

## In This Issue

- Informed Consent Observations
- Monitoring: Grants and Contracts
- Helpful Tip : How to "Track Changes" in Research Documents

## Quick Links

UHHS

Center For Clinical Research

Office of Research Compliance (Coming Soon!)

UHCMC IRB

UHCMC Grants and Contracts

## Contact Us

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Lakeside 1400  
11100 Euclid Avenue  
Cleveland, Ohio 44106  
216.844.5576  
E-mail us!

## Informed Consent Observations

The Federal regulations require regulatory bodies such as the UHCMC Office of Research Compliance (ORC) to observe the informed consent process. As such, the ORC will be contacting individual investigators and research personnel to schedule these observations. If you have already participated in an observation of the informed consent process, you will not be contacted again this year.

The goal of the observation is to monitor the three essential elements of the informed consent process. The elements to be assessed are: 1) ensuring that the individual obtaining informed consent establishes adequate comprehension on the part of the subject and study partner (if applicable); 2) the participant demonstrates a voluntary choice to participate; and 3) there is full disclosure of the nature of the research and the participant and research partner's involvement.

## Monitoring: Grants and Contracts

As a component of the Prospective Monitoring Program, the Grants and Contracts files of a protocol are reviewed to ensure compliance with UHCMC Grant Policies. The purpose is to ensure that the participants and UHCMC departments are appropriately reimbursed for all study related activities and that generally accepted accounting principles are applied to sponsored projects.

Some of the common items that are reviewed include:

- a. Grant and research expenditures, including salary, stipends, and patient bills, etc. Be sure to charge all grant expenditures to grant accounts;
- b. Timeliness of payments to other departments for services rendered;
- c. Salary and fringe benefits allocation according to labor distribution policies. Ensure such distributions are consistent with effort reporting by key personnel on the project;
- d. Grant reconciliation procedures after a protocol has ended to ensure grant account closeout; and
- e. Timely payment to participants for participation.

Payment and reimbursement for any research related activity is recommended on an ongoing basis during the conduct of the study in order to ensure accurate accounting of study funds. Please see UHHS policies on charging expenses to grants (UHHS Policy and Procedures, R 14, "Charging Direct and Indirect Costs") and the Grant Close Out Policy. Additionally, please contact the Grants and Contracts Office in the Center for Clinical Research if there are any questions.

## Helpful Tip: How to "Track Changes" in Research Documents

When submitting revised documents (e.g., protocols, informed consent documents, etc.) to the UHCMC IRB for review, be sure to include two copies of the original document, two "tracked changes" copies, and two clean copies with the revisions incorporated into the text. Please see link below for a step by step instructions on how to use [Tracked Changes](#).