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Criteria related to the use and documentation of highly effective contraceptive methods in clinical trials

The Directorate of Research and Innovation in Health of the National Institute of Health, in accordance with the provisions of the Regulation of Clinical Trials of Peru (DS No. 021-2017-SA), Good Clinical Practices (ICH E6 R3) and current international standards applicable to the subject, communicates the following:

1. In the context of conducting clinical trials, a woman is considered to have reproductive potential (i.e., is fertile) from menarche to postmenopause, to unless permanent sterility is present. This criterion is based on biological capacity. and not exclusively in chronological age.

2. Highly effective contraceptive methods are considered to be those that have a failure rate of less than 1% per year when used correctly and consistently, including: Hormonal methods associated with ovulation inhibition, intrauterine devices (IUD/IUS), surgical sterilization, male partner with confirmed vasectomy (documented azoospermia), and sexual abstinence, the latter only when it is continuous and consistent with the participant's lifestyle. These methods are required in clinical trials where there is a potential risk to the embryo or fetus.

3. Sexual abstinence will be considered a highly effective method only when involves the absence of heterosexual intercourse throughout the period of risk associated with the study treatment. Its reliability should be assessed based on the duration of the clinical trial and the participant's usual and preferred lifestyle.

4. The sponsor and the researcher must ensure adequate counseling on the
Prevention of pregnancy (for as long as required), as well as access to an effective contraceptive method, freely chosen and compatible with the conditions of the clinical trial. The provision or financing of these methods is not the responsibility of the participant or their health insurance, whether public or private; this responsibility lies with the sponsor for the duration of the protocol.

5. The principal investigator is responsible for verification throughout the required period
According to each protocol, the contraceptive method used by participants must be recorded, ensuring their commitment to preventing conception, as well as its proper documentation in the corresponding source record. Any change in method or decision by the participant (including, exceptionally, the discontinuation of sexual abstinence) must be indicated immediately, and a method accepted by the protocol must be recorded before the

resumption of sexual activity.

6. Regarding the documentation of the contraceptive method chosen by the participants: the information must be recorded in source records, with date, signature and traceability.

References

1. International Council for Harmonisation. (2024). ICH harmonised guideline: Good clinical Good Practice (GCP) guideline E6(R3). Retrieved March 18, 2026, from https://www.ich.org/page/ich-guidelines

2. International Council for Harmonisation. (2009). Guidance on nonclinical safety studies for the conduct of human clinical trials and marketing authorization for pharmaceuticals M3(R2). https://www.ich.org/

3. Heads of Medicines Agencies: Clinical Trials Coordination Group (CTCG). Recommendations related to contraception and pregnancy testing in clinical trials. https://www.hma.eu/about-hma/working-groups/clinical-trials-coordination-group.html

4. Supreme Decree No. 017-2006-SA.

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