Human Subjects
Office of Research
UNIVERSITY OF GEORGIA

Final Rule
Discussion: Changes to Consent

Overview of Changes Effective January 21, 2018

- ***OHRP Video: What's New in Informed Consent: Revisions to the Common Rule***

https://www.youtube.com/watch?v=F6PBIyN8RKA&feature=youtu.be

Most Relevant Changes for Committee Members

- ***Definition for Legally Authorized Representative***
- ***Key Information***
- ***New elements of consent***
- ***Screening, Recruitment, or Determining Eligibility***
- ***Waivers***
- ***Posting Clinical Trial Consent Forms***

Definition of LAR

- **Legally authorized representative-**---an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

- If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

- *What is UGA Policy?*

LAR under UGA Policy

For the purposes of these policy and procedures, when research will be conducted in Georgia, a legally authorized representative includes a person appointed as a health care agent under a power of attorney for health care or other appropriate legal document, or a court appointed guardian of the person.

In the absence of an appointed individual, then the following may provide consent in the following order of priority:

- Spouse
- Any adult offspring for his/her parents
- Any parent for his/her adult offspring
- Any adult for his/her adult brother or sister
- Any grandparent for his/her adult grandchild
- Any adult grandchild for his/her grandparent
- Any adult niece, nephew, aunt, or uncle related in the first degree

Key Information

Key information includes, but is not necessarily limited to, the following:

- The fact that consent is being sought for research and that participation is voluntary;
- The purposes of the research, the expected duration of the prospective participant's participation, and the procedures to be followed in the research;
- The reasonably foreseeable risks or discomforts to the prospective participant;
- The benefits to the prospective participant and/or to others that may reasonably be expected from the research; and
- Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective participant.

Ideally, the key information is presented within the first page to page and a half of the consent materials.

New Consent Element

Basic element:

- Notice regarding possible future use of data stripped of identifiers
  - *After consultation with Office of Research Legal council, UGA will add this language to ALL consent templates*

Additional elements:

- Notice about possible commercial profit
- Notice about whether clinically relevant research results will be given to subjects
- Notice about whether research might include whole genome sequencing

New consent templates are available on the website (Human Subjects)
https://research.uga.edu/documents/#1493842111222-a0f5af26-4538

Screening, Recruitment, or Determining Eligibility

- **No more requirement to waive consent**
  - *PI is not prompted for justification for waiver*
  - *PI will just need to answer two questions (assurances) and provide a script/document*

Waivers

New waiver criterion for no-signatures:

- Subjects are members of a distinct community in which signing forms is not the norm, minimal risk, and an alternative method for documenting consent is used

New waiver criterion for no consent:

- If research involves identifiable private information or identifiable biospecimens, the IRB must determine that the research could not be carried out without the identifiers included

Posting CT Consents

Federally supported Clinical Trials

- Clinical Trial definition: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

- *Most likely place will be ClinicalTrials.gov*

More info to follow as guidance becomes available

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Revised Common Rule:

https://www.hhs.gov/ohrp/regulations-and-policy/regulations/revised-common-rule-regulatory-text/index.html