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Department of Clinical Research

30 September 2026

Case no. 26/55358

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Letter of Approval

Research project

"HBV-NSE: The effects of hepatitis B vaccination at birth on all-cause early-life morbidity and mortality: An investigator-initiated randomized controlled trial in Guinea-Bissau"

SDU's Research Ethics Committee has approved your project. The committee has received and reviewed your documentation and the project material meets the requirements.

You are kindly asked to inform the other participants in the project about the Committee's decision.

The approval applies to the project settings (test sites, number and characteristics of participants, methods) and to the following documents:

Application Frederik Schaltz-Buchholzer (REC762).pdf
Trial_Protocol_with_reading_guide.pdf
Participant information (rev. version Sept 23 2026).pdf
Testing_and_participation_informed_consent_forms.pdf
CNEPS_Ethical_Approval_and_letter_to_MoH.pdf
SDU_insurance_declaration.pdf

Approval duration and renewal

This approval is valid for 12 months from the date of issue, i.e. until 30/09/2027. It is your responsibility to ensure that there is a valid approval throughout the project period. Well before the expiry date you will receive an invitation to submit a request for an approval renewal.

The renewal procedure is detailed on www.sdu.dk/REC

GDPR, data protection, and regulations regarding laboratory animals

It should be noted that the Committee is not an authority regarding GDPR, neither is it an authority on the regulations regarding laboratory animals. For these matters, you must contact the responsible authorities.

If you will collect, use etc. personal data in connection with this project you must register your project. You can find the registration form on www.sdu.dk/anmeldelse.

Researcher's duties

Please be aware of the following obligations in relation to being granted approval by the SDU REC:

Changes

If significant changes are made during the project, such as adding hypotheses, the amendments must be notified to the committee in the form of additional protocols. These can be implemented only after the Committee's approval of the changes.

Continuous reporting of side effects and incidents

You must report to the committee immediately if suspected serious or unexpected side effects or serious incidents occur during the project. The report must include comments on any consequences for the experiment. Only side effects and incidents occurring in Denmark must be reported.

The report must be submitted no later than seven days after the sponsor or the applicant has got to know the case.

Third countries

If the project involves research in third countries, it is your responsibility to ensure compliance with local rules and requirements, such as local rules for research licensing.

Notification of termination

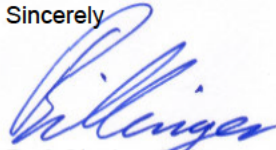
You must inform the Committee upon the completion of the project.
If you discontinue the project earlier than planned, a reason for this must be sent to the committee.
If you do not start the project, the Committee must be notified. The notification must include the reasons for this change of plan.

Review and signature

The project was reviewed on the Committee's meeting on 26/08/2026 with the following attending:

[REDACTED]

On behalf of the Committee
Sincerely



Prof. Stephan Billinger
Chair of the Committee