**WAIVER OF INFORMED CONSENT\***

THE FOLLOWING CONDITIONS ARE NOT RELEVANT IF THE RESEARCH IS SUBJECT TO FDA REGULATIONS\*\*

The Institutional Review Board (IRB) may contemplate granting a waiver from the necessity of acquiring informed consent provided that all the stipulated conditions are satisfied. To apply for such a waiver, a rationale must be presented within the IRB submission, specifically addressing each of the criteria outlined below.

1. **THE STUDY POSES MINIMAL RISK TO PARTICIPANTS:** This criterion is met if the probability or severity of harm/discomfort does not exceed what participants would typically experience in their everyday lives or through standard medical treatment.
2. **THE WAIVER OR MODIFICATION WILL NOT NEGATIVELY IMPACT THE RIGHTS AND WELL-BEING OF THE PARTICIPANTS:** The IRB will evaluate if waiving consent could infringe upon participants' rights, including the "right to privacy". For instance, concerning the "right to privacy", the IRB will examine the protective measures in place to reduce any possible breaches of privacy and will weigh the prospective advantages of participation.
3. **THE RESEARCH COULD NOT PRACTICABLY BE CARRIED OUT WITHOUT THE WAIVER; AND:** For example, obtaining informed consent would not be practicable if the investigator will have no direct contact with subjects and will not know their identities.
4. **WHENEVER SUITABLE, PARTICIPANTS WILL RECEIVE RELEVANT ADDITIONAL INFORMATION FOLLOWING THEIR INVOLVEMENT IN THE RESEARCH:** In social science research that employs deception, debriefing the participants at the end of the study is a standard procedure. However, in certain types of research, debriefing may not be applicable. For instance, in studies proposing the collection of tissue samples without identifiers, the investigator would not be able to offer further details post-participation due to the anonymity of the participants.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

\*For research that includes deception or the use of passive consent methods, these conditions must be fulfilled.

\*\*In studies regulated by the FDA where consent is waived, this is only allowed in circumstances that are life-threatening or pertain to acute care research, provided that certain criteria set by the FDA are satisfied.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Even when all previously mentioned criteria are satisfied, the IRB retains the authority to mandate that a researcher secure informed consent. For instance, the IRB might conclude that the value of the information being pursued does not warrant involving subjects without their awareness.