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**New Informed Consent Form Woes**

*Federally funded and/or VA informed consent conversions*

Back in October, emails were sent to researchers through myIRB to prompt them to convert their Full ICF with HIPAA to an updated form in preparation for the new Common Rule Changes. Since a second round of emails will be sent in early December, the instructions have been tweaked to ease the process for researchers, IRB staff and reviewers.

1. If you currently have a federally funded or VA study with a consent form:

   a. The IRB sent you an email in myIRB with your currently approved consent form(s). The ICFs, however, can only be accessed from the Project History of the study, not in the body of the email. To access the consent form(s), please click on the link for the study in the email.
b. As soon as possible (if you have not done so), submit a revision to convert your current consent provided to you in the **Project History** to the “conversion consent” found on the IRB-01 website at [http://irb.ufl.edu/irb01/forms/forms-2.html](http://irb.ufl.edu/irb01/forms/forms-2.html). This will require a total change in section #5 which you must complete, and a paragraph to add in section #7.

c. After **January 21, 2019**, you will not be able to consent subjects on a non-converted old consent form.

d. Please do **not** submit any additional changes. The revision will be returned if the revision involves changes to study staff, protocol changes, additional ICF changes, etc. To prevent your revision from being returned to you, it is recommended that you copy and paste the **green** sections of items #5 and #7 from “the conversion consent” into the current ICF template(s) the IRB provided to you in the **Project History**.
5. In general, what do you need to know about this Research Study? Why is this research study being done?

Before you participate in any research, you are always volunteering. By signing the consent form, you are not violating any of your legal rights. If you decide not to participate in this research, you will not be considered in any way and you will not lose any benefits or when you are enrolled. If you have questions about your rights as a research subject, please contact the University of Florida Institutional Review Board (IRB) office at (352) 392-8600.

a. In general, what is the purpose of the research? How long will you be involved?

b. What is involved with your participation, and what are the procedures to be followed in the research?

c. What are the possible side effects to you?

d. What are the likely benefits to you or others from the research?

e. What are the appropriate alternative procedures or courses of treatment, if any, that might benefit you?

Additional and more detailed information is provided within the remainder of this informed consent form, please read before deciding if you wish to participate in this study.

The purpose of this research study is to determine the effects of breathing.

You are being asked to be in the research study because you are a healthy individual who appears to meet other eligibility criteria.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

*NOTE: If ClinicalTrials.gov template was in section #5 of the current ICF template, please ensure that this stays in the conversion ICF.

e. The “conversion consent form” is only required for Federally funded and/or VA studies that were previously approved with the long ICF with HIPAA form. This is not a requirement for studies that were approved with a Waiver of Documentation of Informed Consent, a Brief ICF, or banking ICF since these forms are already brief.

2. If you have an existing study with a full or long consent form that is not Federally funded, you are not required to make the change to the “conversion consent form” at this time. You will be advised on how to proceed in late December or after January 1, 2019.

New studies

If you are submitting a new study that will use a long ICF with HIPAA, please use the “integrated HIPAA consent” form, in which the HIPAA authorization has been integrated into the consent form to make it shorter and more concise. Your submission will be returned to you if you use the “conversion consent form” or an older version. Please refer to the Informed Consent Forms WITH HIPAA section of the IRB-01 website for more information.