal data management plan is advised. In selected cases a web-based data management system may be useful but will require additional funding. For simple data collection needs Excel is appropriate for data management (see below).
4. After the study’s personnel have concluded the data collection phase, the information will be de-identified according to current HIPAA law. The 18-identifiers will be removed and the information will be shared with the BIOS statistician. In addition, the study staff will provide the study’s protocol and study objectives/goals and will submit the data in Excel in a format described in the guideline “How to use Excel for data entry” provided by BIOS
5. If the statistician does not have any questions, the initial results will be provided in 14 days. If the statistician asks for another meeting, the data will be ready 14 days after this meeting.
6. For studies that did not have a pre-submission meeting (only retrospective studies), the results will be ready in 30 days after all questions have been answered by the study staff before the data analysis.
7. After the statistical analyses are completed and the manuscript has been drafted the biostatistician will review the manuscript to be sure the statistical analyses support the study conclusion.

**Attachments:** BIOS consulting service form, How to use Excel for data entry form.

**References:** Health Insurance Portability and Accountability Act of 1996 at <http://www.cms.gov/HIPAAGenInfo/Downloads/HIPAALaw.pdf>

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**Last Review Date:** 7/29/2010

**Approval Signatures:**

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Department Chairperson Steering Committee Director

**Effective Date:** 7/29/2010