**IRB Newsletter**  
May 2020

**University of Florida Institutional Review Boards, [http://irb.ufl.edu/](http://irb.ufl.edu/)  
IRB-01: (352) 273-9600  
IRB-02: (352) 392-0433**

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- Obtaining Consent: Special Situation

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**Upcoming Educational Opportunities**

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<td>Wednesday, May 13, 2020 at 12:00PM</td>
<td>IRB Brown Bag: Using COVID-19 EHR Data for Research</td>
<td>We will be talking about COVID-19 patients’ identification, EHR data availability, pitfalls and lessons learned while handling and interpreting data related to COVID-19. Presented via Zoom: <a href="https://ufl.zoom.us/j/93521971288">https://ufl.zoom.us/j/93521971288</a></td>
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The IRB Education Program wants to hear from you. Please send in any requests you have for an upcoming Brown Bag topic to arancat08@ufl.edu.

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**Qualtrics is approved for Protected Health Information**

The University of Florida now was a Business Associate Agreement with Qualtrics, a free software offered to the UF community for creating and delivering online surveys. Research teams are now permitted to use PHI with UF Qualtrics by registering through UF Integrated Risk Management (IRM). For more information, please refer to IRM’s website > Data Guide > UF Qualtrics.

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**IRB's COVID-19 Investigator Guideline on Changes to the Informed Consent Process**

Per the [IRB's COVID-19 Investigator Guideline](http://irb.ufl.edu/), any change in the method for obtaining informed consent must be approved by the IRB prior to implementation. Please note that the updated informed consent method must be detailed in your protocol and on the Informed Consent Process SmartForm page. For example, your method for distributing the consent to the participants (i.e., via a link in an email for e-consent, or via mail with a stamped return envelope for telephonic consent), and how you will receive the signed form must be detailed. Study procedures and/or data collection cannot begin until a fully signed consent form is received.

**Electronic Informed Consent Forms – eIC or eConsent**

The research community is showing increasing interest in using electronic media to supplement or replace paper-based informed consent processes. An eIC may be used to provide information usually contained within the written informed consent document, evaluate the subject’s comprehension of the information presented, and document the consent of the subject or the subject’s legally authorized representative (LAR). The UF IRB has approved the REDCap version of the eIC process, and confirmed that it meets all local and federal consenting requirements. If you wish to use REDCap as your eIC option, please review our [Electronic Informed Consent Forms – eIC Guideline](http://irb.ufl.edu/).

**Telephonic Consent**

The IRB must approve the use of telephonic consent as part of your routine consenting process. Unanticipated telephone consent may be allowed for certain situations, but if you perceive the need for a telephone consent process as a standard part of your research, you will need to submit a revision to your study. For more information and telephonic consent procedures, please review the IRB’s [Telephonic Consent Guideline](http://irb.ufl.edu/).
**Reminders**

**Obtaining Consent: Special Situation Consenting Research Participants Who Can Not Read/Speak English**

Federal Regulations require that information given to a subject as part of the consent process be in language understandable to the subject. Documentation of informed consent by use of an IRB-approved written consent signed by the subject or the subject’s legally authorized representative (LAR) is required unless the IRB has determined that the criteria for waiver of written informed consent is met. For full details about the process please review the IRB’s [Investigator Guideline](#) and [Obtaining Consent: Special Situations](#).

**NOTE:** simply using an interpreter is NOT sufficient.

If you wish to obtain informed consent from a research subject who does not speak or read English, you must do one of the following:

1. **If you are primarily seeking consent from subjects who do speak or read English, but unexpectedly want to enroll someone who does not speak or read English, you must:**
   a. Extra “short form”: Use an IRB approved “short form” that is translated into the subject’s native language. The “short form” is a generic consent form that states general requirements required under the regulations such as the subject is being asked to participate in research, they can refuse to participate without penalty, contact information for the IRB, etc. Based on an analysis of the population of Gainesville, the IRB has already approved short forms in [Spanish](#) and [Hindi](#).
   b. Interpreter: Have a competent interpreter fluent in English and the subject’s native language.
   c. Summary: The competent interpreter should present an IRB approved written summary of the protocol. The IRB approved Informed Consent Form written in English can serve as the written summary.
   d. Researcher: A member of the research team who is approved by the IRB to obtain informed consent should participate in the process, answer questions, and seek informed consent.
   e. Witness: A witness who is fluent in English and the subject’s native language must witness the informed consent discussion. The competent interpreter may serve as the witness.
   f. If the subject gives consent to participate, the following must occur:
      i. The subject (or LAR) should sign and date the “short form”.
      ii. The witness should sign and date (a) the “short form” and (b) the IRB approved Informed Consent written in English.
      iii. The person obtaining consent should sign and date the IRB approved Informed Consent written in English.
      iv. Give the subject copies of the “short form” and the IRB approved Informed Consent written in English.

**NOTE:** We advise that you make a research note to file to document that the above process occurred.

2. **If you know that you will be seeking consent from subjects who do not speak or read English, you must:**
   a. Have the Informed Consent Form translated into the native language by a qualified third party. This should include a back-translation to English to verify the translation is appropriate.
   b. Have the translated consent approved by the IRB.

**What if you need a “short form” for a subject who speaks a language other than Spanish or Hindi?**

1. You will need to have the “short form” translated by a qualified third party. This should include a back-translation to English to verify the translation is appropriate. The English version of the short form that you can translate may be downloaded on the [IRB website](#).
2. Obtain IRB approval: The IRB must review and approve this translated document. A minor revision will need to be submitted to your study. If this is the only change you make, the IRB should quickly review and approved the revision.