

Institutional Review Board Minutes
May 23 & 24, 2002

Due to difficulties in the post-commencement schedules and availability of IRB members, various members of the Board met on two separate days to review protocols 0102-019 and 0102-020.

Members present at 5/23/02 meeting: Allen, Coogan, Ferrari-Comeau, Stewart.

Members present at 5/24/02 meeting: Allen, Finney

The 5/23/02 IRB meeting was opened at 1:00 PM in room C105 of the OT/PT South Annex.

The 5/24/02 IRB meeting was opened at 8:00 AM in room 212 of Jones Hall.

The following recommendations regarding protocols 0102-019 and 0102-020, represent a composite of all comments made during the two Board meetings.

1) Review of Protocol #0102-019

The following issues were raised by members of the Board:

- The principal investigator's signature is required on the cover page.
- Please provide rationale for using a cold pressor test of two-minute duration. Prior investigations in other disciplines frequently utilize the cold pressor to induce blood pressure changes with a thirty second duration. Given that cold pressor thermal exposure in excess of twenty seconds is markedly painful, please consider using a minimum exposure duration which can be supported by current standards in the literature for inducing the cardiovascular changes of interest.
- The protocol states that "parts or all" of the recruitment flyer will be used to solicit subjects. Please be specific and provide the Board with an exact copy of the recruitment flyer intended for use.
- On several occasions, the protocol describes eliciting physiological responses, using the misspelling "illicit." Please the spelling within the protocol.

The following two points are not required revisions, rather methodological considerations members of the Board wished to pass on to the investigators:

- Consider whether the proposed sample is actually old enough to generate sufficient between subject variance in vestibulosympathetic reflex.
- Consider the sequencing and timing of the four physiological assessments, so that the residual lingering physiological effects of the tests conducted first do not invalidate findings generated by subsequent tests.

The Board approved this protocol, pending receipt of a revised protocol which addresses the first four above points (5 approve, 0 disapprove, 0 abstain).

2) Review of Protocol #0102-020

The following issues were raised by members of the Board:

- It is requested that the investigator provide the Board with a copy of the letter/flyer which will be sent to physicians/hospitals/clinics to solicit referral of patients to the study.

- Although not a revision required by the IRB, Board members were puzzled as to why the research design is not comparing the effectiveness of the dynamic wrist splint to a flexible splint.

The Board approved this protocol, pending receipt and acceptance of the referral flyer, and site visit by the IRB chair to inspect the final version of the dynamic splint (5 approve, 0 disapprove, 0 abstain).

Members present on 5/24/02 reviewed protocol #0102-020.

3) Review of Protocol #0102-021

The following issues were raised by members of the Board:

- For a study of this type are individual subject debriefings necessary? A summary report of findings to the participating site would be sufficient.
- Piloting needs to be conducted to determine how long it will actually take a participant to complete the surveys. It appears a significant underestimation to assume a high school student can complete the intended survey within just ten minutes. The cooperating high school appears to be allowing only ten minutes time for the task, so the investigators are requested to pilot the survey and modify it so that it may actually be completed by a high school student within the allowed ten minute time frame.
- Please provide the Board with a copy of the recruitment flyer to be used to solicit on-campus subjects.

The Board approved this protocol, pending receipt of a revised protocol which addresses all the above points (2 approve, 0 disapprove, 0 abstain). The revised protocol must include the recruitment flyer and modified instrument for high school age subjects.

Respectfully submitted,
Roger Allen, IRB Chair