



## IRB Newsletter:

### Review of IRB Policy Changes December 2009

#### NEW Policy Revisions

##### Policy 13

**Background:** Federal regulations give the IRB the authority to observe the consent process.

**IRB Policy lists** some situations where the IRB may consider requesting observation of the consent process.

**Revision:** deletion of "previous investigator seri-

ous or continuing non-compliance" and addition of "PI has a history of previous study with problems relating to the consent process for participants"

**Rationale for change:** Previous investigator serious or continuing non-compliance found to be often unrelated to consent issues, (e.g., failure to

submit continuing review) and therefore too general to be a helpful criteria for considering observation of the consent process. Therefore, a more specific criteria was added.



Policy 15 Revisions—See revised Policy 15 for all the details

**Background:** Vulnerable populations must have additional protections provided.

**Change:** addition of criteria for IRB review

of non-VA studies involving cognitively impaired populations.

**Rationale for change:** Current IRB policy based on VA rules for

studies involving cognitively impaired participants. These VA-based rules were being applied to non-VA studies.

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## For NON-VA Studies Involving Cognitively Impaired Populations

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To enable submission of your study for consideration under the new criteria, a new Supplemental Form for Studies with Cognitively Impaired or Persons with Impaired Decision Making has been developed and posted.

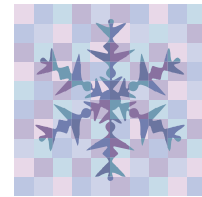
Please include this supplemental form with your initial submission if your study is NOT a VA study and you are proposing to include this vulnerable population.

As you plan your research, be sure to consider issues such as:

- how you will assess the capability of the participants to give consent
- who will determine if the participants can give consent and how will that determination be documented
- the presence of any additional methods that can help improve consent capability (for example, visual aids or single sheet summaries)

- whether the consent capacity may fluctuate over the course of the study, and if so, how re-consent or re-assent will be obtained

- your assessment of the risks and benefits of the proposed study



## Additional considerations

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- how you will identify who is able to give legally authorized consent on behalf of an individual who is determined to be incapable of providing their own consent

-how you will obtain assent if utilizing a legally authorized representative (LAR) for consent (note IRB must approve consent by LAR)

How you ensure that the LAR is informed regarding his/her roles and obligations

-whether research will be conducted outside of the state of Tennessee

-how you will observe dissent

-whether the individual's health care provided will be consulted or notified

## Questions ?

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Contact:

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