Issue 1: The re-consent issue.

* Apply for each study of narrow consent on an individual study basis. In each case why re-consent is not possible.
* Lead with the protocol on why re-consent is not possible.

Annexures on 36 studies.

Send a standard letter to all 36 sites and ask them by assessing possibility of re-consent. Correspondence would be useful.

Attach the forms for informed consent. For each study attach an example of a consent form.

South African document that we need to argue with.(Ethics guidelines) response based

* Risk is minimal. (easy to argue):
* Security mechanisms (deals with identifiability)
* You cannot go ahead without the waiver.

If you don’t get the data overall, this will jeopardise the quality of the study. Overall justification. Truly representative of Africa.

Make the argument that individual study basis and then finally an overall justifiable.

POPIA clause 57. Identification Section 15 not different from original intent. Prior authorization does not apply.

Don’t refer to precedent in the document. Shifts merit away from your own merits.

Issue 2: Ethics clearance from ethics boards in other countries.

Refer to the DTAs and say that the provider : Undertake that you will ask PIs if they . Dear PI do you need to get ethics approval on each study. If yes can we assist you with your ethics application.

Wits may ask for ethics letter . Perhaps add something about this in the DTA.

Include letter to them and response. (Try not to lead them too much).

Risk: wits ethics committee guidance in the DTA is not sufficient.

Split up between legal and ethical compliance(specific countries where there is a requirements).

Using of the legal chatbot to understand implications of the law.