



Study Activities & Subject Rights

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Dr. Williams is Associate Professor of Pediatrics in the Division of Pediatric Allergy and Immunology at Duke University Medical Center. He practiced general pediatrics in North Carolina for 4 years before returning to academic medicine and a subspecialty fellowship in Allergy/Immunology. He has been involved in clinical research for 20 years. He has been an investigator in studies of childhood immunodeficiency disease, asthma, allergic rhinitis, atopic dermatitis, and food allergy. He is the principal investigator for the American Lung Association Asthma Clinical Research Center at Duke. He has been an IRB member for 5 years, and a Vice Chair since 2007.



Study Activities

- Do what you said you would do
 - Don't deviate from protocol
- Before any change, submit amendment to IRB
- Tell the IRB when there are problems, deviations, adverse events
- Submit Final Report when all work done



Research Equation

Funding + IRB Approval = Study



Grant



Submission

(Prepare your IRB Submission with the same care you do your Grant Submission & life will be good)





Limits of IRB Approval

- Valid for ***no more than 1 year*** and not 5 seconds longer, (termination date is at 12:00 **AM** on day of termination of IRB approval)



Limits of IRB Approval

- Amendments (**ANY** change requires IRB Approved to revise the Protocol **BEFORE** changes implemented)
- Final Report Means **FINAL**—The IRB Box is Closed

**IRB Approved Protocol
Good for 1 year max!**



Subject Rights

- Assessment of Decision Making Capacity
- Withdrawal
- HIPAA & Undesignated Future Research
- Repositories & Databases

Assessment of Decision Making Capacity



- Presumption of normal capacity in adults
- IRB will need to know about capacity if:
 - Study setting of delirium or psychiatric disease
 - Study of disease that could lead to decreased capacity



Assessment of Decision Making Capacity

- In suspect settings: need a plan to assess capacity
 - Simple or complex as needed
 - Still need assent of subject if capable
- Return of decision making capacity
 - Could this happen?
 - If so re-consent may be needed



Withdrawal From a Study

- There must be no limitation on withdrawal from human research
- Subjects who withdraw should do so in writing

Research Subjects and HIPAA



HIPAA: aka The Privacy Rule

HIPAA changes the definition of human subject:

An ~~living~~ individual about whom an investigator obtains
(1) data through intervention or interaction with the
individual, or (2) identifiable private information

The change is that the individual need not be living.



Research Subjects and HIPAA

Remember the confidentiality you promised in the consent form applies to:

- Individually identifiable health information that:
 - Relates to physical or mental health or condition
 - Relates to health care received
 - Relates to payment for health care
- And contains any HIPAA identifiers



Undesignated Future Research

- Database and Repository Policy
 - Required to comply with Privacy Rule
- Applies to
 - Data: even retained contact information
 - Samples: blood, tissue, DNA, etc



Undesignated Future Research

- Samples stored elsewhere
 - Consent form may include storage (with opt out)
- Samples stored at Duke
 - Separate IRB protocol and consent required
 - Possibly a simple project, see website examples



Repositories & Databases

Why a separate protocol?

- IRB must approve human research
- Use of retained samples constitutes a separate project
- When you design a project that will use those samples, IRB must approve the use
- Separate protocol and consent required