NATIVIDAD RESEARCH SUBJECT'S BILL OF RIGHTS

The rights below are the rights of every person who is asked to be in a Research Study or Expanded Access to Treatment Program. As a participant I have the following rights:

1) To be told what the study or expanded access program is trying to find out,

2) To be told what will happen to me and whether any of the procedures, drugs, or devices are different from what would be used in standard practice,

3) To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to me for research or expanded access to treatment purposes,

4) To be told if I can expect any benefit from participating, and, if so, what the benefit might be,

5) To be told of the other choices I have and how they may be better or worse than being in the study or expanded access treatment program,

6) To be allowed to ask any questions concerning the study or expanded access program both before agreeing to be involved and during the course of the study,

7) To be told what sort of medical treatment is available if any complications arise,

8) To refuse to participate at all or to change my mind about participation after the study or expanded access program is started. This decision will not affect my right to receive the care I would receive if I were not in the study or expanded access program,

9) To receive a copy of the signed and dated consent form

10) To be free of pressure when considering whether I wish to agree to be in the study or expanded access treatment program.

If I have any questions or concerns, I can ask my doctor, or the researcher/research assistant. In addition, I may contact the Natividad Institutional Review Board (IRB) at 831-783-2534 or write to Natividad IRB, 1441 Constitution Blvd. Salinas, CA, 93906 Attention: Melanie Guzman, IRB Coordinator or email at irb@natividad.com