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Compliance with the Clinical Trials Regulations in the presentation and authorization of informed consent forms

The Clinical Trials Regulation, approved by Supreme Decree No. 021-2017-SA, prescribes in Chapter II of Title III the obligation to obtain informed consent in the manner and form, through the Informed Consent Form, which must comply with the requirements established in article 34 of the same regulatory body;

In order to simplify the evaluation procedures and in application of the aforementioned regulatory framework, **IT IS HEREBY ANNOUNCED:**

The Sponsor requesting authorization for the execution of a Clinical Trial must submit the Informed Consent Form (main) and all additional, complementary or specific Consent Forms[1] as appropriate, according to the nature of the Clinical Trial and the participating population;

Furthermore, administrators are urged to ensure that each informed consent form submitted:

* Adequately reflect the specific characteristics of the study and the group of participants it is intended for.
* Use clear, truthful, complete, and understandable language.
* Maintain documentary traceability of your ethical approval and regulatory authorization before of its application.

The **National Institute of Health,** through DIIS-SUDEC, reaffirms its commitment to the protection of research participants and the application of ethical and regulatory practices aligned with international standards.

Sincerely,
Deputy Directorate of Clinical Trials
Directorate of Research and Innovation in Health – DIIS
National Institute of Health

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[1] For example, those applicable to the collection and storage of biological samples for future use, screening, optional investigations or particular cohorts, specific procedures, pregnant women and their partners, minors through informed assent, or those intended for parents or legal representatives who grant the corresponding consent (This list is illustrative and not exhaustive)