INFORMATION FOR PATIENTS

The IMPACT Study:
IMProve **P**regnancy in **A**PS with **C**ertolizumab **T**herapy

The **IMPACT study** will evaluate the addition of certolizumab to usual treatment in pregnant women with antiphospholipid syndrome (APS) and repeatedly positive tests for lupus anticoagulant (LAC)

Are you eligible to be in the IMPACT study?

To be eligible to enroll in the IMPACT study you must

- Be 18 to 38 years of age.
- Have a diagnosis of APS (we will verify this through your medical record).
- Be repeatedly positive for LAC (we will verify this through your medical record).
- Be successfully pregnant but less than 8 weeks gestation

There are also some conditions or medical problems that may exclude you from participating in this study. A member of our research team will review those with you when you contact us about the study.

If you and your Doctor feel you may benefit from this study and you are interested in more information, please contact one of the individuals below for further information about this study:

Samantha Nielsen
University of Utah, Department of Obstetrics & Gynecology
Research Study Coordinator
(801) 585-7617, sam.nielsen@hsc.utah.edu

D. Ware Branch M.D.
University of Utah, Department of Obstetrics & Gynecology
Maternal Fetal Medicine Specialist
(801) 581-8425, ware.branch@hsc.utah.edu

Marta Guerra
Hospital for Special Surgery, New York
Project Coordinator
(212) 774-7361, guerram@hss.edu

Jane E. Salmon, M.D.
Hospital for Special Surgery, New York
Rheumatologist
(212) 606-1422, salmonj@hss.edu

***** Certolizumab is not actively transported across the placenta and is FDA approved for use in rheumatoid arthritis, psoriasis and Crohn's disease. Hundreds of patients with these conditions have used certolizumab throughout pregnancy, without evidence of fetal malformations or adverse pregnancy outcomes.

Certolizumab therapy requires a subcutaneous injection (similar to heparin), every other week, from week 8 to week 28 of pregnancy. This is the period when we believe APS causes damage to your placenta, negatively affecting your pregnancy (your health and that of your baby).

Certolizumab will be provided free of charge to patients who are found to be eligible for and agree to participate in the study.