

Washington University Nutrition Obesity Research Center (NORC) Pilot and Feasibility Awardees Conducting Studies in Human Subjects

All P&F projects proposing a clinical trial of more than minimal risk to human subjects require prior approval by NIDDK and a Data and Safety Monitoring Plan (DSMP).

Please respond below to determine if your project will require NIH approval and a DSMP before receiving funding:

Date: _____

PI Name: _____

Phone number: _____

eMail: _____

Project Title: _____

Is the NORC P&F project:

Human Studies related? Yes ____ No ____

Human Studies exempt? Yes ____ No ____

A Clinical Trial? Yes ____ No ____

A Clinic Trial considered more than minimal risk? Yes ____ No ____

Vertebrate Studies related? Yes ____ No ____

Provide the ClinicTrials.gov Identifier for this trial, if applicable (see below to determine if your study is a clinical trial): _____

The following four questions are used to determine whether a study meets the NIH clinical trial definition. If the answers to the four questions are all "Yes", the study is a clinical trial. If any of the answers to the questions are "No", the study is not a clinical trial.

Does the study involve human participants? Yes ____ No ____

Are the participants prospectively assigned to an intervention? Yes ____ No ____

Is the study designed to evaluate the effect of the intervention on the participants?
Yes ____ No ____

Is the effect that will be evaluated a health-related biomedical or behavioral outcome?
Yes ____ No ____

Note: If the proposed project is selected, funds will not be distributed until human study approval (and animal study approval if relevant) is submitted to Stephanie Paton (spaton@wustl.edu)