

Features of Hepatocellular Carcinoma in Hispanics Differ from African Americans and Non-Hispanic Whites

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Informed consent waiver was granted due to the retrospective review posing minimal risk and due to the waiver of informed consent not adversely affecting the rights or welfare of subjects.

UIC IRB specific language is included below for further clarification:

2. Alteration or waiver of informed consent would not adversely affect the rights or welfare of subjects
Examples:

- A. *Measures to prevent adversely affecting the rights or welfare of subjects in the retrospective chart review above include privacy notice that patients receive when they register at University of Illinois Hospital & Health Sciences System notifying them that their records may be used without their authorization for research purposes and appropriate procedures in place to protect confidentiality, i.e., primary risk of this research. Also, information learned will not impact the subjects as they experienced this treatment effect in the past. The investigators have access to records as part of their clinical duties.*
- B. *Measures to prevent adversely affecting the rights or welfare of subjects in the records review for research purpose above include privacy notice that patients receive when they register at University of Illinois Hospital & Health Sciences System notifying them that their records may be used without their authorization for research purposes and appropriate procedures in place to protect confidentiality, i.e., primary risk of this aspect of the research. Also, information learned will not impact the subjects as they experienced this treatment effect in the past. The investigators have access to records as part of their clinical duties.*
- C. *The phone script used contains brief overview of the study (purpose, aims, risks). After hearing study overview, subjects who express continued interest are asked to self disclose eligibility information. Subjects may refuse to answer a question or decline continued participation. Unless subjects permit, data collected during the screening process will be de-identified or be destroyed*

3. Research could not practicably be carried out without the

UIC Guidance for Investigators: Informed Consent Template, Version 1.2

sponsored by NIH the subject should be informed that private, identifiable information will be kept confidential and will only be used for research and statistical purposes. If, due to sample size or some unique feature, the identity of the individual cannot be maintained, the subjects need to be explicitly notified. If the investigator intends to disclose any information, the subject needs to be explicitly informed what information would be disclosed, under what circumstances, and to whom. The UIC Social Behavioral Informed Consent template contains language identifying that confidentiality can only be broken if the subjects reports immediate harm to themselves or others and reportable communicable diseases (for example, tuberculosis [TB] or HIV/AIDS).

Waiver or Alteration of Consent: Examples of protocol-specific justifications for the 4 waiver criteria.

1. Research involves no more than minimal risk
Examples:
- A. *Research involves retrospective review of medical records to ascertain frequency of weight gain with pregbalin treatment in elderly women; Data is coded and the file containing the key linking identifiers to data kept in a separate location from data file and both files encrypted.*
- B. *Research involves medical records review to identify potential subjects during the recruitment aspect of the research; Data is coded and the file containing the key linking identifiers to data kept in a separate location from data file and both files encrypted. Data deleted or de-identified for subjects determined to not meet eligibility criteria or who later decline participation in the consent process once the recruitment aspect of the research is completed. Research has no impact on subjects past clinical care or services received.*
- C. *Subjects who respond to flyer or when contacted self disclose the minimum necessary information to further assess eligibility criteria in the phone screen and interest in participating in the research.*

Signed by corresponding authors as follows:

Name: Neeta K. Venepalli

Signature:  Date: 11-20-16