<table>
<thead>
<tr>
<th>Data Request (DR)</th>
<th>Data Analysis Concept Sheet (DACS)</th>
<th>New Works Concept Sheet (NWCS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A proposed investigation for which existing data from an IMPAACT (or Pediatric AIDS Clinical Trials Group [PACTG]) study are being requested for analyses to be performed without Statistical and Data Analysis Center (SDAC) statistician IMPAACT funding.</td>
<td>A proposed investigation involving analysis of existing data from an IMPAACT (or PACTG) study to be undertaken by SDAC with IMPAACT funding.</td>
<td>A proposed investigation involving use of existing biological specimens from an IMPAACT (or PACTG) study that may or may not require IMPAACT funding and may or may not involve analysis work by SDAC</td>
</tr>
</tbody>
</table>
ANCILLARY STUDIES

- If the IMPAACT Network has not designated a study as concluded or openly available for use by investigators outside of the protocol team, the objectives of the proposed investigation should not overlap with the objectives stated in the study protocol or with secondary analyses defined by the protocol team after receipt of the final analysis report.

- For DACSs and DRs: The objectives should also not overlap with objectives specified in an approved IMPAACT DACS or NWCS that is not yet completed.

- For NWCSs: The objectives should also not overlap with objectives in an approved IMPAACT NWCS that is not yet completed.
ANCILLARY STUDIES REVIEW PROCESS

- Study proposals using the appropriate template form should be submitted to impaact.capsubmissions@fstrf.org
- The Operations Center will then assign a number to the proposal and initiate the IMPAACT review process

Submit proposal; tracking number assigned
Review by relevant chair (protocol, NWCS, DACS)
Relevant Scientific Committee review
Relevant Leadership Group review
Capsule, DACS, NWCS, and DR Templates are available at: https://impaactnetwork.org/resources/study-proposals.htm
Capsule, DACS, NWCS, and DR Templates are available at: https://impaactnetwork.org/resources/study-proposals.htm
An SDUA is required for the following:

- Any export of human genomic data
- Any NWCS
- Export of data under a DR or DACS
- Shipment of specimens and/or data sets for an approved IMPAACT protocol if the activity has not been described in the protocol or DAIDS Clinical Trials Agreement
- Export of data from multiple studies for a meta-analysis or other grouped analysis, even if not developed as a formal DR or DACS
Information on available biological specimens for concluded studies can be accessed on the interactive ACTG/IMPAACT Specimen Repository website:

www.specimenrepository.org
P1025 (10039): Perinatal Core Protocol

Study Status: Closed to Follow Up
Study Restriction: United States

What is P1025?

P1025 is a prospective observational cohort study that provides a framework for collection and evaluation of data and collection of repository specimens from HIV-infected pregnant and postpartum women and their infants. The study is designed to assess maternal and infant safety, and the effectiveness of new and existing interventions prescribed for prevention of mother-to-child transmission (MTCT) of HIV and/or women's health.

Study Documents:

- P1025 Protocol V4 (31 Dec 2008) with CM #1, CM #2, CM #3, CM #4, CM#5, and LoA#1 - 24 May 2013

Sites where the study is implemented:

<table>
<thead>
<tr>
<th>CRS ID</th>
<th>Site Name</th>
<th>City</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>5083</td>
<td>Rush University Hospital</td>
<td>Chicago</td>
<td>United States of America</td>
</tr>
</tbody>
</table>
Further details on DACS, DRs, NWCS, capsules, and concept sheet development and review processes are available in the IMPAACT Network Manual of Procedures (MOP)

https://impaactnetwork.org/resources/policies-procedures.htm

- Section 9: Protocol Development and Modifications
  - Capsule and Concept Sheet development and review
- Section 15: Ancillary Studies and Investigations
- Section 19: Publications Requirements and Procedures