



**EMPOWAR Placenta sampling collection
Working Practice Document (WPD)**

EMPOWAR WPD number:

9

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Draft

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Date authorised:

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1. PURPOSE

The purpose of this WPD is to describe the process for collecting and preparing the placenta samples for adult participants in the EMPOWaR study and to ensure that all participating sites are consistent in their methods of collection and storage. This document should be retained in the ISF, section 7.

2. DEFINITIONS

ISF Investigator Site File

PI Principle investigator at the site

WPD Working Practice Documents

3. WHY

The specific guidelines for taking placenta samples are created to help ensure accuracy and repeatability across the participating sites

4. WHO

This WPD applies to all staff delegated by the PI for the task of collecting and preparing samples.

5. PROCEDURE

Two methods of placental collection are described.

All sites should use the STANDARD COLLECTION PROTOCOL.

The **ENHANCED COLLECTION PROTOCOL** should only be used by sites that have the research infrastructure available to support the more in-depth sample processing.

5.1 Standard collection protocol (ALL SITES)

5.11 RNA samples

- Cut a piece of placenta (no covering membranes) about 10mm x 10mm x 10mm and divide into four pieces.
- Place the pieces into a pot containing RNAlater.
- Transfer to research laboratory
- After a 24hrs, remove RNAlater solution and store samples in labelled microtube (1 sample per tube) at -80C until subsequent analysis and/or transfer to Edinburgh.

5.2 Enhanced collection protocol / sample processing (ONLY in sites able to accommodate extended sample processing required)

5.21 RNA samples

- Cut a piece of placenta (no covering membranes) about 10mm x 10mm x 10mm and divide into four pieces.
- Place the pieces into a pot containing RNAlater.
- Transfer to research laboratory
- After a 24hrs, remove RNAlater solution and store samples in labelled microtube (1 sample per tube) at -80C until subsequent analysis and/or transfer to Edinburgh.

5.22 Frozen samples:

- With placenta membrane side down, cut a piece of placenta of 1cm x 1cm x 1cm from a cotyledon at the centre of the placenta and cut into four pieces.
- Place the pieces into a small 'frozen' tube
- Snap-freeze samples at -80C
- Deliver samples to research laboratories and store at -80C until subsequent analysis and/or transfer to Edinburgh.

5.23 Histology samples

- With placenta membrane side up, cut a piece from the centre of a cotelydon full thickness from the maternal to fetal side, at least 10mm wide.
- Place this into a universal container containing 10% neutral buffered formalin (NBF)
- Deliver samples to research laboratory
- Fix samples in NBF for 24hrs
- Remove formalin and cover sample with 70% IMS
- Store in 5C fridge until subsequent processing and/or transfer to Edinburgh.

6. TRANSFER OF FROZEN SAMPLES (or other samples)

Transfer of frozen samples to the University of Edinburgh.

The research team at the University of Edinburgh should be contacted to arrange receipt of the samples before any arrangements are made for transfer (see contact details below).

Human clinical or research specimens may contain infectious biological agents which are hazardous to health. The transport regulations within the UK are based upon the UN Model Regulations for the Transport of Dangerous Goods. The latest revision of

this set of regulations was prepared by the Department for Transport (DfT) authority (Revision 5: February 2011).

Blood samples taken as part of the EMPOWAR clinical trial will be in UN Model Regulations category B and must be consigned/shipped frozen in dry ice as UN3373 using a locally approved courier. The courier should provide specific information on their approved **labelling** and shipping **documentation** which must comply with the P650 packing instruction required by the UN 3373 code. Full details of the code can be obtained at:-

http://www.dft.gov.uk/426155/425453/800_300/infectioussubstances.pdf

Samples sent should be transferred with a copy of the EMPOWaR tissue collection log.

Contact details to arrange the collections:

Sonia Whyte
EMPOWaR Trial Manager
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