

## **Adult to Adult Living Donor Liver Transplantation Cohort Study (A2ALL) Data Archive**

The A2ALL study consisted of three separate phases: “Retrospective”, “Cohort”, and “Core”. The retrospective data were obtained from chart review during January 1, 1998 and February 28, 2003 (called “Retro”). From February 28, 2003 through August 31, 2010, the majority of data were collected prospectively, supplemented with a small portion of data collected retrospectively (called “Cohort”). Similarly data collection from February 2011 through January 2015 was primarily prospective, with a small amount of retrospectively collected data (called “Core”).

The A2ALL Archive contains the Protocol, Manual of Operations, Forms, and Study data. The files are organized into the following directories:

- Data
- Documentation
- DSIC
- Forms

### **A2ALL Forms**

The A2ALL forms directory contains:

- Retrospective – This subdirectory contains the following files and subdirectories corresponding to the “Retro” phase of the A2ALL study. These forms are comprised of screenshots from the A2ALL BioDBx web-based data entry system. Each form is associated with a single data module described in the Manual of Operations (M.O.O.). In turn, the M.O.O. describes individual data elements (variables) in each module, along with element definitions, answer formats, and raw data sources. For information on skip logic which deems whether a form should be filled out, refer to Appendix 1. For extensive information on data collection flow, refer to the flowchart in the M.O.O., pages 74-78. Note that corresponding SAS variable names in raw data files do *not* appear on study forms. Rather, the variable crosswalk is a link between the A2ALL forms and corresponding SAS variables.
  - Donor folder – This subdirectory contains the following forms for donors in the A2ALL study:
    - DNR Demographics.pdf (corresponds with Module 26. Donor Demographics, p.160 in M.O.O.)
    - DNR Evaluation.pdf (corresponds with Module 27. Donor Evaluation, p. 161-162 in M.O.O.)
    - Donor Intraop.pdf (corresponds with Module 28. Donor Intraoperative Data, p. 163-165 in M.O.O.)
    - DNR Hospitalizations.pdf (corresponds with Module 29. Donor Hospitalizations and Module 29a. Liver Diagnosis Codes, p. 166-168 in M.O.O.)

- DNR Morbidity.pdf (corresponds with Module 30. Donor Morbidity, p. 169-173 in M.O.O.)
- Donor Complication Severity forms (corresponds with Module 31. Donor Complication Severity and Module 31a. Definitions of Donor Adverse Events, p. 174-179 in M.O.O.)
  - DNR Bile Leak Comp Severity.pdf
  - DNR Abscess Comp Severity.pdf
  - DNR Ascites Comp Severity.pdf
  - DNR Aspiration Comp Severity.pdf
  - DNR Biliary Strict. Comp Severity.pdf
  - DNR Bowel Ob. Comp Severity.pdf
  - DNR Cardiopulmonary Arrest Comp Severity.pdf
  - DNR CHF Comp Severity.pdf
  - DNR Dehiscence Comp Severity.pdf
  - DNR DVT Comp Severity.pdf
  - DNR Encephalopathy Comp Severity.pdf
  - DNR GI Bleed Comp Severity.pdf
  - DNR HAT Comp Severity.pdf
  - DNR Hernia Comp Severity.pdf
  - DNR Ileus Comp Severity.pdf
  - DNR Inf Vena Cava Thromb Comp Severity.pdf
  - DNR Infection Comp Severity.pdf
  - DNR Intra-abdom. Bleed Comp Severity.pdf
  - DNR Liver Failure Comp Severity.pdf
  - DNR Liver TXP Comp Severity.pdf
  - DNR MI Comp Severity.pdf
  - DNR Neuropraxia comp Severity.pdf
  - DNR PE Comp Severity.pdf
  - DNR Pleural Effusion Comp Severity.pdf
  - DNR Pneumothorax Comp Severity.pdf
  - DNR Portal VT Comp Severity.pdf
  - DNR Psych Comp Severity.pdf
  - DNR Pulmonary Edema Comp Severity.pdf
  - DNR Re-Explor. Comp Severity.pdf
  - DNR Respiratory Arrest Comp Severity.pdf
- DNR Survival.pdf (corresponds with Module 32. Donor Patient Survival (survival status), p. 180 in M.O.O.)
- Recipient folder – This folder contains the following forms for transplant recipients in the A2ALL study:
  - RCP Demographics.pdf (corresponds with Module 3. Recipient Demographics, p. 97 in M.O.O.)

- List & Txp Info.pdf (corresponds with Module 4. Listing and Transplant Information, p. 98 in M.O.O.)
- RCP Cond. @ Listing.pdf (corresponds with Module 5. Recipient Condition at Listing, p. 99-102 in M.O.O.)
- RCP Cond. @ Enrollment.pdf (corresponds with Module 6. Recipient Condition at Enrollment, p. 103-106 in M.O.O.)
- RCP Cond. @ TXP.pdf (corresponds with Module 7. Recipient Condition at Transplant, p. 107-110 in M.O.O.)
- HCC Data @ Listing.pdf (corresponds with Module 8. HCC Data at Listing and Module 8a. HCC Assessment Form, p. 111-114 in M.O.O.)
- HCC Data @ Enrollment.pdf (corresponds with Module 9. HCC Data at Enrollment, p. 115-117 in M.O.O.)
- HCC Data @ TXP.pdf (corresponds with Module 10. HCC Data Immediately Prior to Transplant, p. 118-120 in M.O.O.)
- HCV Data @ Enrollment.pdf (corresponds with Module 11. HCV at Enrollment and Module 11a. Knodell Score, p. 121 in M.O.O.)
- HCV Data @ TXP.pdf (corresponds with Module 12. HCV Data at Transplant, p. 122 in M.O.O.)
- RCP Intraop.pdf (corresponds with Module 13. Recipient Intraoperative Data, p. 123-127 in M.O.O.)
- HCC Explant.pdf (corresponds with Module 14. HCC Explant Assessment, p. 128-129 in M.O.O.)
- RCP Baseline Immuno.pdf (corresponds with Module 15. Recipient Baseline Immunosuppression and Rejection Episodes, p. 130-131 in M.O.O.)
- Recurrent Rejection Episodes.pdf (corresponds with Module 16. Multiple Rejection Episodes and Treatment, p. 132 in M.O.O.)
- RCP Hospitalization 10.pdf (corresponds with Module 17. Recipient Hospitalizations and 17a. Liver Diagnosis Codes, p. 133-135 in M.O.O.)
- RCP Morbidity.pdf (corresponds with Module 18. Recipient Morbidity, p. 136-141 in M.O.O.)
- Recipient Complication Severity forms (corresponds with Module 19. Recipient Complication Severity and Module 19a. Definitions of Recipient Adverse Events, p. 142-148 in M.O.O.):
  - RCP Bile Leak Comp Severity.pdf
  - RCP Ascites Comp Severity.pdf
  - RCP Biliary Stricture Comp Severity.pdf
  - RCP Bowel Obstruction Comp Severity.pdf
  - RCP Chronic Rejection Comp Severity.pdf
  - RCP DVT Comp Severity.pdf
  - RCP Encephalopathy Comp Severity.pdf
  - RCP GI Bleed Comp Severity.pdf

- RCP HAT Comp Severity.pdf
- RCP Ileus Comp Severity.pdf
- RCP Infection Comp Severity.pdf
- RCP Ing. Vena Cava Thromb. Comp Severity.pdf
- RCP Intra-ab. Abscess Comp Severity.pdf
- RCP Intra-ap. Bleed Comp Severity.pdf
- RCP Neuropraxia Comp Severity.pdf
- RCP Portal VT Comp Severity.pdf
- RCP Recurrence Comp Severity.pdf
- RCP Re-Explore Comp Severity.pdf
- RCP Re-TXP Comp Severity.pdf
- HCV Recurrence & Rx.pdf (corresponds with Module 20. HCV Post-op Recurrence and Treatment (Rx) Data, p. 149-152 in M.O.O.)
- HCC Recurrence & Rx.pdf (corresponds with Module 21. HCC Post-op Recurrence and Treatment (Rx) Data, p. 153-154 in M.O.O.)
- Graft Outcomes.pdf (corresponds with Module 22. Graft Outcomes, p. 155 in M.O.O.)
- RCP Survival.pdf (corresponds with Module 23. Recipient Patient Survival (survival status) and Module 23a. Recipient Cause of Death Codes, p. 156-157 in M.O.O.)
- Study Enrollment.pdf – Enrollment form for all participants (corresponds with Module 2. Recipient Study Enrollment, p. 96 in M.O.O.)
- Core – This subdirectory contains the following files corresponding to the “Core” and “Cohort” phases of the A2ALL study:
  - A2ALL-APS-POQrAppendix2 SM 081012.pdf – A prospective survey regarding pain after transplant surgery
  - A2ALL Cohort CRFs - data collection forms.pdf – This document contains screenshots from all forms from the “Cohort” phase of the A2ALL trial. Note that “DNR” indicates a donor form and “RCP” indicates a recipient form. Forms include:
    - DNR Study Entry Info
    - DNR Evaluation
    - RCP Study Entry Info
    - RCP @ DNR Eval
    - HCV Data @ Enroll
    - HCC @ Enroll
    - RCP Pre-TXP Q1
    - HCV Pre-Txp Qtr1
    - HCC Pre-TXP Qtr 1
    - DNR Intraop
    - RCP @ TXP
    - RCP LDLT Intraop

- RCP DDLT Intraop
  - HCV @ TXP
  - HCC @ TXP
  - HCC Explant
  - HCC Explant Tumor
  - DNR Post-Op W1
  - RCP Post-Txp W1
  - HCV Post-TXP W1
  - HCV Bx Path W1
  - RCP Post-Txp W2
  - DNR Post-Op M1
  - RCP Post-Txp M1
  - HCV Post-TXP M1
  - HCV Bx Path M1
  - DNR Post-Op M3
  - RCP Post-TXP M3
  - HCV Post-TXP M3
  - HCV Bx Path M3
  - RCP Post-Txp M6
  - HCC Post-TXP M6
  - DNR Post-Op Y1
  - RCP Post-Txp Y1
  - HCV Post-TXP Y1
  - HCV Bx Path Y1
  - HCC Post-TXP 12M
  - HCC Post-TXP 18M
  - HCC Post-TXP 2Y
  - Rejection Tx 1
  - DNR Hospitalizations 1
  - RCP Hospitalizations 1
  - DNR Comp Severity 1
  - RCP Comp Severity 1
  - AE-SAE Report 1
- A2ALL Core CRFs - data collection forms.pdf – This document contains screenshots from all forms from the “Core” phase of the A2ALL trial. Note that “DNR” indicates a donor form and “RCP” indicates a recipient form. Forms include:
- Demographics 060414
  - DNR HRQOL RCP Assessment 072312
  - DNR Intraop 102512
  - Donor Complications 062912
  - Donor Hospitalization 062912
  - HRQOL Only Donor Assessment 050613

- HRQOL Only Donor Complication 011413
- Post-Don Month 1 Assessment 102512
- Post-Don Month 3 Assessment 102512
- Post-Don Week 1 Assessment 102512
- Post-Don Year Assessment 102512
- Post-Txp Month 1 Assessment 061013
- Post-Txp Month 3 Assessment 061013
- Post-Txp Week 1 Assessment 061013
- Post-Txp Week 2 Assessment 061013
- Post-Txp Year Assessment 061013
- RCP Intraop 102512
- RCP Study Entry Information 102512
- Recipient Complications 072413
- Recipient HCC Explant Assessment 062912
- Recipient Hospitalization 062912
- HCV Advanced Disease Assessment 071513
- HCV Post-TXP BX Results 050613
- HCV Study Information 071513
- HCV Study Subject Flow 050313
- HCV Transient Elastography Report 091412
- HCV Transplant Information 071513

## **A2ALL Documents**

The A2ALL Documents directory contains:

- Retrospective: Documents pertaining to the “Retro” phase of the A2ALL study:
  - Retro Protocol 101104 Final.pdf (Study Protocol)
  - Retro MOO 070909.pdf (Manual of Operations)
  - NIDDK\_CDR\_retro\_DOCUMENTATION.doc (Data Documentation provided by the A2ALL data coordinating center).
    - This file has descriptions of the legacy datasets, user-defined formats, and variable crosswalks.
  - Variable Crosswalks:
    - xwalkNIDDK\_RECIP.xls - This Excel workbook links each of 1068 variables in the Recipient dataset to its corresponding data collection form. The spreadsheet includes variable labels and SAS user defined format names. The second tab of the workbook expands the SAS user defined formats to include the entire format definition. The workbook also includes 327 fields which exist on the Recipient forms, but are not present in the dataset, because they have entirely missing values. These fields are indicated by variable name=“N/A: Field not populated”.
    - xwalkNIDDK\_DONOR.xls - This Excel workbook links each of 478

variables in the Donor dataset to its corresponding data collection form. The spreadsheet includes variable label and SAS user defined format names. The second tab of the workbook expands the SAS user defined formats to include the entire format definition. The workbook also includes 284 fields which exist on the Donor forms, but are not present in the dataset, because they have entirely missing values. These fields are indicated by variable name="N/A: Field not populated".

- Core – Documents pertaining to the “Cohort” and “Core” phases of the A2ALL study:
  - A2ALL Cohort MOO.pdf (Manual of Operations for “Cohort” phase)
  - A2ALL Cohort Protocol Amendment II 031006.pdf (Protocol for “Cohort” phase)
  - A2ALL Core MOO Version 1.5 – includes data collection forms.pdf (Manual of Operations for “Core” phase)
  - A2ALL Core Protocol Amendment 3 V2.1.pdf (Protocol for “Core” phase)
  - A2ALL Core SAF Documentation Final.pdf (Description of the data files included for the “Cohort” and “Core” phases of the study)
  - Analyses File Documentation.pdf (Description of the analysis files included for the “Cohort” and “Core” phases of the study)
  - The following codebooks at various time-points post-transplants, containing information regarding variable coding and the corresponding question on the forms:
    - Long-term follow-up Time 1 Codebook December 2012.doc
    - Prospective study 1 year follow-up Codebook December 2011.doc
    - Prospective study 2 year follow-up Codebook December 2011.doc
    - Prospective 3 month follow-up Codebook October 2011.doc
    - Prospective study 6 month follow-up Codebook December 2011.doc
    - Prospective study Predonation Codebook May 2014.docx
- A2ALL Bibliography\_revised\_April 2016.docx – List of all publications from the A2ALL study as of April 2016
- A2ALL public study website URL.pdf – Link to study website
- IDs\_with\_Images.xlsx – Listing of all A2ALL IDs that have images available in the repository. These images are not included in the regular data package, however, they can be made available upon request.

## **A2ALL Data**

The A2ALL data directory contains the following raw datasets in *PC-SAS*, v.7-8-9 format:

- Retrospective – Data from the “Retro” phase of the study:
  - CONTENTS.lst
  - niddk\_cdr\_retro\_dnr.sas7bdat (Donor data set)
    - Formatted SAS data set containing raw data collected from Donor participants
    - 478 variables, 1011 observations

- niddk\_cdr\_retro\_pairs.sas7bdat (Donor to Recipient data set)
  - Formatted SAS data set that links Donor with Recipient participants via participant ID
  - 4 variables, 1011 observations
  - Matched Recipient IDs are missing for 1 Donor IDs: 3351
- niddk\_cdr\_retro\_rcp.sas7bdat (Recipient data set)
  - Formatted SAS data set containing raw data collected from Recipient participants
  - 1068 variables, 819 observations
- niddk\_cdr\_retro\_rcp\_srtr.sas7bdat (SRTR Recipient data set)
  - Formatted SAS dataset containing data submitted to the Scientific Registry of Transplant Recipients (SRTR)
  - 53 variables, 819 observations
- formats.sas7bcat/formats.txt - SAS user-defined formats associated with aforementioned datasets
- Core – Data from the “Core” and “Cohort” phases of the study. See “A2ALL Core SAF Documentation Final.pdf” and “Analyses File Documentation.pdf” in the Documentation folder for more information on these datasets:
  - A2ALLDnrDataDictionary.xls – Data dictionary for all donor-related datasets
  - A2ALLRcpDataDictionary.xls – Data Dictionary for all recipient-related datasets
  - Formats\_Cohort.sas
  - Formats\_Comb.sas
  - Formats\_Diagnosis.sas
  - Formats\_Retro.sas
  - cif\_death1.sas7bdat
  - cif\_death2.sas7bdat
  - cif\_death3.sas7bdat
  - cif\_death4.sas7bdat
  - cif\_death5.sas7bdat
  - cif\_death6.sas7bdat
  - cif\_death7.sas7bdat
  - cif\_death8.sas7bdat
  - cif\_gf\_death.sas7bdat
  - cif\_gf\_retxp.sas7bdat
  - crisk\_death.sas7bdat
  - crisk\_gf.sas7bdat
  - dnr\_basic\_all.sas7bdat
  - dnr\_basic\_rc.sas7bdat
  - dnr\_comp\_all.sas7bdat
  - dnr\_comp\_rc.sas7bdat
  - dnr\_eval\_rc.sas7bdat
  - dnr\_hosp\_all.sas7bdat
  - dnr\_hosp\_rc.sas7bdat



- dnr\_hrqolonly\_assessment.sas7bdat
- dnr\_hrqolonly\_comp.sas7bdat
- dnr\_intraop\_all.sas7bdat
- dnr\_intraop\_rc.sas7bdat
- dnr\_postdnt\_all.sas7bdat
- dnr\_postdnt\_rc.sas7bdat
- donor\_pain\_survey.sas7bdat
- ltqol\_surveys.sas7bdat
- outcomes\_all.sas7bdat
- outcomes.sas7bdat
- prospectqol\_surveys.sas7bdat
- rcp\_basic\_all.sas7bdat
- rcp\_basic\_rc.sas7bdat
- rcp\_comp\_all.sas7bdat
- rcp\_comp\_rc.sas7bdat
- rcp\_dnreval\_enroll\_all.sas7bdat
- rcp\_eval\_rc.sas7bdat
- rcp\_exp\_all.sas7bdat
- rcp\_exp\_rc.sas7bdat
- rcp\_hcvadvdis\_x.sas7bdat
- rcp\_hcvelast\_x.sas7bdat
- rcp\_hcvstudyinfo\_x.sas7bdat
- rcp\_hcvsubflow\_x.sas7bdat
- rcp\_hcvtxpinfo\_x.sas7bdat
- rcp\_hosp\_all.sas7bdat
- rcp\_hosp\_rc.sas7bdat
- rcp\_intraop\_all.sas7bdat
- rcp\_intraop\_rc.sas7bdat
- rcp\_list\_retro.sas7bdat
- rcp\_list\_r.sas7bdat
- rcp\_posttxp\_all.sas7bdat
- rcp\_posttxp\_bx\_all.sas7bdat
- rcp\_posttxp\_bx\_rc.sas7bdat
- rcp\_posttxp\_rc.sas7bdat
- rcp\_pretp\_c.sas7bdat
- rcp\_rej\_rc.sas7bdat
- rcp\_txp\_all.sas7bdat
- rcp\_txp\_rc.sas7bdat

## **A2ALL DSIC**

The A2ALL DSIC directory contains:

- A2ALL\_DSIC\_Core.pdf - A report of an examination of the repository for completeness by statisticians and quality control specialists at the Repository. Core datasets were checked for completeness. The published data from the A2ALL study were compared to values recalculated from the A2ALL data in the NIDDK repository.
- A2ALL\_DSIC\_FINAL\_Nov2010\_Retro.pdf - A report of an examination of the repository for completeness by statisticians and quality control specialists at the Repository. Retrospective datasets were checked for completeness. The published data from the A2ALL study were compared to values recalculated from the A2ALL data in the NIDDK repository.
- A2ALL\_Images\_DSIC.pdf - A report of an examination of the repository for completeness by statisticians and quality control specialists at the Repository. Data related to the A2ALL Images were checked for completeness. The published data from the A2ALL study were compared to values recalculated from the A2ALL data in the NIDDK repository.

**NOTE:** The dnr\_basic\_all.sas7bdat dataset in the Core data contained a typo for the subject with dnr\_ID 'D1901'. The value for the variable 'dnr\_rgtlobe\_vol\_rcx' had a decimal misplaced in the original version of the dataset sent by the DCC. This value was corrected for the final version of the dataset that is currently included in the data package. The 'dnr\_lvol\_prednt\_rcx' variable was also adjusted accordingly.

## Appendix 1. A2ALL Module Descriptions

### Recipient Modules

<u>Recipient Data Modules (in MOO)</u>	<u>Core Module</u>	<u>Purpose (based on MOO pp.69-70)</u>	<u>Notes / skip logic (based on MOO pp. 181-185)</u>
2. Recipient Study Enrollment	x		The date that the RCP's potential donor had their history and physical is defined as the study enrollment for the subject.
3. Recipient Demographics	x		
4. Listing and Transplant Information	x	Validates SRTR transplant date. Tells us whether we need to fill out intraoperative or morbidity data.	
5. Recipient Condition at Listing	x	Collects information about the recipients' condition when first listed for transplant. Validates some SRTR elements.	
6. Recipient Condition at Enrollment	x	Captures changes in the recipients' status in the interval between listing and enrollment.	
7. Recipient Condition at Transplant		To collect bsln covariates for LDLT vs CAD analyses. Captures changes in the recipients' status in the interval between enrollment and transplant.	Completed if subject answered 'yes' to transplant surgery (in Module 4).
8. HCC Data at Listing - 8a. HCC Assessment Form		To collect bsln characteristics of HCC, and ablative treatments prior to Enrollment.	Completed if subject has HCC at the time of listing (in Module 5). For HCC assessment, refer to Form 8a.
9. HCC Data at Enrollment		To collect characteristics of HCC, and ablative treatments between listing and enrollment. Shows disease progression while on the waiting list.	Completed if subject has HCC at time of enrollment (in Module 6).
10. HCC Data Immediately Prior to Transplant		To collect bsln characteristics of HCC, and ablative treatments between enrollment and TXP. Shows disease progression while on the waiting list.	Completed if subject has HCC at time of transplant (in Module 7).
11. HCV at Enrollment - 11a. Knodell Score		To collect characteristics of HCV. Possible covariate for analysis of survival or hospitalization. This form covers the period from listing to enrollment.	Completed if subject has HCV at time of enrollment (in Module 6). The Knodell score (Module 11a) to be entered on this form should be taken directly from the pathologist's report. If it's not available, enter none.

<u>Recipient Data Modules (in MOO)</u>	<u>Core Module</u>	<u>Purpose (based on MOO pp.69-70)</u>	<u>Notes / skip logic (based on MOO pp. 181-185)</u>
12. HCV Data at Transplant		To collect baseline characteristics of HCV for LDLT vs CAD analysis. Shows the progression of disease in the interval between enrollment and transplant.	Completed if subject has HCV at time of transplant (in Module 7). The Knodell score (Module 11a) to be entered on this form should be taken directly from the pathologist's report. If it's not available, enter none.
13. Recipient Intraoperative Data		To collect possible predictors of outcomes comparing LDLT vs CAD for recipients.	Completed if subject answered 'yes' to transplant surgery (in Module 4).
14. HCC Explant Assessment		To exclude patients who did not have HCC at the time of transplant. To confirm pre-operative assessment of cancer stage.	Completed if subject has HCC at time of transplant (in Module 7) and answered 'yes' to transplant surgery (in Module 4). Refer to the explant assessment form for tumor grading.
15. Recipient Baseline Immunosuppression and Rejection Episodes		To collect information on rejection (Aim 3.2.2). To collect information on post-operative complications (Aim 3.6.1).	Completed if subject answered 'yes' to transplant surgery (in Module 4). Baseline refers to the time immediately post-transplant. For the immunosuppressive regimen at baseline, check all that apply; this will also include any antibody induction treatment used at the time of the transplant procedure.
16. Multiple Rejection Episodes and Treatment		To collect information on rejection (Aim 3.2.2). To collect information on post-operative complications (Aim 3.6.1).	Completed if there was >1 treated rejection episode. An individual form is completed for each treated rejection episode.
17. Recipient Hospitalizations and 17a. Liver Diagnosis Codes	x	To collect information on recipient hospitalizations.	An individual form is completed for each hospitalization. For liver diagnosis codes refer to pick list of diagnoses (Module 17a).
18. Recipient Morbidity		To collect information on post-operative complications (Aim 3.6.1). To collect information on frequency of specific complications. To collect information on post-operative resource utilization.	Completed if subject answered 'yes' to transplant surgery (in Module 4).
19. Recipient Complication Severity - 19a. Definitions of Recipient Adverse Events		To collect information on the particular complication(s) reported on the RCP Morbidity Form.	Completed if subject answered 'yes' to any complications on the Recipient Morbidity Form (Module 18); one form per complication. Each Severity Form is named for the complication it describes (e.g., 'Biloma Severity Form'). For definitions of recipient adverse events, see Module 19a.

<u>Recipient Data Modules (in MOO)</u>	<u>Core Module</u>	<u>Purpose (based on MOO pp.69-70)</u>	<u>Notes / skip logic (based on MOO pp. 181-185)</u>
20. HCV Post-op Recurrence and Treatment (Rx) Data		To collect HCC recurrence (Aim 3.3.1). HCV severity at 1 year post treatment. Fibrosis progression at 1 year and most recent follow-up. Presence of cholestatics hepatitis.	Completed if subject has HCV at time of transplant (in Module 7). The Knodell score (Module 11a) to be entered on this form should be taken directly from the pathologist's report. If it's not available, enter none.
21. HCC Post-op Recurrence and Treatment (Rx) Data		HCC Recurrence (Aim 3.4.2). HCC post-op ablations.	Completed if subject has HCC at time of transplant (in Module 7).
22. Graft Outcomes		To compare graft outcomes in LDLT and CAD recipients. To collect information on graft loss (Aim 3.3.2).	Completed if subject answered 'yes' to transplant surgery (in Module 4), or if subject answered 'yes' to being re-transplanted (in Module 23).
23. Recipient Patient Survival (survival status) and 23a. Recipient Cause of Death Codes	x	To compare survival between LDLT & CAD recipients.	For recipient cause of death, refer to code list (Module 23a).

## Donor Modules

<u>Donor Data Modules (in MOO)</u>	<u>Core Module</u>	<u>Purpose (based on MOO pp.69-70)</u>	<u>Notes / skip logic (based on MOO pp. 181-185)</u>
25. Donor Study Enrollment	x		
26. Donor Demographics	x		
27. Donor Evaluation	x		Same as donor 'history and physical'.
28. Donor Intraoperative Data		To collect possible predictors of morbidity for donors.	Completed if the donor was accepted and transplant was performed (Module 25).
29. Donor Hospitalizations- 29a. Liver Diagnosis Codes		To collect information on donor hospitalizations.	An individual form is completed for each hospitalization. For liver diagnosis codes refer to pick list of diagnoses (Module 29a).
30. Donor Morbidity		To collect information on post-operative complications (Aim 3.6.1). To collect information on frequency of specific complications. To collect information on post-operative resource utilization.	
31. Donor Complication Severity - 31a. Definitions of Donor Adverse Events		To collect information on the particular complication(s) reported on the DNR Morbidity Form.	Completed if subject answered 'yes' to any complications on the Donor Morbidity Form (Module 30); one form per complication. For definitions of donor adverse events, see Module 31a.
32. Donor Patient Survival (survival status)	x	To collect information on donor outcomes.	