



**Nova Southeastern University
Standard Operating Procedure for GCP**

Title: <u>Identification of Subjects in Communications</u>		Version # 1
SOP Number: OCR-PRIV-001	Effective Date: August 2013	Page 1 of 2

PURPOSE: Referencing individuals in verbal or written communications should be mindful of confidentiality.

POLICIES:

1. For communications outside of the Center/College (or it's affiliates), the randomization number should be the only method used to reference a specific subject (NOTE: subject initials are derived from personally identified information therefore NOT de-identified and would have to have a written HIPAA Authorization in place or other mechanism of disclosure without written authorization such as an IRB privacy waiver).
2. For communications within the Center/College or between its affiliated companies, any communications being conducted electronically (email, fax etc), shall abide by the same standard due to the risk of inadvertent delivery to an unintended recipient.
3. In the event documents must be communicated which contain information that is not de-identified, the document should be modified to a redacted version that strips it of all HIPAA defined identifiers as well as other proprietary information.

Procedure for Redacting Identifiers for Release of Documents

1. Copy or print the document (word processing tools such as "Track Changes" make it difficult to completely alter an original document). This is referenced as the "First Copy".
2. Read the First Copy and with a thick black pen, render unreadable any information that is a HIPAA identifier (names, dates etc) as spelled out in said policy.

3. Note any information that may be proprietary to the sponsor and redact per policy
4. Note any information that may be proprietary to the Center/College (i.e. business practices, referral sources, financial information etc) and redact per policy or under advisement of the Vice President Research and Technology Transfer and Administrative Director Office of Clinical research.
5. Once all information is fully blacked over, make 2 copies ("Second Copies") of the document. This prevents the blacked-out information from being readable from the backs of pages.
6. Proof the Second Copies so that no information can be deciphered.
7. Shred the First Copy, send one Second Copy and keep one Second Copy for the files.