

INFORMED CONSENT FORM GUIDELINES

In order to comply with FDA/OHRP regulations, all informed consent forms should include the following:

1. Specify IRB Griffin Hospital Study number
2. Title of Study
3. Principal Investigator
4. Invitation to Participate in a Research Study
5. Purpose of the Study
6. Description of Procedures
7. Study Outline (if needed)
8. Risks and Inconveniences
9. Special precautions for women of child-bearing potential (if needed)
10. Potential Benefits (to the individual and to society)
11. Economic Considerations
12. Alternative Treatments
13. Confidentiality (how it will be safeguarded)
14. Investigator Compensation

The Institutional Review Board (IRB) of Griffin Hospital has requested that the Investigators disclose to you, the study subject, the nature of any and all compensation I am receiving from the _____ Corporation, the study sponsor, as well as address other potential forms of compensation. Accordingly you should know that I am being paid a standard fee directly by _____ Corporation to recruit study subjects and to conduct the research. However, there is no other financial relationship between myself, or members of my family, and the _____ Corporation. This includes any proprietary interests such as patents, trademarks, copyrights or licensing, equity interests or grants, consulting fees, honoraria or equipment. The Griffin Hospital IRB has determined that this level of compensation does not pose a significant conflict of interest in the performance of this study.

15. In Case of Injuries (e.g., if the study subject is physically injured by the study drug or by study procedures properly performed and the study subject has followed the directions of the study staff, what compensation is available in the way of medical treatment. Assurance that they will not be responsible for the costs of treatment for such injuries beyond what is covered by their personal medical insurance. No other compensation will be provided by the study).

16. Voluntary Participation

- a. Include notes that "refusal to participate or withdraw from the study will not effect your care at Griffin Hospital or by your physician. You may withdraw at any time without penalty or loss of benefits to which you would otherwise be entitled."
- b. Provide the subject with the name, address and phone number of he person to contact in order to withdraw from the study.

17. Questions

- a. regarding their participation in the study, an injury or a medication reaction, the subject should be directed in this paragraph to call the Principal Investigator at a phone number that is provided.
- b. regarding their rights as a research subject, the subject should be directed in this paragraph to contact Dr. Brian Karsif at 203-732-1447.
- c. If they feel that their confidentiality rights were violated, they may file a complaint with the Griffin Hospital Privacy Officer, Edward J. Berns, Esq. Griffin Hospital, 130 Division St, Derby, Ct 06418 or by phone at 203-732-7506.

18. Use and Disclosure of Your Protected Health Information

This is to be used when seeking subject authorization to utilize their PHI as part of a compound consent form. You may also use a separate HIPAA Research Authorization form.

19. Authorization/Signature

“ I have read the consent form and I have been able to ask questions. I will receive a copy of this consent form.”

Subject Signature

Date

Witness Signature

Date