

## Scott & White Hospital & Clinics Clinical Research at Scott & White

Please complete this form for each of your studies that are currently enrolling subjects. This information will be used to create a web page available for viewing by the general public. Please use lay terminology as in the consent form. The information should be complete and accurately describe your studies.

Study Title: Targeting INflammation using SALSalate for Type 2 Diabetes, Stage II (TINSAL)

Project ID#: 81664

Department: Endocrinology

Sponsor: National Institute of Diabetes and Digestive and Kidney Diseases of the National Institutes of Health in collaboration with the Joslin Diabetes Center

1. Provide a brief synopsis of the study (purpose of the study from abstract, consent form, or protocol using lay terminology):

Condition(s):	Treatment(s):
Diagnosis of Type 2 Diabetes without insulin therapy	Salsalate is part of the aspirin family and is approved by the Food and Drug Administration (FDA) for treating arthritis and other pain disorders. Small studies suggest that salsalate may improve sugars and inflammation in people with type 2 diabetes.

2. Who is eligible to participate in the study (basic qualifications such as age, gender, etc.)?

Age: Adults, ages 18-74

Gender: Male and Female

- Be on stable medication therapy for at least 8 weeks.
- Cannot have used insulin therapy for more than 30 days within the last year.
- Fasting blood glucose (sugar) levels less than 225 mg/dL at screening.
- Hemoglobin A1c (HbA1c) levels between 7% and 9.5% at screening.

3. What may be involved/required for subject participation (visits, tests, and/or logs, etc.)?

- Study participation will last about 50 weeks consisting of 11 office visits and 1 telephone visit.
- Office visits will take approximately 30 minutes to 2 hours depending on the tests that will be performed at that visit.
- Some of the tests to be performed are : routine blood draws and urine specimens, two electrocardiograms (ECG), two physical exams
- Other study duties include: answering questionnaires, home blood sugar testing each day, keeping a diary of blood sugar readings, taking study medication as directed, and reporting for scheduled study visits.

The study medication (salsalate) and a home blood sugar testing meter with strips will be provided to enrolled subjects at no cost. All study related office visits and tests (including ECG,

physical exams, and laboratory tests) will also be provided at no cost. Subjects may receive a stipend for their participation.

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3. Contact Information:

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10/20/08

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