2010

Office of Clinical Research

Nova Southeastern University

OFFICE OF CLINICAL RESEARCH

NOVA SOUTHEASTERN UNIVERSITY

WHO WE ARE

The primary function of the Office of Clinical Research (OCR) is to support NSU faculty investigators before, during, and after a clinical trial. The OCR's team of certified research professionals and attorneys support you at each step of your study, from managing research processes and coordinating services to offering best-practice solutions to meet your research hurdles.

TOP INVESTIGATOR TIPS

Christina Garcia-Godoy, D.D.S., CCRP

Good Clinical Practice

Good clinical practice (GCP) sets the standard for designing, conducting, monitoring, and reporting clinical research. A Certified Clinical Research Professional (CCRP) improves clinical trial quality, reduces risks to research subjects, and ensures compliance with FDA regulations and GCP guidelines. By adhering to GCP guidelines, researchers reassure trial subjects that their rights, well-being, and confidentiality are protected. It also helps ensure data from the trial is credible.

William Parker, D.D.S.

Mentoring

Mentoring plays a significant role in developing and training future researchers. Mentors for the dental residency program in periodontics guide and advise residents through the research process, helping them to determine research questions, design and implement trials, disseminate findings, and present outcomes.

Kenneth Johnson, D.O., FACOOG

Recruitment

A thorough understanding of both the patient population and the condition being researched is critical to successful recruitment. Recruiting volunteers beyond the NSU patient population and including them in the study better serves the community at large. A detailed, comprehensive monitoring of research volunteers establishes a rapport and builds trust for the clinical trial process and program.

Ana Castejon, Ph.D.

Collaboration

In the search for biological markers for autism spectrum disorders, the College of Pharmacy, in conjunction with the Mailman Segal Institute for Early Childhood Studies and the College of Osteopathic Medicine, are investigating the unsolved scientific basis of this disease. The long-term goal is to expose the association between biological signatures of autism and behavioral impairment in this syndrome. Through collaborative efforts, they have designed a clinical trial that will contribute to the scientific knowledge of autism spectrum disorders.

Rachel Stacey Coulter, O.D.

Special Population—Clinical Research of Children

Performing research studies on children and other special population groups presents researchers with additional challenges. Children's vulnerabilities and developmental levels mean that researchers in pediatric studies must also include, and communicate with, parents as well as children. In addition, children undergo periods of rapid change in physiology and cognition that researchers must consider when designing a research study. Due to these unique challenges, researchers often do not include pediatric and other special population patients in clinical trials. However, research studies on these patients are desperately needed to provide clinicians with appropriate information for making clinical decisions.

OCR'S SERVICES

FACULTY INVESTIGATOR SUPPORT SERVICES

The OCR offers an extensive range of research support services to meet all your research needs.

CONSULTATION SERVICES

The OCR's team of experts will personally consult with you before you even begin your study. They will determine the study's feasibility and help you plan your research trial.

CONTRACT SERVICES

As your advocate, the OCR reviews your confidential disclosure agreements, clinical trial agreements, and other contracts. The OCR will ensure your legal rights—including intellectual property, publication, and indemnification rights—are protected. The OCR's attorney will also negotiate contract terms on your behalf.

FINANCIAL SERVICES

The OCR will help you develop an accurate budget that considers expenses and hidden costs specific to your clinical trial. It also negotiates payment terms and the budget for you.

LIABILITY SERVICES

The OCR works directly with risk management and submits all the necessary information on your behalf, ensuring your study is approved and covered by NSU's insurance carrier.

IRB SERVICES

The OCR helps you create and submit complete packages to the Institutional Review Board (IRB). It will help you prepare and complete forms required for your package. Additionally, the OCR ensures all documents comply with approved guidelines, including documents for informed consent and HIPAA authorization. As an IRB liaison, the OCR assists you with additional IRB requirements, amendments, revisions, or continuations.

TRAINING SERVICES

The OCR provides training and preparation services to faculty investigators and key personnel through consultations and Web tutorials, including Collaborative Institute Training Initiative (CITI) courses such as the Basic Course, Good Clinical Practice, and Responsible Conduct of Research. Training seminars are provided in collaboration with the IRB, Grant Lab, and Office of Grants and Contracts.

WEB SERVICES

Additional information, tools, forms, and further explanation of services can be found at *www.nova.edu/ocr.*

OCR'S PROCESS

New Project/Protocol

OFFICE OF CLINICAL RESEARCH

Consultation
Protocol Review and Feasibility

Study Documents to OCR

IRB Assistance | Risk Management | Budget and Payment Schedule | Contract Review

Reassess and Revise

Approve Study

Establish Banner Account

Custom EMR Templates for Research

To learn more about the Office of Clinical Research, contact

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