Grand Valley State University Institutional Review Board (IRB)	
G-18: Guidance on News Stories about Human Subjects Research Projects	
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What is the Institutional Review Board (IRB) and how is it involved in news stories?

- The IRB oversees all research involving human subjects at GVSU to ensure the rights and welfare of the subjects are protected.
- The first step of research consent is recruitment and advertisement, so the IRB must review and approve all recruitment materials.
- Special interest news stories can be used to increase recruitment.

What are some things to watch for?

- FDA-regulated products require the highest level of oversight:
  - Nutritional supplements
  - Band-Aids and crutches
  - Medications and immunizations
  - Apps and software that diagnose or monitor health conditions, i.e. blood pressure monitors and the Apple Watch
- Even if not FDA-regulated, any promotion of ongoing research must be carefully worded so as to avoid the appearance of recruitment and/or advertising for human subjects research.
- If the news story is intended to promote recruitment, it must receive IRB approval prior to publication.

What are some things that should not be included in news stories?

- It is extremely important to never make the following statements regarding ongoing research initiatives:
  - Claims, either explicit or implicit, that the drug, biologic, device or other type of intervention is safe or effective for the purposes under investigation;
  - Claims, either explicit or implicit, that the test article is known to be equivalent or superior to any other drug, biologic, device or intervention;
  - Terms such as “new treatment,” “new medication,” or “new device” without explaining that the test article is investigational and not FDA-approved; and
  - Promises of “free medical treatment” when discussing research initiatives.

Whom do I contact with questions?

- The Office of Research Compliance and Integrity: 616-331-3197 or rci@gvsu.edu
  - Stacey Gardner, Research Compliance Specialist
  - Ben Vesper, Director

Applicable Federal Regulations

FDA Guidance Document

"No claims should be made, either explicitly or implicitly, that the drug, biologic or device is safe or effective for the purposes under investigation, or that the test article is known to be equivalent or superior to any other drug, biologic or device. Such representation would not only be misleading to subjects but would also be a violation of the Agency's regulations concerning the promotion of investigational drugs [21 CFR 312.7(a)] and of investigational devices [21 CFR 812.7(d)]."

> -From "Recruiting Study Subjects: Guidance for Institutional Review Boards and Clinical Investigators". Published January 1998.

Prohibition of promotion and other practices [21 CFR 812.7]

A sponsor, investigator, or any person acting for or on behalf of a sponsor or investigator shall not:
(a) Promote or test market an investigational device, until after FDA has approved the device for commercial distribution.
(b) Commercialize an investigational device by charging the subjects or investigators for a device a price larger than that necessary to recover costs of manufacture, research, development, and handling.
(c) Unduly prolong an investigation. If data developed by the investigation indicate in the case of a class III device that premarket approval cannot be justified or in the case of a class II device that it will not comply with an applicable performance standard or an amendment to that standard, the sponsor shall promptly terminate the investigation.
(d) Represent that an investigational device is safe or effective for the purposes for which it is being investigated.

Promotion of investigational drugs [21 CFR 312.7(a)]

A sponsor or investigator, or any person acting on behalf of a sponsor or investigator, shall not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug. This provision is not intended to restrict the full exchange of scientific information concerning the drug, including dissemination of scientific findings in scientific or lay media. Rather, its intent is to restrict promotional claims of safety or effectiveness of the drug for a use for which it is under investigation and to preclude commercialization of the drug before it is approved for commercial distribution.