



DIRECT
DIABETES RESEARCH ON PATIENT STRATIFICATION

STANDARD OPERATING PROCEDURE (SOP)

**Diabetes Research on Patient Stratification (DIRECT)
All Work Packages**

PROCEDURE FOR THE TRANSFER OF MATERIALS.

VERSION NUMBER: 1.1
EFFECTIVE DATE: 11th July 2012
REVIEW DATE: 11th July 2013

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DATE APPROVED:

11 July 2012

Procedure for the Transfer of Materials into and within the DIRECT Consortium

1. Purpose

The purpose of this SOP is to outline the procedure for the material transfer of samples into and within the DIRECT consortium.

2. Applicability

This SOP applies to; all personnel involved in the DIRECT consortium; all work packages.

3. Procedure

Samples will be brought into the DIRECT consortium at various points in the programme. These samples fall into the following categories:

1. Samples that are prospective and are collected and identified as components of the DIRECT sample tracking system at the time they are taken (prospective samples);
2. Samples that have been previously collected within a non-DIRECT study and whose use is dictated by the consents obtained for those studies (retrospective samples).

The terms and conditions set forth in Section 9 of the DIRECT Project Agreement dated December 6th, 2011, apply to all material transfer arrangements.

1. Process for Prospective samples

Prospective samples taken as part of a study formulated and managed by DIRECT consortium participants do not require a Material Transfer Agreement (MTA) Record Form for their exchange or transfer. These samples are logged into the DIRECT sample tracking on the day they are collected and are recognised at individual sample level as belonging to the consortium. Each sample can be tracked in terms of shipments made through the DIRECT database and chain of custody is thus a feature of the DIRECT sample tracking system. If for any reason a receiving laboratory requests the provision of the MTA Record Form (for example to meet local requirements), then the Record Form can be exchanged following the process outlined below for Retrospective samples. However, this is not considered to be the usual process for prospective samples within DIRECT.

2. Process for Retrospective samples

Retrospective samples are samples owned by a participating laboratory which were originally collected under the auspices of a non-DIRECT managed study. Custodianship rights and obligations rest with the providing laboratory. In order to recognise the obligations and to understand the historical context of these samples, certain pieces of information on the samples need to be acquired prior to their requisition into the DIRECT consortium. Exchanges of these samples between laboratories also need to acknowledge the existence of this information.

a) First shipment into DIRECT (Retrospective samples):

At the time of the first shipment of samples into the DIRECT consortium, the MTA Record Form (3 pages) will be completed and signed by a responsible person from

the providing laboratory. This form will be sent to the laboratory receiving the samples for counter signature. Sample tracking is at the level of box or rack unit with accompanying sample logs/inventories to enable the receiving laboratory to understand the organisation of the samples within each box.

The completed MTA Record Form will be sent by the receiving laboratory to [REDACTED] [REDACTED] ([REDACTED]) or [REDACTED] ([REDACTED]), Work Package 9 (WP9), for storage and at this point the MTA Record Form will be given a number (assigned to all 3 pages of the MTA Record Form). This MTA Record form with a number assigned shall also be sent to [REDACTED] for upload into the members' area of the DIRECT website. An excel spreadsheet will be used to track all MTA Record Forms generated within DIRECT. This spreadsheet will be updated regularly by WP9 members. Updates of this spreadsheet (ie. the list of transferred retrospective sample sets) will be provided to [REDACTED] ([REDACTED]) on a regular basis for deposition in the member's area of the DIRECT website.

b) Subsequent shipments within DIRECT (Retrospective samples) with permission from original providing laboratory to allow onward shipments:

The receiving laboratory may need to subsequently send samples to another DIRECT laboratory. The paperwork required in advance of this type of shipment is page 3 of the MTA Record Form (including the MTA Record Form number to link the third page to the other 2 pages of the MTA Record Form). If there are changes to either page 1 and/or page 2, then all 3 pages will be sent. All MTA Record Forms will be available for download from the members' area of the DIRECT website. The receiving laboratory signs in advance of the providing laboratory and the providing laboratory sends a copy of the signed MTA Record Form page 3 to [REDACTED] ([REDACTED]) or [REDACTED] ([REDACTED]), WP9, for storage and tracking. Should the receiving laboratory need to access the pages 1 and 2 of the MTA Record Form, these pages can be collected from the members' area of the DIRECT website using the MTA Record Form number as an identifier. These subsequent MTA Record Forms will be allocated derivative numbers that link them to the original shipment. Each MTA Record Form (either 3 pages or 1 page) will be sent to [REDACTED] together with the updated spreadsheet.

Subsequent shipments within DIRECT (Retrospective samples) without permission from original providing laboratory to allow onward shipments:

The receiving laboratory and providing laboratory follow the process outlined above. In addition, the same process must occur between the original providing laboratory and the receiving laboratory.

Shipments to non-DIRECT laboratories:

This type of shipment falls outside the scope of this SOP.