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| • Questions of the Week: Child Assent                                                                  | 1. Are children ages 7 years and older required to give assent? Per the Assent of Children Guideline ([http://irb.ufl.edu/wp-content/uploads/Assent-of-Children.pdf](http://irb.ufl.edu/wp-content/uploads/Assent-of-Children.pdf)), please note the following:  
  • Assent is **not recommended** in children less than 7 years old, irrespective of risk or benefit;  
  • Assent **is recommended**, but **not required** for children between the ages of 7 and 14, irrespective of risk or benefit;  
  • Assent **is required** *for children over the age of 14, irrespective of the risk or benefit*.  
    a. Unless there is an incapacity  
    b. If there is a potential for direct benefit, and there is a conflict between the subject and LAR, then an Ethics Committee review is required*.  
  2. What happens if a parent wants to consent their child to a study, but the child says “no”? Per the Research with Children FAQs section of the OHRP website at [https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/children-research/index.html](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/children-research/index.html), if a parent says “yes” and a child says “no”, the child’s decision prevails. However, (as shown in the paragraph beneath the highlighted section of the attached screen shot), the regulations state at [45 CFR 46.408(a)](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/children-research/index.html) that if the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research (i.e., a cancer treatment protocol), the assent of the children is not a necessary condition for proceeding with the research. |
Investigator Guideline Updates

New Guidelines

- Research Roles
- Media Organizations - Research Involvement
- DNP Student Projects - Role of the IRB

Updated Guidelines

- Case Reports
- Consent2Share - Study Subject Recruitment
- Quality vs Research

Data Use Agreement (DUA) Brain Teaser

Which of the following is false?

1. A DUA is needed if a researcher is either releasing or receiving a limited data set (LDS).
2. A LDS can include limited health information such as, dates of admission, discharge, service, death or date of birth; city, state, five digit zip code; and ages in years, months or days or hours.
3. A DUA is also needed if the information is de-identified under HIPAA.

*Answer: #3 – A DUA is not needed if the information is de-identified under HIPAA (all of the 18 HIPAA identifiers are removed). For non-human research involving access to de-identified data and/or specimens, a signed Confidentiality Agreement for Data and/or Specimens is needed.*

UF IRB Offices Closed

IRB Offices will be closed on Wednesday, 9/25/2019 due to our annual retreat. We will resume normal hours of operation on 9/26/2019.
UF CTSI Clinical Research Professional Advisory Council Seminar Series

How to Have Crucial Conversations around Diversity, Equity and Inclusion

- Friday, September 27, 2019
- Noon-1 PM
- Communicore 1-11 in Gainesville or Alumni Auditorium in Jacksonville
- Lunch is provided

Presented by
Antonio Farias, M.A., M.F.A., Chief Diversity Officer, University of Florida
Mr. Farias is the inaugural Chief Diversity Officer at the University of Florida. Prior to his position at UF, he served as the VP for Equity and Inclusion/Title IX and Section 504 Officer at Wesleyan University (2013-2018) and was the inaugural Chief Diversity Officer at the United States Coast Guard Academy (2005-2013)

Program Description
The program will provide instruction in having crucial conversations – those with high stakes, differences of opinion and strong emotions – that will aid participants in addressing issues around diversity, equity and inclusion with colleagues, patients and their families.

This course is approved for 1.0 contact hours – UF Health Shands is a CE Provider recognized by the Florida Board of Nursing (FBN# 50-1790). Participants must attend the entire program in order to receive credit.

Registration link: https://www.ctsi.ufl.edu/2019/02/27/research-coordinator-seminar-series/

Sponsored by
UF CTSI Diversity & Cultural Competency Council (DC3)
Within the UF CTSI Clinical Research Professionals Advisory Council, the DC3 was established to help UF clinical research professionals become competent communicators and actors in the intersectional areas of diversity and culture. With the clinical research professional and community member in mind, this council seeks to develop opportunities in raising awareness of distinct needs for diversity and inclusion while identifying and disseminating best practice information in the UF clinical research community.