IHVN Institutional Review Board (IRB), Guidelines, and Required Documents

The Institute of Human Virology Nigeria (IHVN) IRB is set up to provide ethical cover and oversight to all research studies to be implemented in IHVN or in partnership with IHVN. Our duty is to provide you with the necessary support to ensure all ethics requirements are met and provide a safety net for the protection of study participants. We are here to guide investigators and study staff on what is required and are welcome to schedule a virtual meeting with you or your representative if you so desire. Kindly find below the necessary documents required to make a new application or a continuing review. Approvals are typically given for 1 year.

IHVN IRB Requirements for a New Ethical Submission

1. Cover letter
2. Study Protocol
3. Participant Informed Consent form
4. Principal Investigator / Co-investigators CV
5. Principal Investigator / Co-investigators updated certificate of GCP (Good Clinical Practise) and HSP (Human subject protection)
6. A one-page summary of the protocol in simple English
7. List of all implementing sites.
8. Material Transfer Agreement (if applicable)
9. Adverts for recruiting trial participants (if applicable)

For continuing ethical reviews, protocol amendments, safety event reporting, questions and clarifications, and all other forms of correspondence please email the address: IRB@ihvnigeria.org

All new protocol applications should be sent through this link: https://forms.gle/f3UKEmFxBkiHUrrC9

IHVN IRB Requirements for a Continuing Ethical Review

1. Cover letter requesting for renewal of study for another year.
2. Study protocol to be submitted only if amendments were made (clean and tracked version)
3. Summary report of the study in the last 1- year.

NB: Note that changes to the Investigator of Record (IoR)/protocol amendments should be reported to the IHVN IRB within 1 month of these changes.

SUPPORT for NAFDAC (REGULATORY) REQUIREMENTS **FOR CLINICAL TRIALS ONLY**

IRCE Regulatory Unit Support for NAFDAC application (This service is provided within the context of IRCE and IHVN staff, designates or partners only).

1. Study protocol
2. Participant Informed consent form
3. Principal Investigator's CV and Co-investigators
4. Principal investigator GCP and Co-investigators
5. Investigator's brochure (IB) of Investigational product
6. Financial conflict of interest form for Principal investigator and site investigators (Site PIs)
7. Evidence of Insurance cover for the trial participants
8. Evidence of agreement between sponsor and investigator
9. Patient Information leaflet (PIL)
10. Favourable ethical approval (Can be sent later after completion of application)

NAFDAC APPLICATION FOR IMPORT PERMIT FOR CLINICAL TRIAL INVESTIGATIONAL PRODUCT

11. Certificate of Analysis (CoA) of Investigational product.
12. Good Manufacturing Practice (GMP) of IP.
13. A sample of investigational product labelling of IP (on vial/packet)
14. Unit quantity of packaging of IP e.g. (how many vials are in a pack) or how many tablets are in a bottle
15. Quantity of tablets/vials requesting importation

NAFDAC application can now be submitted electronically via the portal known as e-CTAP: https://nafdac.smapply.io/acc/r/?g=82858. Note also that ethical approval is not required at the time of application to NAFDAC. Application to NAFDAC can be done in parallel (concurrently) with the ethics application. This means that ethics approval can be sent later to NAFDAC when it is given, on which premise, NAFDAC then issues regulatory approval to your study.