

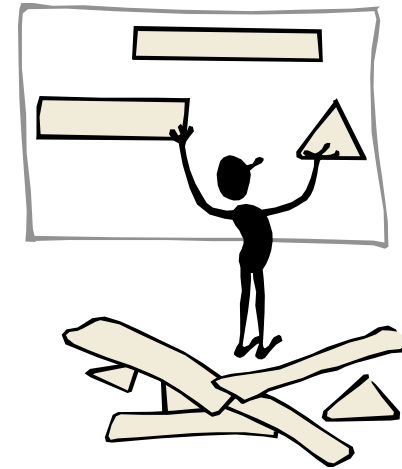


**REVISED: IRB INFORMED  
CONSENT POLICY 15.1 (WHAT  
YOU NEED TO KNOW)**

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# MAJOR CHANGES



- Standardization of format
- Definitions added
- Required elements and suggested clauses reorganized
- Addition of IRB responsibility statement
- Witness and PI signatures and signature times no longer required
- Subject re-contact requirement clarified
- Full title no longer required on every consent form page
- Clarification of requirement for 24 hour number



# STANDARDIZATION OF FORMAT

- All UAMS IRB policies will be put in this format.
- Easier to find items
- Easier to reference sections in other policies
- Clearly defines the purpose of the policy
- Added Definitions section for clarification



# DEFINITIONS ADDED

- Coercion
- Exculpatory Language
- Human Subject
- Identifiable
- Informed Consent Process
- Legally Authorized Representative (LAR)
- Mandated Reporter
- Private Information
- Undue Influence



# REORGANIZATION OF REQUIRED ELEMENTS



- Old policy had one section for Federally mandated elements and another section for Institutionally mandated elements.
- Both Federally and Institutionally mandated requirements in one section.
- Easier to create a consent process that includes all the required elements when they are listed in one place.
- All elements required “as applicable” are now located in one section.



# REORGANIZATION OF SUGGESTED CLAUSES

- All suggested clauses are located in one section
- Suggested clauses text is not required language
- Make sure that clauses do not include exculpatory language
- Make sure that clauses do not obligate the Institution without prior authorization
- For assistance with developing a consent form that includes all the proper clauses, contact the Research Support Center (RSC)



# ADDITION OF IRB RESPONSIBILITY STATEMENT

- Describes the IRB's responsibilities pertaining to its review of the consent process, which include:
- Ensuring the process includes all required elements and protects the safety and welfare of the subjects
- Making sure any written consent form is consistent with other study documents, such as the protocol
- Ensuring the IRB's consent process review is documented sufficiently
- Requesting revisions as necessary to ensure that proposed activities are clear and the intended subjects can make a fully informed decision



# NO MORE REQUIRED WITNESS AND PI SIGNATURES



- No requirement for witness signature
- No requirement for PI signature
- Does not alleviate the responsibility of the PI to be involved in the study
- ORC, and others, may assess evidence of PI involvement
- Consent process must still be documented sufficiently so that a reviewer can determine:
  - That the subject was consented properly
  - That the process outlined in the protocol is followed without deviation



# REMOVAL OF SIGNATURE TIME REQUIREMENT

- Time requirement has been removed
- Consent process must be documented in such a way as to show that the subject was consented according to the protocol.



# CLARIFICATION OF REQUIREMENT FOR HIPAA DISCLOSURE STATEMENT

- All subjects providing protected health information must sign a HIPAA Disclosure Statement
- This statement may be included in the consent form or be a separate document
- Unless the IRB grants a HIPAA waiver
- HIPAA waiver must requested in advance
- After-the-fact waiver request= circular file



# CLARIFICATION OF REQUIREMENT FOR RE-CONTACTING SUBJECTS

- The subject must consent to re-contact for the purpose of future research
- This consent must be a separate statement on the consent form that allows the subject to consent to the study and also opt out for re-contact



# TITLE NO LONGER REQUIRED ON EVERY PAGE OF THE CONSENT FORM

- When the title is so long that it is not feasible to put the entire title on each page, it is allowable to put the title on the first page only
- Each subsequent page must have a unique identifier, such as the protocol number.



# CLARIFICATION OF REQUIREMENT FOR 24 HOUR NUMBER

- Not all studies require a 24 hour number
- If one is available, it should be provided
- The IRB may determine that the study warrants a 24 hour number, depending on the potential risk to the subjects



# MUST SUBMIT MODIFICATION

- All consent documents must be modified and submitted to the IRB for approval prior to taking advantage of these changes
- ORC will look at approval letters and approved documents when reviewing your study



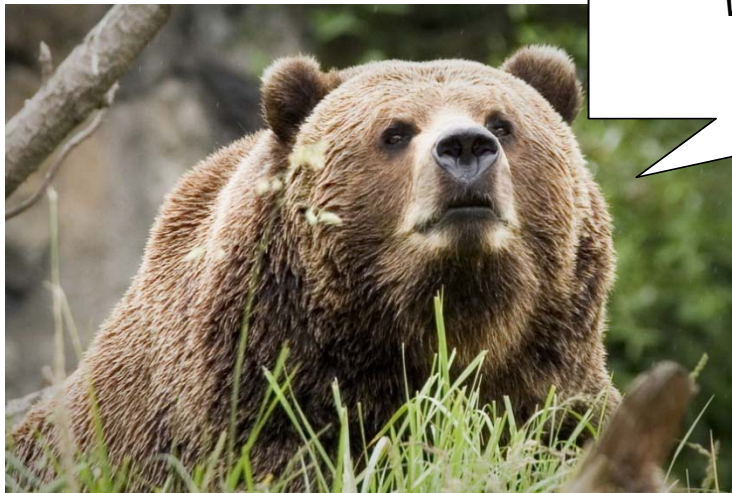
**The IRB votes on your proposed consent process...**



# THIS BEARS REPEATING...



*Keep using your old consent process and forms until the IRB approves your new consent process and forms! Failure to do so may cause the IRB to disallow use of data!*



*Losing data because the approved consent process wasn't followed is a real bear!!!*



# What Does This Mean For My Current Study?



- Continue current consent process until the new one is approved
- New process entails submitting a new form for IRB approval
- What if I have big stacks of blank consent forms already printed out with all those signature and time lines and old requirements?



# What Will ORC Look For When It Reviews Studies?

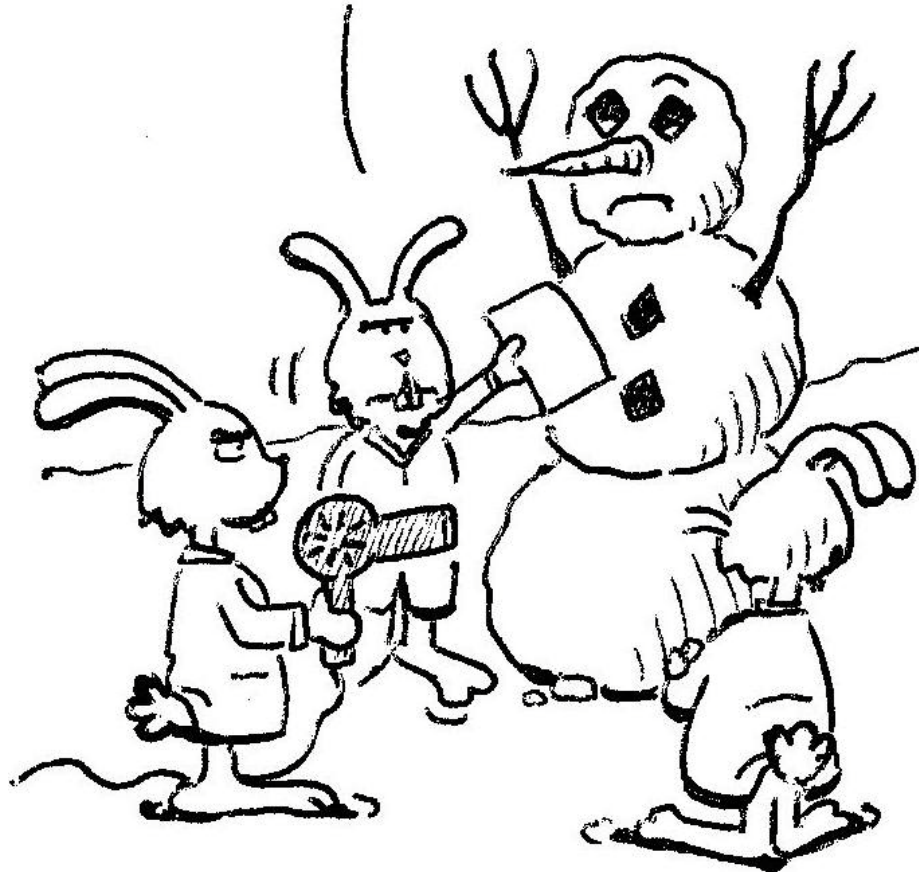
- Evidence of PI involvement
- Documentation that your consent process was followed
- Does your consent form match your protocol?
- Thorough informed consent process documented in a thorough informed consent process note...



# What's Up With These Informed Consent Process Notes?

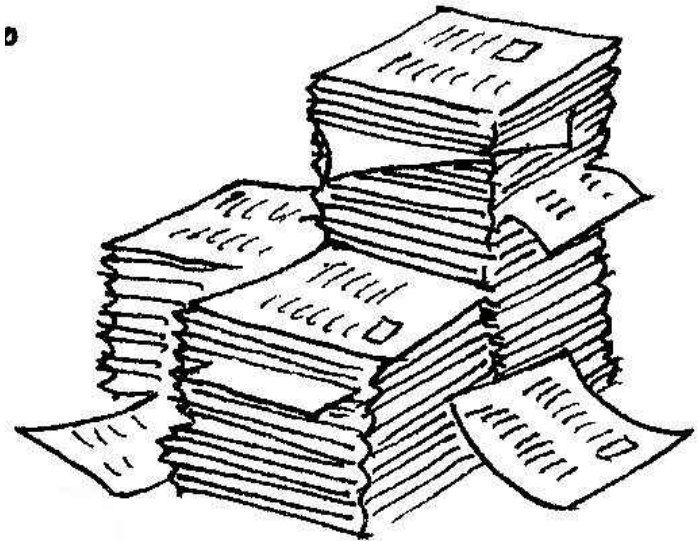
- See IRB Policy 15.5 – separate note to file
- Isn't this duplicative?
- Why is this important?

JUST SIGN THE CONSENT FORM,  
AND NOBODY GETS HURT!



# Not just another piece of paper...

- An OK Note – meets the IRB Policy 15.5 requirements
- A Great Note – Meets the Requirements, and Then Some...



# NOW AVAILABLE FROM ORC



## ○ NICE Reviews

### New Investigator Consult and Education

*Voluntary, no-cost ORC review of newly approved studies before enrollment. Looks at IRB review, proposed processes and documentation. Call us to schedule one.*

## ○ Self-Assessment Tools and Templates

*Click on link at [uams.edu/orc](http://uams.edu/orc)*



# Questions????



- Call your friendly, neighborhood IRB at 686-5667
- Submit a query to IRB Questions (on Global Email)
- Call or email your friendly, neighborhood Research Compliance Office (686-8062; 526-6270)

