

Q-BITES

THE QUARTERLY NEWSLETTER BY CRM



<http://theconversation.com/informed-consent-for-stem-cell-research-why-it-matters-and-what-you-should-know-45899>

ASSENT FORM

Voice of Minors

Dr Wong is conducting a pediatric interventional study. She intended to recruit Alex, a 7-year-old, into the study. Using the study's informed consent form, Dr Wong explained the study to Alex's parents during one of Alex's clinic visit. Alex parents agreed to enroll Alex into the study. However, when Dr Wong talked to Alex about the study, Alex cried and expressed that he did not want to participate in the study as he is afraid of blood taking.

Should Dr Wong enroll Alex as she has obtained consent from Alex's parents?

Medical Research and Ethics Committee (MREC) Guideline

With respect to minor's emerging maturity and independence, MREC requires that assent should be obtained (either orally or in the form of assent form) from minors aged 7 to less than 18*. They should be:

- ✓ given a basic understanding of the research process
- ✓ informed about what they are expected to do
- ✓ given an opportunity to express their preference regarding participation in the study

Dissent of the minor must be respected even if their legally acceptable representative (LAR) agrees to enroll the minor into the study participation of the minor**.

After referring to MREC Guideline, Dr Wong decided not to enroll Alex into the study and advised Alex's parents to further discuss the study with Alex in private.

*except for emancipated minors.

** except when the intervention involved in the research holds out a prospect of direct benefit that is important to the well-being of the minor and is available only in the context of the research.

A COCKROACH STORY

Don't React; Respond

There's a commotion in a quiet restaurant. A cockroach just flew in from nowhere and landed on a table where 3 ladies sat.

All 3 ladies jumped and screamed in fear. They were swinging their arms frantically trying to chase the cockroach away. Their reaction was contagious and everyone at the restaurant got panicky.

The waitress rushed to their table. As the waitress reached the table the cockroach landed on her. The waitress stood firm. She did not jump, scream nor swing her hands around. She calmly observed the cockroach on her vest. When she was confident enough, she grabbed the cockroach and threw it out of the restaurant, ending the commotion.

The cockroach was not responsible for the commotion. It was the inability to handle the disturbance that caused the commotion. The waitress was not disturbed. She handled the situation with calm and perfection.

Many times, we fail to realize that it's not the problem that disturbs us, but it's our inability to handle the problem that disturbs us. Similarly, when we are faced with panicky situations like SAEs, Unscheduled Visits, Audits, Protocol Deviations, and many others, take time to handle the situation in an appropriate manner. Do not let the "cockroach" disrupt your judgement.

Remember, don't react; RESPOND.