Each serious adverse event (SAE) and potential SAE needs to be reported **within 24 hours** to be reported to the study coordinator (by phone or by mail):

Dr. Liesbeth Lewi
UZLeuven
Herestraat 49
B-3000 Leuven
Belgium

Liesbeth.Lewi@uzleuven.be

Tel 003216344200
Fax 003216344205

She will evaluate together with the Steering Committee (Dr. Jan Deprest, Dr. Asma Khalil, Dr. Dick Oepkes and Dr. Enrico Lopriore) if it concerns a SAE.

Additionally**, within 48 hours**, the attached registration form should be sent by mail or fax.

Each SAE will be reported to the Data Safety Monitoring Committee as well as the Central Ethical Committee of UZ Leuven Belgium.

Definition of SAE in the TRAPIST trial

Postoperative complications within the first 2 weeks after the intervention

1. Need for transfusion for postoperative hemorrhage
2. Placental abruption
3. Sepsis
4. Bowel perforation
5. Admission of the patient to ICU
6. Death of the patient

Definition of potential SAE in the TRAPIST trial

If other events occur that are possibly related to the study (such as aplasia cutis), then these will also have to be reported. If these are judged to be true SAE, then the DSMC and Central Ethical Committee will be informed.

Members of the Data Safety Monitoring Committee

Ed Juszczak (Clinical Trialist, University of Oxford, UK), Magnus Westgren (Fetal Medicine Specialist, Karolinska Institute, Sweden), Colin Morley (Pediatrician, University of Cambridge, UK), Keith Reed (parent organisation, TAMBA, London, UK)

SERIOUS ADVERSE EVENT REPORT FORM TRAPIST TRIAL

Subject identifier:	Study group allocation (early/late):
Study center:	Date of the SAE:

Serious adverse events

Postoperative complications within the first 2 weeks after the intervention:

1. Need for transfusion for postoperative hemorrhage	□ Yes	□ No
2. Placental abruption	□ Yes	□ No
3. Sepsis	□ Yes	□ No
4. Bowel perforation	□ Yes	□ No
5. Admission of the patient to ICU	□ Yes	□ No
6. Death of the patient	□ Yes	□ No

Please specify additional details or circumstances of SAE:

Potential serious adverse events

Please specify details or circumstances:

Relationship of event the study intervention

□ Unrelated (clearly not related to the study intervention)

□ Possible (may be related to the study intervention)

□ Definite (clearly related to the study intervention)

What steps were taken to treat serious adverse event?

Signature of Principal Investigator: **Date:** **(dd/mmm/yyyy)**

Send to Liesbeth.Lewi@uzleuven.be or fax to 0032 16 34 42 05