



INSTITUTIONAL REVIEW BOARD

THE UNIVERSITY OF UTAH

75 South 2000 East Salt Lake City, UT 84112 | 801.581.3655 | IRB@utah.edu

IRB: IRB_00071845

PI: Charles Saltzman

Title: EXEMPTION UMBRELLA: Value of the treatment of musculoskeletal disorders at the University of Utah Covered Entity for patients with soft tissue and bone tumors.

Thank you for submitting your request for approval of this study. On 4/4/2014, a designated IRB member has determined that your study is exempt from further IRB review, under **Exemption Category 7**. Note the following delineation of categories:

- Categories 1-6: Federal Exemption Categories defined in 45 CFR 46.101(b)
- Categories 7-11: Non-Federal Exemption Categories defined in University of Utah IRB policy at http://irb.utah.edu/_pdf/IGS - Exempt Research 090113.pdf

You must adhere to all requirements for exemption described in University of Utah IRB policy (http://irb.utah.edu/_pdf/IGS - Exempt Research 090113.pdf). This includes:

- All research involving human subjects must be approved or determined exempt by the IRB before the research is conducted.
- All research activities must be conducted in accordance with the Belmont Report and must adhere to principles of sound research design and ethics.
- Orderly accounting and monitoring of research activities must occur.

Ongoing Submissions for Exempt Projects

- **Continuing Review:** Since this determination is not an approval, the study does not expire or need continuing review. This determination of exemption from continuing IRB review only applies to the research study as submitted to the IRB. You must follow the protocol as proposed in this application
- **Amendment Applications:** Substantive changes to this project require an amendment application to the IRB to secure either approval or a determination of exemption. **Investigators should contact the IRB Office if there are questions about whether an amendment consists of substantive changes.** Substantive changes include, but are not limited to
 - Changes that increase the risk to participants or change the risk:benefit ratio of the study
 - Changes that affect a participant's willingness to participate in the study
 - Changes to study procedures or study components that are not covered by the Exemption Category determined for this study (listed above)
 - Changes to the study sponsor
 - Changes to the targeted participant population
 - Changes to the stamped consent document(s)
- **Report Forms:** Exempt studies must adhere to the University of Utah IRB reporting requirements for unanticipated problems and deviations: <http://irb.utah.edu/submit-application/forms/index.php>
- **Final Project Reports for Study Closure:** Exempt studies must be closed with the IRB once the research activities are complete: <http://irb.utah.edu/submit-application/final-project-reports.php>
- **Annual Reports:** A report of the specific, individual projects/analyses must be submitted annually to the IRB via the ERICA Report Form for acknowledgement. This report must include the names of the

investigators who conducted the specific project, the date each project began and ended (if ended), the actual or estimated number of participants whose data/tissue were or will be analyzed for each project, and a short description of the specific aims and procedures for each project. The Exemption Umbrella Annual Report Template is found here:
http://irb.utah.edu/_doc/Exemption%20Umbrella%20Annual%20Report%20Template.xlsx.

If you have questions about this, please contact our office at 581-3655 and we will be happy to assist you. Thank you again for submitting your proposal.

Click [IRB_00071845](#) to view the application.

Please take a moment to complete our customer service survey. We appreciate your opinions and feedback.