Welcome to the University of Toronto Lupus Clinic

The purpose of this newsletter is to provide our patients, their families and clinic supporters with information on the latest activities of the University of Toronto Lupus Clinic. We will include some background information about why the Lupus Clinic is special, updates on our Clinic staff and results of some of our recent research studies as well as future directions.

We hope you find this publication useful.

What is Lupus?

Since there are continually new patients entering the Clinic, we will start by providing some basic information about the disease.

Most patients know that systemic lupus erythematosus (SLE) is considered an autoimmune disease. Under normal conditions, the immune system plays a key role in protecting the body from harmful agents such as viruses and bacteria; in SLE however, antibodies are directed against oneself.

In patients with SLE, the immune system produces a number of antibodies that react with cell components resulting in chronic inflammation in different parts of the body. Lupus strikes 1 in 1000 Canadians, mainly women in the child-bearing years.

About the University of Toronto Lupus Clinic

The Lupus Clinic was first established in 1970 as a patient care referral centre and was designed to promote expert care for patients with lupus, to train future rheumatologists and to facilitate research into this disease. There are now over 1100 patients registered in the Lupus Clinic, making it one of the largest centres for specialized lupus care and research internationally. Patients are referred to the Clinic from all areas of Ontario. A large proportion of patients are receiving their primary lupus care at the Clinic. Some patients are followed by their local rheumatologists, but continue to be followed in the Clinic at intervals.

Patients are evaluated by a physician, usually a rheumatology trainee, who is particularly interested in this disease. All patients are reviewed by one of the clinic directors (see page 2) either in person or by chart review. In this way, patients are evaluated in a standard way according to a specially designed format, which includes physical examination, blood and urine tests at each visit.

The Lupus Databank Research Program was established in 1987 with the fund raising assistance of volunteers, many of whom were patients at our Clinic. This databank has allowed for the long-term study of SLE to discern the natural history and response to therapy in this disease.

Funding for core staff required for this research program continues to be funded by patient groups such as the Lupus Foundation of Ontario and private donations through the Arthritis & Autoimmunity Research Centre (AARC) Foundation. Project-specific research is funded through peer-review grants.
Meet the Clinic Doctors

Dr. Murray Urowitz is Director of the University of Toronto Lupus Clinic, Professor of Medicine, Senior Staff Physician, Toronto Western Hospital and Senior Scientist with the Toronto Western Hospital Research Institute. He is also Medical Advisor to the Ontario Lupus Association and Principal Investigator for the Systemic Lupus International Collaborating Clinics (SLICC) Registry for Atherosclerosis in SLE.

Dr. Dafna Gladman is Co-director of the University of Toronto Lupus Clinic, Professor of Medicine, and Senior Staff Physician, Toronto Western Hospital. Dr. Gladman is also the Director of the HLA Laboratory and Senior Scientist with the Toronto Western Research Institute. She is also a Medical Advisor to the Ontario Lupus Association. Dr. Gladman is also director of the University of Toronto Psoriatic Arthritis Clinic.

Dr. Paul Fortin is Co-Director of the University of Toronto Lupus Clinic. He is an Associate Professor of Medicine and Senior Staff Physician, Toronto Western Hospital. He is a Senior Scientist at the Toronto Western Research Institute. Dr. Fortin is Director of the Canadian Network for Improved Outcomes in SLE (CaNIOS) and Director of Clinical Research for the Arthritis Centre of Excellence. Dr. Fortin is also Director of the Antiphospholipid Syndrome Clinic.

Clinic Fellows

The Lupus Clinic is part of the University of Toronto Rheumatology Training Program and hosts several trainees from Canada and abroad who have completed their specialty training in rheumatology and who come to our Clinic to gain further training and expertise in the management of patients with SLE and in clinical research.

Dr. Roopa Prasad joined our Clinic as a Clinical Research Fellow in February of 2003 and plans to stay for a two year period. Dr. Prasad comes from Wales where she did her training in Rheumatology. She will be seeing patients on our Tuesday Clinic. Dr. Prasad has already completed a research project in SLE, which she presented at the Canadian Rheumatology Association National Meeting in February of 2004.

We are also pleased to welcome Dr. Mandana Nikpour from Australia. Dr. Nikpour joined our program in October of 2003 and will be seeing patients on our Thursday Clinic. She plans to stay for at least two years and has become involved in some exciting research projects in heart disease in SLE.

In addition, two senior fellows from the Rheumatology Training Program of the University of Toronto work in the Clinic for a period of six months each.

Temporary Clinic Move

In October of 2002 the Clinic moved from the first floor of the hospital to the fifth floor of the Edith Cavell Wing. Our current location on the fifth floor is a temporary one and was required in order to accommodate construction of the new East Wing of the Hospital. The Lupus Clinic will be returning to the first floor of the new East Wing in 2005. We are excited to be moving to this newly designed area which will offer state of the art facilities with the entire Musculoskeletal Health and Arthritis Program (Rheumatology & Orthopedics) in one area. Please bear with us in our temporary location. We know the elevators can be challenging. We will keep you informed of details of our next move.
Research Update

All research at our clinic is carried out under the auspices of Drs. Urowitz, Gladman and Fortin, who encourage the participation in research of students at all levels of their medical training such as post-graduate rheumatology fellows who are specialist trainees, general medical residents, and medical students.

Research at the Clinic also involves students of other health care professions such as psychology, biostatistics and epidemiology. This exposure to clinical research at an early stage in their careers turns students on to the field of rheumatology and increases awareness of SLE. In turn, the fresh ideas of the students greatly enhance our research program.

In this section of the newsletter we will provide a summary of results of several recently completed studies and those currently underway or planned for the near future. On pages 8 and 9 we provide a table with a complete list of current studies and contact information for each study.

Heart Disease in SLE – A Major Focus

A major focus of our research over the last few years has been in the area of heart disease in SLE patients. Women with SLE are known to develop atherosclerotic heart disease (thickening of arteries) earlier than the general population. Because of these changes, women with SLE are at an increased risk of developing related problems such as heart attacks and angina up to five times more frequently than the general population.

In order to further understand the mechanisms involved in the development of early atherosclerosis in SLE and to develop preventative therapies, we have established a strong collaborative research team with the Division of Cardiology at the University Health Network and have developed multi-centre collaborative studies addressing this specific question as outlined below.

DIMPI Study

One of the first studies we completed in this area was designed to establish just how prevalent coronary artery disease is and to examine the type of changes that are seen in women with SLE. To do this we asked women to undergo a Dual Isotope Myocardial Perfusion Imaging (DIMPI) study. This is a highly sensitive and specific heart imaging technique that can show early coronary artery disease before the patient actually experiences any clinical signs of heart disease. Our study demonstrated that 33% of patients who have never demonstrated any clinical symptoms of heart disease had arterial changes suggestive of coronary artery disease.

Population Risk Factor Study

We questioned the role of traditional risk factors for coronary artery disease in the general population compared to our SLE population. This study was carried out in collaboration with the Montreal Cardiology Prevention Clinic. From this work we were able to determine that while traditional risk factors for coronary artery disease such as family history, hypertension, high cholesterol, etc., play a role in the development of heart disease in women in the general population and women with SLE, there are other factors beyond this that contribute to the early development of heart disease in women with SLE.

Toronto Risk Factor Study

To answer the questions arising from these earlier studies, we obtained a grant from the Ontario Heart and Stroke Foundation to undertake a large study examining the presence of known risk factors for the development of coronary artery disease in women with SLE compared to healthy women of the same age. The study involved 250 women from our Lupus Clinic and 250 healthy control patients attending the family practice unit at our hospital. This study revealed that while women with SLE have an increase in some of the traditional risk factors for heart disease such as hypertension, diabetes, and elevated cholesterol, these features do not fully explain the high prevalence of heart disease in women with SLE. Thus, SLE itself may be a risk factor for premature heart disease.
Heart Disease in SLE (Continued)

Database Studies

We have carried out several studies looking at heart disease using information contained in our large database. We presented the results of a quality improvement study looking at how potential risk factors for heart disease such as hypertension, obesity and high cholesterol have been handled by rheumatologists in the past and the effect of interventions on the ultimate outcomes for our patients. This study was helpful in that it provided a long-term overview of treatment trends and their success in treating this condition. Our database has also allowed us to examine the natural history of high cholesterol in SLE patients over a prolonged period of time and its impact on eventual outcomes. It is known that elevated cholesterol is a significant risk factor for development of coronary artery disease in the general population. This study showed that this is of particular concern for SLE patients and that early identification and treatment of high cholesterol is very important. These database studies have also allowed us to determine that the use of antimalarials, a standard treatment for active SLE, may in fact help to reduce high cholesterol.

The Next Steps:

All of these studies performed to date along with studies carried out at other centres indicate the need for further understanding of the mechanisms for coronary artery disease in SLE, as well as better management of traditional risk factors and testing of preventative therapies.

SLED STUDY

We have now taken the next step and designed a drug trial to try and overcome these changes noted in the blood vessels in our patients. Together with colleagues in our Cardiology Division we applied for and received funding from the Heart and Stroke Foundation of Ontario. This time we are using Sestimibi heart scans and brachial artery ultrasound to assess the blood vessels in our patients. If an abnormality is detected in the Sestimibi scan, the patient will then be able to participate in the drug trial phase of this study. The drug trial phase will assess the effectiveness of a drug called Quinapril used for the treatment of coronary artery disease in the general population. The trial is designed in such a way that all patients will receive the drug, although the investigators will not know whether they are receiving active drug or placebo first. There are currently 22 patients enrolled in the trial phase. At least 50 patients are required in order to have sufficient numbers for analysis. Contact information for this study is provided on page 8.

Health Improvement and Prevention Program (HIPP)

This is a multi-centre study of the Canadian Network for Improved Outcomes in SLE (CaNIOS) (see page 5). The goal of this study is to demonstrate that a co-ordinated intervention program will improve health status of patients with SLE compared to usual care. This intervention program will specifically target the prevention and/or modification of risk factors for coronary artery disease such as high blood pressure, high cholesterol and smoking cessation. Patients who agree to participate in this study will participate in a standardized Health Improvement and Prevention Program that will be coordinated by a case manager nurse in collaboration with the Lupus Clinic physicians. Patients will participate in an individualized educational program including a cardiovascular disease prevention program, stress reduction and a bone health program for those patients identified as at risk for development of osteoporosis. The program will last 24 months and assessments including cardiac imaging studies, bone density measurement, quality of life and health status questionnaires will be completed at three to four time points throughout the study. Contact information for the HIPP study is provided on page 9.
**STRENGTH IN NUMBERS – Multi-centre Collaborations**

**SLICC Registry for Atherosclerosis in SLE**

The Systemic Lupus International Collaborating Clinics (SLICC) is an international group of rheumatologists and lupologists from 29 centres who have been working together on lupus research since 1987. In the past they have collaborated to develop standardized outcome measures so that physician-researchers could better measure and describe the course of lupus and its response to new therapies. These outcome measures are now widely used by lupus researchers throughout the world and allow comparison of patient populations among centres. The SLICC group has been working on the important area of heart disease in SLE through the development of the Registry for Atherosclerosis. The long-term goals of this registry are to allow researchers to determine the frequency in the population and nature of early atherosclerotic coronary artery disease in SLE, and to identify associated risk factors.

The Registry includes patients who are newly diagnosed with SLE and involves the collection of clinical and laboratory data as well as family history and lifestyle information related to heart disease on an annual basis for a minimum of five years. In addition laboratory samples are being collected for centralized testing of inflammatory measures and banking of DNA.

Under the leadership of Dr. Urowitz, the University of Toronto Lupus Clinic is the co-ordinating centre for the SLICC Registry for Atherosclerosis. Data and laboratory samples that are collected at each of the sites are submitted to our centre for data entry and analyses. Over 500 patients are now enrolled in the Registry. These individuals represent an ethnically, culturally and geographically diverse group of newly diagnosed SLE patients. This unique resource will allow us to determine the nature of early atherosclerotic heart disease and identify risk factors early, leading to preventative therapies.

Although partial funding has been obtained for the Registry through a grant from the Canadian Institute of Health Research, several lupus patient groups have provided generous financial support for this important project including The Lupus Foundation of Ontario and the Ontario Lupus Association.

**Canadian Network for Improved Outcomes in Systemic Lupus Erythematosus**

The Canadian Network for Improved Outcomes in SLE (CaNIOS) was created in 1995 with the specific goal of running a multi-centre study of Methotrexate in SLE. Because of the low prevalence of lupus, the conduct of controlled drug trials can not be done at a single centre. Under the leadership of Dr. Paul Fortin, this group of Canadian lupus researchers has gone on to develop further studies to address specific factors in SLE. These include the Lupus Erythematosus and Psychotherapy study (LEAP) and the SLE and Malignancy study. A new study the Health Improvement and Prevention Program (HIPP) is outlined on page 4. A further study currently underway examines the impact of environment and genetic factors in the development of lupus. CaNIOS has also recently received a grant to carry out a study which will evaluate the risk of thrombosis (unwanted blood clots) in patients with SLE.

CaNIOS currently includes 43 members with centres in eight provinces. Lupus Canada, with an annual matching gift from an AARC Foundation donor, has provided financial support for a national co-ordinator for CaNIOS. The co-ordinator, Ms. Diane Ferland, is based at the Toronto Western Hospital.
**OTHER AREAS OF RESEARCH**

### Osteoporosis in SLE

Other areas of research over the past year have included a study examining osteoporosis (loss of bone density) in women with SLE. Loss of bone density is a common problem for post-menopausal women in the general population, but for women with SLE it has been thought that the risk is much greater due to medications used to treat their disease, particularly prednisone. Our study examined the results of bone density testing in premenopausal SLE patients. The results indicate that osteoporosis occurs commonly in premenopausal women with SLE. Prednisone use in women who had osteoporosis was similar to those without osteoporosis. We have enlarged the study to include all women who have had a bone mineral density between 1995 and 2000. Two thirds of the patients have evidence of reduced bone density, and 18% have frank osteoporosis. Traditional risk factors for osteoporosis, such as age and postmenopausal status predispose women with SLE to bone loss, but the use of steroids does not seem to be a factor. This suggests that there may be some process of SLE itself that plays a role in the development of osteoporosis and that it is essential to monitor patients for this condition. Osteoporosis is as frequent in our men with SLE. In men, steroids do appear to play a role. We plan to further study osteoporosis and its treatment in very near future.

### Fatigue in SLE

Fatigue in SLE is another area that we continue to explore. Profound fatigue is a common complaint that greatly affects the lives of many patients with SLE. We have previously reported that fatigue is not necessarily associated with active disease. To further understand the pattern of fatigue in SLE patients we have been working with Dr. H. Moldofsky of the Centre for Sleep and Chronobiology Sleep Disorders Clinics. Several patients who experience excessive fatigue have undergone overnight sleep studies, which assess their sleep and wakefulness patterns. Preliminary results show that sleep abnormalities are common in these patients. We plan to carry out further studies of sleep patterns and its potential role in fatigue in SLE.

### Assessment of Children of Mothers with SLE

Another unique study we have completed is that of cognitive and developmental assessment of the children born to mothers with SLE. This study was supported by a grant from the Canadian Institutes of Health Research. The purpose of our study was to examine whether similar learning problems or physical developmental abnormalities are found in the children of women with SLE. This study was carried out in collaboration with a team of adult and child psychologists and rheumatologists from the Toronto Western Hospital and The Hospital for Sick Children. We have carried out a complete neuropsychological and physical evaluation of over 57 children of women from our clinic and 49 children of mothers who do not have SLE from the community. We did not identify any children with a diagnosis of lupus and there was no overall difference in intellectual functioning between the two groups.

On further analysis of neuropsychological testing, some differences were found in the SLE group in the areas of learning and memory. However, the differences that were found were mild and the specific differences varied from age group to age group. The only other difference that was found was in the area of behavior. Using a parent-completed questionnaire more parents of children born to mothers with SLE described behavioral issues in their children. The implications of these results are unclear and we do intend to continue studying the nature of these differences and their potential causes.

### Presentations at Scientific Meetings

In 2003 we presented a total of 21 papers at scientific meetings including the Canadian Rheumatology Association and American College of Rheumatology National Scientific meetings. In addition to some of the studies discussed above we presented the following posters:

- Prolonged Remission in SLE
- The Role of C-Reactive Protein in SLE
- The Role of Radiation Therapy in Patients with both a Diagnosis of Lupus and Cancer
- The Effect of Lupus Nephritis on Pregnancy Outcome and Fetal Maternal Complications
- Ethnic Variation in SLE
- Pulmonary Hypertension in SLE
- Evaluation of Endothelial Function in SLE
- Osteoporosis in Patients with SLE: A Quality Assurance Study
- Difference in Disease Features Between Childhood-onset and Adult SLE.

Several of these poster presentations are displayed in the Clinic waiting area.
AWARDS

Dr. Sindhu Johnson and Dr. Tuhina Neogi, both fellows in the Lupus Clinic, under the supervision of Drs. Urowitz and Gladman, in 2002-2003 were recipients of the American College of Rheumatology (ACR) Fellow Award at the National Scientific Meeting in October 2003. This award is given to second year rheumatology trainees in recognition of their meritorious performance throughout training.

Dr. Johnson also received the Ian Watson Award for Lupus Research, presented at the Canadian Rheumatology Association annual meeting for her project describing ethnicity in SLE.

Dr. Johnson presented results at the ACR meeting of several projects she completed with the Lupus Clinic including the following posters:
- Pulmonary Arterial Hypertension in SLE
- Evaluation of Endothelial Function in SLE
- Ethnic Variation in SLE (oral presentation)

Dr. Neogi presented results of the following projects she completed while with the Lupus Clinic:
- Osteoporosis in SLE: A Quality Assurance Study
- Anti-Myeloperoxidase Antibodies are not Associated with Coronary Artery Disease in SLE
- Anti-dsDNA Antibody Testing by Farr and ELISA Techniques are not Equivalent.

ACKNOWLEDGEMENTS

The Lupus Foundation of Ontario Generously Supports the University of Toronto Lupus Clinic Lupus Databank Research Program

In October of 2003 the Lupus Foundation of Ontario hosted a Seminar at the Fort Erie Native Friendship Centre. Guest speakers were Lieutenant Governor of Ontario, The Hon. James Bartleman and Dr. Murray Urowitz.

The Foundation presented a generous donation to lupus research carried out at the University of Toronto Lupus Clinic. Pictured here is Pat Aikenhead, Past President of the Lupus Foundation of Ontario, presenting a cheque for $40,000 to Dr. Urowitz. This donation will support the SLICC Registry for Atherosclerosis and the Lupus Databank Research Program.

We would like to thank the Lupus Foundation for their continued support and partnership.

Dance for the Cure

The 9th Annual "Dance for the Cure" took place in January. The event organized by Tiziana Tolfo, her family and friends, raises funds for lupus research and awareness. For the past three years, part of the proceeds has been donated to the SLICC Registry for Atherosclerosis. We would like to gratefully acknowledge the hard work that Tiziana her family and friends put into this wonderful event and their continued support.

A Special Thanks to Our Patients

We have completed several exciting projects over the past year which have expanded the overall understanding of SLE and which have lead to further planned studies. None of this research would be possible without the continued support of our patients and their families. If you would like any further information or are interested in participating in any of these studies, please speak to your Lupus Clinic physician or the Research Office at 416-603-5800 ext. 2511.
### SUMMARY OF CURRENT RESEARCH STUDIES

#### STUDY NAME: SLICC REGISTRY FOR ATHEROSCLEROSIS IN SLE (SLICC-RAS)

**STUDY OBJECTIVES**
To determine the frequency and nature of early atherosclerotic coronary artery disease in SLE.

**WHO CAN TAKE PART?**
All patients diagnosed within the last 15 months.

**WHAT IS INVOLVED?**
One study visit per year for up to five years. Study visits will include collection of clinical and laboratory information; completion of quality of life and family history questionnaires, and collection of 4 - 6 tubes of blood.

**CONTACT INFORMATION**
Principal Investigator: Dr. Murray Urowitz
Co-investigators: Dr. P. Fortin & D. Gladman and members of SLICC
Research Assistant: Samantha Janes
Ph: 416-603-5800 ext. 2481

#### STUDY NAME: SLICC REGISTRY FOR NEUROPSYCHIATRIC SLE (NP-SLE)

**STUDY OBJECTIVES**
To determine the frequency and nature of neuropsychiatric (central nervous system) manifestations of SLE.

**WHO CAN TAKE PART?**
Patients who qualify for the Registry of Atherosclerosis (above) may also choose to participate in this study.

**WHAT IS INVOLVED?**
At the same time as your annual SLICC Registry for Atherosclerosis study visit additional information concerning any neuropsychiatric events will be collected.

**CONTACT INFORMATION**
Principal Investigator: Dr. John Hanly, Halifax
Co-investigators: Members of SLICC
Research Assistant: Samantha Janes
Ph: 416-603-5800 ext. 2481

#### STUDY NAME: ENDOTHELIAL DYSFUNCTION IN SLE: ITS CONTRIBUTION TO ABNORMALITIES IN CORONARY PERFUSION (SLED)

**STUDY OBJECTIVES**
To examine early changes of atherosclerosis and blood vessel function of patients with SLE and to investigate the ability of the ACE inhibitor Quinapril to reverse abnormalities in endothelial function and myocardial perfusion.

**WHO CAN TAKE PART?**
All patients not currently taking an ACE Inhibitor.

**WHAT IS INVOLVED?**
Study participants will undergo a screen myocardial perfusion imaging study and brachial artery ultrasound (approximately 4-5 hours). Patients who have abnormality on myocardial perfusion will qualify to enter the clinical trial phase of the study. The trial phase involves a further 3 to 5 clinic visits over 10 weeks. Patients are followed by a cardiologist throughout the trial phase.

**CONTACT INFORMATION**
Principal Investigator: Dr. Mark Iwanochko, Division of Cardiology
Co-investigators: Dr. M. Urowitz & Dr. D. Gladman
Research Assistant: Joanna Cichon
Ph: 416-603-5800 ext. 2352

#### STUDY NAME: GENETIC AND ENVIRONMENTAL FACTORS IN SLE (GeNES)

**STUDY OBJECTIVES**
To identify genes, environmental factors and gene-environment interactions that may contribute to the development of SLE.

**WHO CAN TAKE PART?**
All SLE patients:
- Patients with both parents living will qualify for the gene component of this study.
- Patients who do not have both parents living may qualify to complete an environmental questionnaire.

**WHAT IS INVOLVED?**
For SLE patients the study will involve one clinic visit where 5-6 teaspoons of blood will be drawn (at the time of their usual clinic bloods) for DNA isolation. They will also be asked to complete a series of questionnaires that gather information regarding environmental exposures. The questionnaires will take approximately 1 hour to complete. Family members participating in this study will be asked to provide 9 tubes of blood. This may be arranged at a laboratory close to home.

**CONTACT INFORMATION**
Principal Investigator: Dr. Paul Fortin
Co-investigators: Members of CaNIOS
Research Assistant: Tamara McKenzie
Ph: 416-603-5800 ext. 2822
### STUDY NAME: IDENTIFICATION OF B CELL TOLERANCE & FUNCTIONAL ABNORMALITIES IN IMMUNOPATHOGENESIS OF SLE (B-cell)

**STUDY OBJECTIVES**  
To determine whether B cells (immune cells that produce antibodies) are abnormal in patients with SLE.

**WHO CAN TAKE PART?**  
SLE patients between the age of 24 to 40 years with minimally active lupus.

**WHAT IS INVOLVED?**  
A single blood draw of 2 to 10 tubes of blood which may be drawn at the same time as your regular clinic blood.

**CONTACT INFORMATION**  
Principal Investigator: Dr. Joan Wither  
Co-investigators: Drs. P. Fortin, M. Urowitz & D. Gladman  
Research Assistant: Tamara McKenzie  
Ph: 416-603-5800 ext. 2822

### STUDY NAME: HEALTH IMPROVEMENT AND PREVENTION STUDY (HIPP)

**STUDY OBJECTIVES**  
To demonstrate that a coordinated intervention program will improve health status in SLE compared with usual care.

**WHO CAN TAKE PART?**  
Women with SLE and no previous history of heart disease or osteoporosis.

**WHAT IS INVOLVED?**  
In addition to their usual clinic care, patients who participate in this study will take part in a Health Improvement and Prevention Program (HIPP) and be followed for a 24 month period. Patients will participate in the HIPP program either in the first 12 month or second 12 months of the study. The HIPP program will be led by a case-manager nurse, and will include a 4 week, 6 hour educational course followed by development of an individualized program. Several outcome assessments including questionnaires on health status, cost and coping, and blood vessel and bone density studies will be performed at baseline, 12 and 24 months. This will allow us to determine the effectiveness of a formal intervention program over usual care.

**CONTACT INFORMATION**  
Principal Investigator: Dr. Paul Fortin  
Co-investigators: Members of CaNIOS  
Nurse Co-ordinator: Anne Cymet  
Ph: 416-603-5800 ext. 2895

### STUDY NAME: THE ROLE OF THROMBOPHILIC FACTORS IN PERSONS WITH SLE (ThromboFIL)

**STUDY OBJECTIVES**  
To measure how often blood clots occur in persons with SLE, and explore how antiphospholipid antibodies (aPL) may increase the risk of these clots.

**WHO CAN TAKE PART?**  
Patients diagnosed with SLE within the past 5 years, and who have not had any blood clots for more than 1 year before the diagnosis of SLE.

**WHAT IS INVOLVED?**  
One study visit per year for up to three years. Study visits will include completion of family history and health status questionnaires, collection of 4 tubes of study bloods for clotting factors and DNA storage. Telephone interviews will also be carried out at 6, 18 and 30 months.

**CONTACT INFORMATION**  
Principal Investigator: Dr. Paul Fortin  
Co-investigators: Members of CaNIOS  
Research Associate: Erika Chang  
Ph: 416-603-5800 ext. 3157

### STUDY NAME: PROSPECTIVE COHORT OF PATIENTS WITH ANTIPHOSPHOLIPID ANTIBODIES (TAPS)

**STUDY OBJECTIVES**  
To examine the clinical and laboratory mechanisms and long-term outcomes of patients with antiphospholipid antibodies, which are associated with abnormal blood clotting.

**WHO CAN TAKE PART?**  
All patients who have antiphospholipid antibodies with or without lupus.

**WHAT IS INVOLVED?**  
Once a year clinical and laboratory information will be collected as part of your routine clinic visit. Some extra blood will be drawn for future testing of specific antibodies.

**CONTACT INFORMATION**  
Principal Investigator: Dr. Paul Fortin  
Co-investigators: Drs. D. Gladman & M. Urowitz  
Research Associate: Erika Chang  
Ph: 416-603-5800 ext. 3157
STUDIES PLANNED FOR FUTURE

INVESTIGATION OF RETINAL DYSFUNCTION IN PATIENTS WITH SLE TAKING HYDROXYCHLOROQUINE (HCQ)

STUDY OBJECTIVES
To test a new diagnostic tool for earlier diagnosis of retinal damage due to HCQ use.

WHO CAN TAKE PART?
Patients between 20 to 50 years age. One group currently taking HCQ and a control group who have never taken HCQ.

WHAT IS INVOLVED?
This study will require two visits. The first is will take approximately two hours and the second visit will take 30 minutes. Several routine tests of vision will be performed as well as a newer test called the multifocal electroretinogram (mfERG).

Principals Investigator: Dr. Michael Easterbrook
Division of Ophthalmology
Co-investigators: Drs. D. Gladman & M. Urowitz

REVISING ACR DIAGNOSTIC/CLASSIFICATION CRITERIA FOR SLE

STUDY OBJECTIVE
To revise the existing diagnostic/classification criteria for lupus.

WHO CAN TAKE PART?
Patients with SLE as well as patients with other rheumatologic diagnosis to act as a control group.

WHAT IS INVOLVED?
This is a collaborative multi-centre study of the SLICC group and will involve approximately 10 to 12 patients from the University of Toronto Lupus Clinic and 10 to 12 controls. Clinical data that is collected as part of a regular lupus clinic visit and one set of blood samples will be submitted to the study co-ordinating centre at Johns Hopkins University in Baltimore.

Principal Investigator: Dr. M. Petri
Johns Hopkins University, Baltimore
Co-investigators: Members of SLICC

RISK FACTORS FOR OSTEOPOROSIS IN WOMEN WITH SLE

STUDY OBJECTIVE
To determine bone mineral density in women with SLE and identify associated risk factors for osteoporosis.

WHO CAN TAKE PART?
All women with SLE.

WHAT IS INVOLVED?
All women who have not had a bone mineral density study (DEXA) in the past two years will be asked to undergo this assessment. Blood will be obtained to determine vitamin D levels and study of genes known to affect bone density. Clinical and laboratory information of patients with low bone density will be compared to those with normal bone density to identify potential risk factors.

Principal Investigator: Dr. M. Urowitz
Co-investigators: Dr. D. Cole, Department of Laboratory Medicine
Dr. D. Gladman

NOVEL THERAPEUTICS – Clinical Trials of New Drugs in Lupus

Several new medications have been developed over recent years for treatment of other autoimmune diseases such as rheumatoid arthritis including newer “biologic” therapies that target a specific cellular process in the immune response.

This is an exciting time in lupus research as several pharmaceutical companies are now developing and testing similar drugs for the treatment of lupus. These new therapies will target specific organ system involvement such as kidney disease or will target general lupus disease activity in the hopes of sparing treatment with steroids.

The University of Toronto Lupus Clinic has developed a Clinical Trials Program, which is managed by our clinical trials nurse co-ordinator, Vicki Lapp. Through this program we will be able to offer our patients the opportunity to participate in these clinical trials of new therapies. We are in the process of evaluating several study protocols and submitting them for Ethics Committee review.

If you are interested in more information about participation in a clinical trial of new therapies in SLE you can contact Vicki at 416-603-5800 ext. 2077. Further information about specific clinical trials will be posted at the Clinic.
Donations

The Arthritis & Autoimmunity Research Centre (AARC) Foundation at University Health Network raises funds for Canada’s largest and most comprehensive facility dedicated to research in arthritis, autoimmune diseases, musculoskeletal health and orthopaedic surgery – including the Lupus Databank Research Program. The Arthritis & Autoimmunity Research Centre at UHN brings together the innovation, talent and resources needed to achieve global impact and provide exemplary patient care, research and education.

Donations to the Lupus Databank Research Program can be made through the AARC Foundation, which provides a tax-deductible receipt for all donations.

The Arthritis & Autoimmunity Research Centre Foundation
R. Fraser Elliott Building
190 Elizabeth Street, 5th Floor, Rm. 5S-801, Toronto, ON M5G 2C4
Tel: (416) 340-4989  Fax: (416) 340-3496  Website: www.aarcfuhn.ca
Charitable Organization Number 11920 0773 RR0001

Donations may be made by cheque, payable to the AARC Foundation, at the Lupus Clinic, by phone at 416-340-4989 or at the Toronto Western Hospital Cashier’s Office on the Main Floor.

Thank you!