STANDARD OPERATING PROCEDURE FOR
ACQUIRING AN ULTRASOUND IMAGE

SOP Number: 3DUS 300.03

Version Number & Date: 3rd version; Date: 28 Feb 2011

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Revision Chronology:

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<th>Version Date</th>
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Printed Name       Signature       Date (dd/mmm/yyyy)
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Approved By: Grace Parraga ______________   ___/___/____

300.03
Performing A 3-Dimensional Ultrasound Scan
Page 1 of 4
28 Feb 2011
1. INTRODUCTION & PURPOSE

This standard operating procedure (SOP) describes the procedure for carrying out ultrasonic image acquisition in the ultrasound suite to ensure the safety of study subjects and optimization of test results.

2. SCOPE

This SOP applies to all use of the equipment in the ultrasound suite on human subjects.

3. APPLICABLE REGULATIONS AND GUIDELINES

Health Canada:
- Laboratory Biosafety Guidelines: 2004
- National WHMIS Compliance Policy: 3 January 2002

University of Western Ontario:
- Health Sciences Research Ethics Board for Research Involving Human Subjects Guidelines: July 2001

Canadian Society of Diagnostic Medical Sonographers (CSDMS) Standards

Personal Health Information Protection Act (PHIPA): 1 November 2004

4. REFERENCES TO OTHER APPLICABLE SOPs

This SOP is applicable to all 3DUS SOPs
All SOPs on Good Clinical Practices are applicable to this SOP

4. ATTACHMENTS

A. UWO Incident Reporting Form

6. RESPONSIBILITY

It is the responsibility of the principal investigator at this investigative site to approve all SOPs. The principal investigator assumes ultimate accountability for all SOPs. It is the responsibility of all personnel involved in supervising, managing or conducting testing in the ultrasound suite to follow this SOP.

7. DEFINITIONS

The following definitions from the International Conference on Harmonisation, Good Clinical Practice: Consolidated Guideline apply to this SOP:
Adverse Event (AE): An adverse event, as used in these SOPs, refers to any untoward medical occurrence in a patient or clinical investigation subject administered an investigational product or procedure that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.

Good Clinical Practice (GCP): A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

Medicinal (Investigational) Product: A medicinal (investigational) product, as used in these SOPs, refers to any drug product, equipment or procedure being tested by the clinical trial, to which the subject would not otherwise be exposed as part of ordinary medical care.

Sponsor: An individual, company, institution, or organisation that takes responsibility for the initiation, management, and/or financing of a clinical trial.

8. PROCESS OVERVIEW

A. Qualification of personnel
B. Policies and Procedures Safeguarding Patients and Ultrasound Personnel
C. Obtaining a 3D Carotid Ultrasound Image
D. Obtaining Other Ultrasound Images

9. PROCEDURES

A. Qualification of Personnel

Scans may be performed by a sonographer (certified by ARDMS or CSDMS) or by a physician.
Other research personnel performing ultrasound scans may do so after initial and ongoing training by a certified sonographer or physician and at the discretion of the principal investigator.

B. Policies and Procedures Safeguarding Patients and Ultrasound Personnel

ALARA Principle
Personnel must be familiar with and show evidence of practicing the ALARA (as low as reasonably achievable) principle.
Incident Reporting
All personnel are responsible for reporting any accidents or complications that occur in the facility to the principal investigator, and as required (according to regulations and/or the protocol) to the University of Western Ontario, the UWO HSREB, and/or the Sponsor of the study.

- Incidents must be reported to UWO using the form (Attachment A) found at: [http://www.uwo.ca/humanresources/docandform/forms/ohs/aiir.pdf](http://www.uwo.ca/humanresources/docandform/forms/ohs/aiir.pdf)
- Adverse Events must be reported to the UWO HSREB using the online system found at: [https://grant2.vm.its.uwo.ca/sae/SAELogin.aspx](https://grant2.vm.its.uwo.ca/sae/SAELogin.aspx)

Subject Confidentiality

- All PFL personnel must adhere to professional ethics and behaviour ensuring subject confidentiality
- All equipment containing digital copies of subject information must be password protected and the software locked when not in use
- All paper copies of subject information must be stored securely, according to the principals of good clinical practice

C. Obtaining a 3D Carotid Ultrasound Image

1. Input patient information and set 3D parameters
2. Select appropriate transducer
3. Position patient in a semi-upright position, turn patient’s head to the left and apply ultrasound gel to right side of neck
4. Position the 3D ultrasound transducer over the carotid bifurcation
5. Select ‘3D acquire’ and a volume will be obtained
6. The first ‘3D’ scan will be the test scan to determine if all required information has been obtained.
7. Obtain the type and number of scans indicated by the protocol for which the scans are being performed
8. Repeat steps 3-7 for the left carotid if indicated by the protocol
9. Save all volumes to the hard-drive and archive to an external drive

D. Obtaining Other Ultrasound Images

Imaging for other types of scans should be carried out according to the protocol for which the scans are being obtained. The sonographer and/or the study physician should define specific steps for image acquisition based on the protocol.