Research being conducted in the Dermatology Clinical Trials Office:

1. **Chronic Plaque Psoriasis**- Dr. David Adams
   Plaque psoriasis is a chronic inflammatory skin disease characterized by scaly, raised plaques. Plaque psoriasis has of variable severity with worldwide prevalence of 2-3%. Although, not life-threatening, plaque psoriasis is a medically significant disease that can profoundly impact a patient's quality of life. We have participated in various studies for plaque psoriasis such as: topical, injectable biologics, and oral medications. We are still searching for new options that are beneficial and safe for long-term use. We are currently studying an investigational oral medication that is expected to move forward into the marketing phase. This would offer our participants a new potentially effective and safe treatment for their plaque psoriasis.

2. **Discoid Lupus Erythematosus (DLE)/Subacute Cutaneous Lupus Erythematosus(SCLE)-**
   Dr. Jennie Clarke
   Systemic lupus erythematosus (SLE) is a multi-organ autoimmune. The skin is involved up to 85% of systemic erythematosus (DLE/SCLE) cases and may be the only organ system involved. The occurrences of lesions, which can be disfiguring on visible, sun exposed areas are emotionally devastating and add to the psychological burden of the disease. DLE has been reported to have a dramatic negative impact on the patient's quality of life leading to physical and psychological disability. The areas most commonly affected are a person's scalp, face, neck shoulders and upper arms. The lesions are red, scaly and painful. Some suffer from hair loss in large patches on the scalp and open sores in their mouth or nostrils. The lesions can leave scarring which can be very embarrassing. We are in a Phase 2 trial of an investigational oral medication taken twice daily. The medication currently available to treat DLE or SCLE when used over a long period of time can cause toxicity. It is hopeful that the maximum dose is tolerated well by the participants and the investigational medication is studied further in a phase 3 trial.

3. **Acne Vulgaris**- Dr. Diane Thiboutot and Dr. Andrea Zaenglein
   Acne is one of the most common treated conditions by Dermatologists. One of the medications to treat severe acne vulgaris is Isotretonoin (Accutane), an oral medication closely followed by the IPledge program mandated by the FDA. Isotretinoin is the most potent FDA-approved medication for the treatment of acne, especially in terms of its ability to reduce sebum (oil) production by the skin. Since isotretinoin has potentially serious side effects including teratogenicity, there is a need for alternative therapeutic strategies to treat severe acne. One of the difficulties in identifying potential alternative agents is the fact that relatively little is known on a molecular and cellular level about the mechanism of action of isotretinoin. We are continuously conducting mild, moderate and/or severe acne vulgaris studies throughout the year to enhance the treatment options for teens and adults who suffer from acne vulgaris. Our studies have involved several

combinations of investigational and/or FDA approved topical and/or oral medication. Numerous participants have had their acne improve to "clear " or "almost clear" during our clinical trials when other treatment options have failed. Acne vulgaris research is very important as the results could impact people's quality of life and enhance self –esteem.

4. **Papulopustular Rosacea**- Dr. Diane Thiboutot

   Rosacea is a chronic, inflammatory skin condition that affects adults. It causes redness on the face and produces small, red, pus-filled bumps or pustules. The cause of rosacea is unknown, but researchers believe it's likely due to some combination of hereditary and environmental factors. Although anyone can develop rosacea, you may be more likely to develop rosacea if you: have fair skin and light hair and eye color, are between the ages of 30 and 60, especially if you're going through menopause, experience frequent flushing or blushing, have a family history of rosacea. There is no cure to eliminate rosacea, but effective treatment can relieve signs and symptoms. Most often this requires a combination of prescription treatments and certain lifestyle changes. Topical medications may be used along with oral medications or as part of a maintenance program to control symptoms. Dermatology Clinical Trials Office has fully executed research studies applying topical and oral medications both Investigational and FDA approved products. Since there is no cure for rosacea there is a necessity for the clinical trials office to continue research at the Dermatology Clinical Trial Office.

5. **Hidradenitis Suppurativa-HS**- Dr. David Adams
   HS is a painful, chronic, skin disease occurring in 1% of the population characterized by recurrent inflamed, painful, cysts, nodules, and abscesses, which may rupture to form fistulas and scarring. The most commonly involved locations are the groin and axilla but can affect other areas. Hidradenitis Suppurativa has a severely negative effect on patients' quality of life. There are no FDA approved treatments for this condition. Current treatments are driven primarily by expert opinion, experience and case reports or small studies. We recently completed a study using anti-inflammatory biological therapy with some encouraging results. We look to a larger study to confirm these results and possible FDA approval.

6. **Melanoma-** Dr. Bryan Anderson
   Melanoma can be a life-threatening diagnosis. Our research team is working to identify cancer cell markers by collecting a blood sample form patients who are having an excision of the cancerous lesion. It will look at the potential identification of precancerous cells that can be treated at a much earlier stage. Even though participants cannot be identified once their blood is drawn, they have the option to allow their left

over blood to be used for future research testing. This research could possibly help guide early detection of cancer.