

FAQ's for Subject Enrollment Policy

Q: Is this a new policy?

A: No. It is a revised policy. The original policy became effective in 2006. The revised policy clarifies which clinical research projects require notification regarding consented subjects and clarifies that this notification must be received within 24 hours of consenting a subject.

Q: Does this policy apply to all clinical research studies?

A: No. This revised policy applies to clinical research projects involving human subjects in which (1) a drug, device or biologic is being studied and/or (2) a procedure, lab test or intervention will be performed. This policy does not apply to chart reviews, tissue banking or questionnaires.

Q: Does this policy apply to unfunded studies? Industry studies?

A: Yes. This revised policy applies to all clinical research studies that meet the criteria set forth in the policy, regardless of funding, or source of funding. For example, it applies to investigator-initiated unfunded studies, industry-funded studies and NIH funded studies.

Q: Do I need to provide the notification within 24 hours of consenting a subject or enrolling a subject?

A: You need to provide the notification within 24 hours of consenting a subject.

Q: I am busy. Do I really need to do this within 24 hours of consenting a subject?

A: Yes. It is critical that the University is aware of all consented subjects as soon as possible. This information enables the University to track the subject's billing and make sure all bills, for both research related items as well as those for clinical care, are correct. Accurate billing is an important component of University compliance, especially when billing governmental payers such as Medicare. This information also helps minimize incorrect bills being sent to subjects.

Q: Can I just send the consent form or provide the subject's name?

A: No. CRRC needs more than just the subject's name and study title to track the subject. For example, there may be many people named "John Smith" in the billing systems and we need to make sure we are tracking the correct subject on the correct study.

Q: What is Velos? How do I learn more about getting studies built in Velos?

A: Velos is software the University has licensed for tracking clinical research studies. If your study is built in Velos, subject notification is very simple and you will not need to submit the Enrollment Tracking Form. For more information on Velos, please contact Sean Rinehart at srinehart@med.miami.edu or 305.243.2314.

Q: Am I also required to notify Jackson if I am using Jackson for the study?

A: Yes. In addition, if you are using any Jackson resources for your study, Jackson policy requires you to notify Jackson by the next business day after consenting a subject.

Q: Does this replace current reporting obligations to the IRB?

A: No. You must still comply with all IRB reporting obligations, such as reporting serious adverse events.

Q: Who can I contact for more information about this policy?

A: Suzanne Page, CRIS Director, at spage3@med.miami.edu or 305.243.8596.