
Ethical Considerations in Pediatric Research

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General Considerations

- Careful review of proposed protocol for scientific merit, subject benefit and ethical design are key.
 - Realistic assessment regarding study feasibility.
- Well trained investigators and staff, along with well documented Standard Operating Procedures, are critical.
- Ethical considerations vary by age of child.
 - Every study involves the entire family and partnering with parents is essential.
- Recognizing that ethical issues in pediatric studies affect all aspects of the study.

Ethical Considerations: Newborn to 1 Year Old

- Parents of 2 month olds are often overwhelmed.
 - Parents of children this age often have misinformation (internet, media, mom's group).
- Education is crucial.
 - Staff must have adequate to time to educate parents and ensure that they understand the study.
 - Studies done in this age can often involve 1-2 year commitment.
- Staff must be well trained.
 - Able to clearly communicate expectations to parents.
 - Proficient in obtaining required blood draws.

Ethical Considerations: 1-2 Year Olds

- Education remains critical.
- Maintaining subject involvement in a study that may have begun more than 1 year earlier.
 - Informed consent document may have been signed in infancy.
- Specific challenges: multiple amendments and modifications to a study that began as infants.
 - 17 modifications
 - 4 changes to the informed consent document
 - Alterations to treatment (vaccine) schedule

Ethical Considerations: 2-6 Year Olds

- Children in this group can protest (needles, shots, etc).
- Staff must be well trained on involving the child in the process.
 - The child must be on the team as “an assistant”.
 - The first visit with the child needs to go well.
 - If not, parents and subjects will often not come return and there will be a high attrition rate.
- As an ethical issue, we do not want to enroll a child in a study only to have the child and parent refuse to return.

Ethical Considerations: 7-12 Year Olds

- Child assent along with parental consent now is required.
- Many studies now require pregnancy tests for girls 10 years and older.
 - Staff has to be trained how to sensitively approach and discuss.
 - The subject must have privacy.
- Need an *already* developed contingency plans to protect and take care of your patient.
 - Standard Operating Procedures for how to handle a positive pregnancy test must be in place.
 - Need to have considered various scenarios in advance.

Ethical Considerations: 13-18 Year Olds

- Need to recruit both the teen and the parents.
 - The teen has to be 100% committed.
- Important ethical challenges.
 - Pregnancy remains an important issue
 - Non-compliance by teen subjects
 - Most safety data collection is done by the subject
- Critical ethical issue is recognizing that teenagers will respond to incentives.
 - Anyone recruiting teenagers must be very careful to walk a fine line between reasonable reimbursement and coercion.

Conclusions

- Ethical considerations vary by age.
- Appropriate investigator and staff training are essential.
- Recognizing and addressing ethical issues in pediatric studies will ensure a successful study.