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27 June 2024

**GENERAL NOTICE:**

**INSURANCE AND NON-INTERVENTIONAL STUDIES WHERE SAMPLES ARE TAKEN**

The University of the Witwatersrand, Human Research Ethics Committee: (Medical) has recently debated when a study is interventional or not interventional, particularly where blood samples are being taken.

The committee is concerned that there are still risks, albeit limited, with blood samples being taken, and believes that there needs to be a form of cover for participants if something goes wrong.

The committee understands that it is not possible to get clinical trial insurance linked to ABPI for a non-interventional study. That does not obviate the institution from having liability cover, and the individual health practitioner from being a member of the Medical Protection Society or equivalent, for their personal liability cover.

The committee therefore agreed that, while insisting on study insurance is not always possible, it would like to stress that there is still a responsibility to the participants, and liability on the part of the Investigators, if there is an injury. Participants must be adequately protected. Sites must have plans/SOPs in place to cover participants in this instance, should injury occur.

Your urgent attention to the above would be appreciated.

Regards,

A handwritten signature in black ink that reads "Paul Ruff".

Paul Ruff (Jul 2, 2024 10:07 GMT+2)

**Professor Paul Ruff**  
**Chair, Wits HREC (Medical)**

**For and on behalf of the University of the Witwatersrand, Human Research Ethics Committee (Medical)**