New Policy for All Cancer-Relevant Human Subject Research Studies

A Protocol Review Management System (PRMS) must be utilized by a cancer center to receive National Cancer Center (NCI) designation.

The University of Florida Health Cancer Center (UFHCC) incorporates the use of a Scientific Review and Monitoring Committee (SRMC), which serves as the scientific and monitoring arm of the PRMS. The SRMC provides the initial review for the scientific merit, methodology, validity of statistical analysis, and potential feasibility based on anticipated accrual goals and scientific priority for appropriate studies.

As of July 20, 2017, any cancer-relevant research study, including behavioral research, at the University of Florida must be reviewed by the SRMC in addition to any UF IRB. The University of Florida defines a cancer relevant study as one that:

- Specifies enrolling patients with a known or suspected diagnosis of cancer as part of eligibility criteria; or

- Includes research endpoints related to cancer, associated symptoms or risk factors (including smoking or tobacco-associated studies, surveys, hepatitis or HPV vaccines, etc.); or

- The local PI plans to exclusively enroll current, former or potential cancer patients into the study.

Of course, it is impossible to list every possible scenario in which a study would be considered as cancer-relevant. In general, it means that your research involves cancer patients; uses data, tissue, or blood specimens from cancer patients; or will lead to findings that may be significant to cancer patients.

To learn more about this requirement, please go the SRMC website at: http://cancer.ufl.edu/clinical-trials-2/clinical-trials-office-2/srmc/.

For more information, please contact the SRMC Coordinator, Timmy Guinn, at timguinn20@ufl.edu or (352) 294-8697 or the Associate Director, Alison Ivey, at aivey@ufl.edu or (352) 294-8567.
When submitting a new revision in myIRB you can help to decrease review time and allow reviewers to rapidly identify proposed modifications, the justification for those modifications and to link those changes to any amended documents by including the following items in your submission:

- **In question 1.0** of the revision SmartForm, provide an overview of all of the proposed changes to the protocol, consents documents, recruitment materials, study questionnaires, SmartForm pages, etc. and provide a list of any revised IRB-approved documents being attached to the modified study in myIRB.
  - We suggest that when you specify the proposed changes to the protocol or ICF that you also indicate the section where the change is being made.
  - We also suggest that when you specify any changes to recruitment materials, study instruments or SmartForm pages; you indicate where the change is being made.
  - We also suggest that you ensure that every document modified is uploaded as a **track changes** version and has a date in the filename to identify it as 'new'.

- **In question 2.0** of the revision SmartForm, it is critically important to include the scientific, editorial or other justification/purpose for each change. Also if the revision is due to newly identified risks or impact on prospect for benefit, you should discuss the plans (if any) for informing current and former subjects.
  - We also suggest in the justification that you include the effect the changes have on the likelihood for harm and prospects for benefit (if any) to subjects and any impact on risk-benefit assessment.

For more information on how to submit a new revision request, please refer to pages 42-53 of the **myIRB Researcher Manual.**

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**True or False?**

1. Use or disclosure of PHI for research requires either the individual subject’s authorization or IRB approval for a HIPAA Waiver of Authorization.

2. Authorization is the same thing as Informed Consent.

3. Sitting in on conferences or board discussions of patients to identify potential research participants is permitted if the researcher does have a direct-care relationship with the patients.

*Correct Brain Teaser responses: (1) = True, (2) = False and (3) = True.*