

## **Now, let us understand the role of Legally Acceptable Representative (LAR) and Impartial Witness (IW) in the Informed Consent Process applicable**

**LAR:** A legally acceptable representative (LAR) is a person or organization authorized by law to give consent on behalf of prospective participants to take part in a clinical trial. When this representative provides consent, they are also responsible for any related activities, such as the initial consent process, re-consenting if needed and handling withdrawal of consent, if applicable

**IW:** An impartial person, not connected to the trial and free from influence by those involved, who is present during the informed consent process if the participant or their legally acceptable representative cannot read. This person reads the consent form and any other relevant documents supplied or read to the participant and/or their legally acceptable representative

**Paper ICF:** A paper Informed Consent Form (ICF) typically has 2 main parts: the Information Sheet and the Consent Certificate. The information sheet provides comprehensive details about the study such as its purpose, procedures, risks, benefits, confidentiality and the participant's rights. Consent certificate is used to document the consent and will be signed only if the participant agrees to take part in trial. It includes signature lines for the participant (or Legally Authorized Representative), researcher and if required, an impartial witness

**eConsent:** An electronic consent form (eConsent) in a clinical trial is a digital way to obtain a participant's informed consent. It uses tools like videos and graphics to explain the study, allows participants to review information at their own pace and supports electronic signatures. eConsent can be done in person using devices such as a tablet or remotely via a secure link.

**Version Control:** Informed Consent Forms (ICFs) are typically version controlled through a combination of version numbering and version date. ICFs are version controlled according to the Standard Operating Procedures (SOPs) established by the study sponsor or Clinical Research Organization (CRO) Whether paper or

electronic, ICF version(s) and process must be reviewed and approved by the Ethics Committee before initiation of a clinical trial.

When obtaining and documenting informed consent (on paper or electronically), the investigator must follow all relevant regulations, Good Clinical Practice (GCP) and the ethical principles based on the Declaration of Helsinki. Whether consent occurs in person or remotely, the investigator must verify the participant's (or legally authorized representative's) identity according to applicable regulatory requirements

**Audio Visual Consent:** On November 19, 2013, the Drugs Controller General of India (DCGI) issued an order making it mandatory to audiovisually (AV) record the informed consent process for all participants in clinical trials in India. This directive required that, in addition to obtaining written informed consent, an AV recording of the process showing the information provided to the subject and their understanding must be maintained for every participant.

This requirement was implemented to improve transparency, enhance participant protection and strengthen the quality and reliability of the consent process in clinical trials conducted across India. It also addressed past ethical concerns regarding inadequate consent documentation

Refer this link for the DCGI Order:

[DCGI-Order-dated-2013-11-19-on-AV-recording-of-Informed-Consent.pdf](#)

The New Drugs and Clinical Trials Rules (NDCT Rule) 2019, specifically requires AV recording for vulnerable participants in clinical trials of new chemical or new molecular entities Refer this link for more information on THE NEW DRUGS AND CLINICAL TRIALS RULES, 2019: As amended vide GSR 778(E)dated 14-10-2022, w.e.f. 14-10-2022 : [Circulars](#)