Nova Southeastern University
Standard Operating Procedure for GCP

Title: Referencing Investigational Products in Public		Version # 1
SOP Number: OCR-RR-002	Effective Date: August 2013	Page 1 of 1

PURPOSE: Referencing the investigational product to individuals, agencies or the general public is unavoidable. It should be done in a manner that is factual, non-coercive and respectful of any proprietary information held by others.

POLICIES:

1. The identity of the drug/device and the sponsoring company are usually restricted from disclosure to the general public by a confidentiality agreement. Without written permission, this information should not be disclosed except to viable subjects going through the initial informed consent process.
2. Neither the Investigators nor any other employee shall imply or endorse an investigational product to prospective subjects or referral sources as "new". The only exception is using the FDA's official classifications of "Investigational New Drug" and "New Drug Application".
3. Neither the Investigators nor any other employee shall imply or endorse an investigational product as "effective".
4. Neither the Investigators nor any other employee shall imply or endorse an investigational product as "safe".
5. Neither the Investigators nor any other employee shall imply or endorse an investigational product as an alternative "treatment" for the client's symptoms unless it is to a drug that the FDA has granted "Treatment IND" status.
6. Neither the Investigators nor any other employee shall imply or endorse an investigational product as equivalent or superior to any other drug, biologic or device
7. If the drug/device is already marketed but being tested for something it is not labeled for, it may be referred to as "approved" only for what it is approved for coupled with the disclaimer of the investigational nature.