IRB Module – Sample Study

Answer the protocol SmartForm pages as follows.

> **Tip:** Save time by cutting and pasting text from the protocol document to the protocol SmartForm pages.

Basic Information

Title of protocol: Cinnamon bark, water-soluble cinnamon extract, and metformin as initial treatment for type 2 diabetes mellitus

Short title: <Your Name> Cinnamon and type 2 diabetes

Brief Description:

We are studying whether or not cinnamon bark or water-soluble cinnamon is an effective nutraceutical for the initial treatment of diabetes when compared to standard therapy of metformin 1000 mg (extended-release). This study will enroll 309 patients in randomized, doubled-blind, clinical trial and should be complete in a little over a year. Once consented, all subjects will have hemoglobin A1C, lipid panel, height, weight, and waist circumference measured along with standard demographic info. After randomization, they will receive one of the 3 medications from the pharmacy--thus investigators and subjects will be blinded as to their treatment. Subjects will be strictly counseled to have no further medication adjustments during this time. They will receive standard diabetic teaching. After 90 days of treatment, each subject will again have hemoglobin A1C, lipid panel, height, weight, and waist circumference measured. Subjects will bring in any remaining medication to determine adherence rates to the study protocol.

Principal Investigator: Principal Investigator <your number>
(This should be pre-populated; please do not change the PI to your name)

Does the investigator have a financial interest related to this research? No

Will an external IRB act as the IRB of record for this study? No

Attach the Protocol:

HRP-503 Template available for download at http://www.buffalo.edu/research/research-services/compliance/irb/policies-procedures-toolkit.html

Funding Sources

Add the *Diabetes Research and Education Foundation*

Study Team Members

Add yourself as a person involved in the design, conduct, or reporting of the research.

Add at least one other protocol team member.

Study Scope

Are there external sites where the investigator will conduct or oversee the research? No

Does the study (use drugs or biologics)? Yes

Does the study (use a device)? No

Drugs

Add the following information:

- Metformin

Consent Forms and Recruitment Materials

Add the following information:

- *HRP-502 Template* available for download at http://www.buffalo.edu/research/research-services/compliance/irb/policies-procedures-toolkit.html

CITI Training

There are no fields to update on this page; a connection between the Click Portal and CITI will automatically add course information for your study team members. At present there are some issues with integration between the two systems. These issues have caused the IRB to manually verify CITI completion for all study personnel.