

Templates

IRB

The following verbiage is recommended to use in OUHSC Institutional Review Board (IRB) application on IriS that is related to the CHPM. If you have any further questions, please contact the CHPM Director via email carol-dionne@ouhsc.edu.

Safety statements:

Participant Safety. Blood pressure will be recorded before and after each visit. Additionally, between each trial, participants' heart rate (bpm), oxygen saturation (%O₂Sat), pain rating (VAS-pain), and perceived exertion (Report of Perceived Exertion [RPE]) will be recorded. Blood pressure, heart rate and oxygen saturation monitoring safety guidelines of American Heart Association (www.heart.org) will be followed. Visual Analogue Scale (VAS-Pain). The subjects will use this continuous 10cm (from 0cm=no pain to 10cm=maximal pain) analogue scale to report pain perceived³³ initially, throughout the trials (sit-stand, walk, turn, lift, carry), and at the end of the data collection. This test has demonstrated good test–retest reliability and construct validity with a minimum clinically important difference equal to 1.37 cm.³³ Report of Perceived Exertion (RPE). The subjects will use the RPE (6 [“easy”] - 20 [“very difficult”]) scale to report perceived exertion that will take less than 1 minute each query. The RPE score has been found directly correlative with cardiac work during performance of activities by patients with a wide variety of psychological and physical conditions.³⁴

Data Safety. The proposed study is expected to amass data collected on _____ who will have met the approved selection criteria. Data will include personal health information (PHI) which will be immediately de-identified at the time of consent and kept separate from any identifying information that would link study outcomes to specific individuals. Study results will be reported as a group, not by any one individual. Further, all signed consent and HIPAA forms will be locked and secured in the Principal Investigator's secured office, physically separate from the limited-access, encrypted electronic data spreadsheets kept for the study. The PI will audit data on a regular, monthly basis for quality and fidelity.

However, all de-identified data linked to the hypotheses will be presented at peer-reviewed venues and disseminated in publications, as well as in any reports required by, and in accordance with, the NIH sponsor.

Investigator Compliance. It is incumbent on every member of the research team to undergo timely and updated compliance training as per the requirements of OUHSC and the NIH to assure adherence of data safety and protection of human subjects. It is the responsibility of the Principal Investigator to maintain full compliance (investigator training, security of data, etc.) throughout the entire investigation.

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MOU Memorandum of Understanding

This document serves the on-campus OUHSC Community. **Please contact the CHPM staff or Director by emailing CHPM@ouhsc.edu or by calling the core facility at: 405-271-2131 ext 47161.**

Contract

This document serves the Community off from the OUHSC campus (e.g., OU-Norman, OMRF, etc). **Please contact the CHPM staff or Director by emailing CHPM@ouhsc.edu or by calling the core facility at: 405-271-2131 ext 47161.**