Genomics of Drug Induced Renal Injury (DIRI) : Screening Log

DR1 - CRF 01

Patient ID: | | | | | | |

Coordinator ID: | | | | | |

Form ID: | | | | | | - | | | | | |

1. Date of Screening: | | / | | / | | | | (mm/dd/yyyy)

2. Patient location during the index event of this study: ○ Inpatient ○ Outpatient

Demographics

Please enter patient data as recorded at hospital admission (for inpatient) or clinic visit (for outpatient) around which the index event occurred. Ethnic and racial data are self-reporting by the patient based on modified NIH categorization as follows:

- American Indian or Alaska Native: A person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliations or community attachment.
- Asian: A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent.
- Black or African American: A person having origins in any of the black racial groups of Africa.
- Native Hawaiian or Other Pacific Islander: A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.
- White: A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.
- Hispanic or Latino: In this study "Hispanic or Latino" refers to the ethnic population with origins in the countries of Latin America.

3. Gender: ○ Male ○ Female

4. Age: | |

5. Weight: | | | . | | kg ☐ **NA**

6. Height: | | | . | | ○ inch ○ cm ☐ **NA**

7. Race:

○ American Indian or Alaska Native
○ Asian
○ Black
○ Native Hawaiian or Other Pacific Islander
○ White
○ Hispanic or Latino
○ Not Reported
○ Other (please specify) **:**

DIRI Phenotypes and Candidate Drugs

8. Select the DIRI phenotype to investigate on this patient:

(Note: Glomerular disorder phenotype requires kidney biopsy findings to be eligible for study.)

○ AKI (Nephrotoxic, Allergic, Mixed)
○ Glomerular Disorder (Hematuria, Heavy Proteinuria, GN)

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9. Review candidate drugs included for study for respective DIRI phenotypes:

Candidate Drugs for AKI Phenotype

A01-Abacavir	C04-Ciprofloxacin	I05-Imipenem	P02-Pantoprazole
A02-Acyclovir	C05-Cisplatin	I04-Indomethacin	P03-Penicillin
A08-Allopurinol	C15-Citalopram	I06-Ipilimumab	P07-Phenytoin
A03-Amikacin	C12-Clindamycin	I07-Irbesartan	P04-Piperacillin/ tazobactam
A04-Amoxicillin	C06-Colistin	K02-Ketoprofen	
A05-Amphotericin	C07-Cylosporine	K01-Ketorolac	P06-Polymyxin
A06-Ampicillin	D02-Daptomycin	L02-Lansoprazole	R01-Rifampin
A07-Atazanavir	D03-Diclofenac	L03-Levofloxacin	S04-Streptomycin
C11-Carbamazepine	D01-Didanosine	M01-Meropenem	S02-Sulfadiazine
C09-Carboplatin	D04-Doxycycline	M02-Mesalamine	S01-Sulfamethoxazole/ trimethoprim
C10-Cefalexin	E01-Esomeprazole	M04-Metformin	
C01-Cefazolin	E02-Etanercept	M03-Methotrexate	S03-Sulfasalazine
C13-Cefepime	F03-Flucloxacillin	N01-Nafcillin	T01-Tacrolimus
C08-Ceftaroline	F01-Foscarnet	N02-Naproxen	T05-Teicoplanin
C02-Ceftazidime	G02-Gemcitabine	N03-Nitrofurantoin	T02-Tenofovir
C14-Ceftriaxone	G01-Gentamicin	O03-Olmesartan	T03-Tobramycin
C16-Celecoxib	I01-Ibuprofen	O01-Omeprazole	T04-Torsemide
C03-Cidofovir	I02-Ifosfamide	O02-Oxacillin	V01-Vancomycin

Candidate Drugs for Glomerular Disorder Phenotype

A04-Amoxicillin	G02-Gemcitabine	N01-Nafcillin	P04-Piperacillin/ tazobactam
A06-Ampicillin	H01-Hydralazine	N02-Naproxen	
B01-Bevacuzimub	I01-Ibuprofen	O01-Omeprazole	P05-Propylthiouracil
C03-Cidofovir	I02-Ifosfamide	O02-Oxacillin	R01-Rifampin
C07-Cylosporine	I04-Indomethacin	P01-Pamidronate	R02-Ritonavir
E01-Esomeprazole	K01-Ketorolac	P02-Pantoprazole	T01-Tacrolimus
E03-Exenatide	L02-Lansoprazole	P03-Penicillin	

10. Does the candidate drug list (item 9) for the selected phenotype (item 8) include at least one of the drugs you wish to investigate on this patient? (Please note that a drug can only be considered for study if the patient was exposed to this drug for at least 24 hours.)

○ Yes ○ No

If No, stop screening for this patient.

11. If Yes, please select up to three drugs from the list you wish to investigate and enter their drug IDs and trade names in order of preference: (Drug ID is the three-character string, e.g. V01 for Vancomycin, which prefixes each drug name in the drug lists in item 9.)

	Drug ID	Trade Name
a. Drug 1 (primary drug):		
b. Drug 2 (optional drug):		
c. Drug 3 (optional drug):		

Chronic Kidney Disease (CKD) Status

12. Lowest serum creatinine between 90 days to 12 months prior to hospital admission or first clinic visit date:

a. CKD Baseline Creatinine: | | | | | . | | ○ mg/dL ○ umol/L ☐ **NA**

b. Date Recorded: | | / | | / | | | | | (mm/dd/yyyy)

13. If CKD baseline creatinine is available, look up in CKD Stage 5 Creatinine Table (Appendix 1 or 2 of this CRF) for the lowest creatinine value at which level this patient would be considered CKD Stage 5 (eGFR < 15 mL/min/1.73 m^2) and record the value below.

a. CKD Stage 5 Creatinine: | | | | | . | | ○ mg/dL ○ umol/L

14. Historical evidence of CKD based on standard criteria: proteinuria, biopsy, ultrasound size.

○ Yes ○ No

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Risk Factors

15. Does patient have high risk for AKI? ○ Yes ○ No ○ Unknown

If yes, please check all applicable risk factors:

- ☐ Age > 75
- ☐ Severe Infection (Sepsis)
- ☐ Chronic Heart Failure
- ☐ Chronic Liver Disease
- ☐ Decreased Albumin (< 3 g/dL or 30 g/L)
- ☐ Anemia (Hb < 9 g/dL)
- ☐ Radiocontrast 72 hours prior to drug exposure
- ☐ Hypotension (Shock, MAP < 60)
- ☐ Diabetes
  - If diabetic, answer the following check list:
  - ☐ Requires Medication
  - ☐ Requires Insulin
- ☐ Hyperglycemia (Glucose > 110 mg/dL or 6.1 mmol/L)
- ☐ Peripheral Vascular Disease
- ☐ Chronic Lung Disease (COPD)

Inclusion Criteria (All answers must be "Yes" for patient to be considered for study.)

16. ○ Yes ○ No **Age ≥ 2 years.**

17. ○ Yes ○ No **Exposure to a DIRI medication to be studied.**

Exclusion Criteria (All answers must be "No" for patient to be considered for study.)

18. ○ Yes ○ No **Unable to provide written informed consent.**

19. ○ Yes ○ No **Patient with a history or have a kidney transplant.**

20. ○ Yes ○ No **Patient with bone marrow transplant.**

21. ○ Yes ○ No **Patient with CKD stage 5 (item 12a ≥ item 13a, mark No if creatinine value not available).**

22. ○ Yes ○ No **On more than 3 causal agents.**

23. ○ Yes ○ No **No history on time course for drug exposure.**

24. ○ Yes ○ No **Incomplete data elements.**

Stop screening for this patient if patient did not meet all inclusion and exclusion criteria.

Kidney Biopsy

25. Was there abnormal result observed in a kidney biopsy performed within four weeks after stopping the drug you wish to investigate? (Please note that kidney biopsy is a prerequisite for glomerular discorder phenotype.)

○ Yes ○ No ○ No biopsy performed

If Yes, please answer the following questions:

a. Date Biopsy Performed: | | / | | / | | | | | | (mm/dd/yyyy)

b. Biopsy Findings: (Check all that apply)

- ☐ Acute Interstitial Nephritis
- ☐ Acute Tubular Necrosis
- ☐ Glomerulonephritis
- ☐ Thrombosis with HUS/TTP/HSP
- ☐ Other:

Stop screening for this patient if you have selected to investigate glomerular discorder phenotype and no kidney biopsy findings were observed.

Road Map for Eligibility Check Using DIRI Criteria

26. Based on the phenotype and DIRI criteria specified in the following, please answer questions in the pertinent sections to determine patient's eligibility for enrollment with this study:

- ○ AKI phenotype with AKIN stage 2 criteria based on rising serum creatinine **----> Complete questions 27 - 29**
- ○ AKI phenotype with AKIN stage 2 criteria based on declining serum creatinine **----> Complete questions 30 - 32**
- ○ Glomerular disorder phenotype **----> Complete questions 33 - 38**

Genomics of Drug Induced Renal Injury (DIRI) : Screening Log

Patient ID: ☐☐☐☐☐☐ **Form ID:** ☐☐☐☐☐ - ☐☐☐☐☐

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AKI Phenotype - Primary Criteria for DIRI - AKIN Stage 2 - Rising Serum Creatinine

Rise in serum creatinine that presents as or progresses to AKIN Stage 2 (KDIGO) in relation to drug exposure.

27. Enter start date/time and stop date/time for the candidate drugs you selected in item 11:

a. Drug 1 (primary drug) Drug ID: ☐☐☐ (copy drug ID from item 11a.)

i. Start Date/Time: ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy) ☐☐:☐☐ (24hr clock)

ii. Stop Date/Time: ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy) ☐☐:☐☐ (24hr clock) ☐ **NA**

b. Drug 2 (optional drug) Drug ID: ☐☐☐ (copy drug ID from item 11b.)

i. Start Date/Time: ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy) ☐☐:☐☐ (24hr clock)

ii. Stop Date/Time: ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy) ☐☐:☐☐ (24hr clock) ☐ **NA**

c. Drug 3 (optional drug) Drug ID: ☐☐☐ (copy drug ID from item 11c.)

i. Start Date/Time: ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy) ☐☐:☐☐ (24hr clock)

ii. Stop Date/Time: ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy) ☐☐:☐☐ (24hr clock) ☐ **NA**

28. Scenario 1 - Use <u>lowest</u> creatinine value as reference

a. Reference Creatinine - Lowest SCr within 90 days prior to drug exposure.

i. Creatinine: ☐☐☐☐.☐☐ ○ mg/dL ○ umol/L

ii. Date/Time: ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy) ☐☐:☐☐ (24hr clock)

b. Qualifying Creatinine - Multiply reference creatinine by 2: ☐☐☐☐.☐☐ ○ mg/dL ○ umol/L

(If this is a pediatric patient and the value is less than 0.5 mg/dL or 44.2 umol/L then enter 0.5 mg/dL or 44.2 umol/L here)

c. First creatinine that is greater than or equal to qualifying creatinine (28b) 24 hours after starting the drug:

i. Found occurrence: ○ Yes ○ No

ii. Creatinine: ☐☐☐☐.☐☐ ○ mg/dL ○ umol/L

iii. Data Date/Time: ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy) ☐☐:☐☐ (24hr clock)

29. Scenario 2 - Use <u>closest</u> creatinine value as reference

a. Reference Creatinine - Closest SCr prior to drug exposure.

i. Creatinine: ☐☐☐☐.☐☐ ○ mg/dL ○ umol/L

ii. Date/Time: ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy) ☐☐:☐☐ (24hr clock)

b. Qualifying Creatinine - Multiply reference creatinine by 2: ☐☐☐☐.☐☐ ○ mg/dL ○ umol/L

(If this is a pediatric patient and the value is less than 0.5 mg/dL or 44.2 umol/L then enter 0.5 mg/dL or 44.2 umol/L here)

c. First creatinine that is greater than or equal to qualifying creatinine (29b) 24 hours after starting the drug:

i. Found occurrence: ○ Yes ○ No

ii. Creatinine: ☐☐☐☐.☐☐ ○ mg/dL ○ umol/L

iii. Data Date/Time: ☐☐/☐☐/☐☐☐☐ (mm/dd/yyyy) ☐☐:☐☐ (24hr clock)

Please log on to the DIRECT study website at https://www.obriendata.org/DIRECT, enter all the patient and durg information you have gathered here into the database so that the software will help you determine which drugs met the DIRI criteria. Then continue at question 39 on page 7 to complete the screening log.

AKI Phenotype - Primary Criteria for DIRI - AKIN Stage 2 - Declining Serum Creatinine

Decline in serum creatinine as defined by AKIN Stage 2 (KDIGO) in relation to drug dose reduction or drug stopping.

Note: This section is not applicable to pediatric patients if the peak creatinine during drug exposure did not exceed 0.5 mg/dL or 44.2 umol/L.

30. Which of the following scenarios will be used for evaluation of DIRI eligibility?

- ○ Decline in serum creatinine in relation to dose reduction
- ○ Decline in serum creatinine in relation to drug stopping

31. Enter start date/time, and date/time of first dose reduction after peak serum creatinine or date/time when drug stopped for the candidate drugs you selected in item 11:

a. Drug 1 (primary drug) Drug ID: ☐☐☐ (copy drug ID from item 11a.)

i. Start Date/Time: ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy) ☐☐ : ☐☐ (24hr clock)

ii. Dose Reduction or Drug Stopping Date/Time: ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy) ☐☐ : ☐☐ (24hr clock) ☐ **NA**

b. Drug 2 (optional drug) Drug ID: ☐☐☐ (copy drug ID from item 11b.)

i. Start Date/Time: ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy) ☐☐ : ☐☐ (24hr clock)

ii. Dose Reduction or Drug Stopping Date/Time: ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy) ☐☐ : ☐☐ (24hr clock) ☐ **NA**

c. Drug 3 (optional drug) Drug ID: ☐☐☐ (copy drug ID from item 11c.)

i. Start Date/Time: ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy) ☐☐ : ☐☐ (24hr clock)

ii. Dose Reduction or Drug Stopping Date/Time: ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy) ☐☐ : ☐☐ (24hr clock) ☐ **NA**

32. a. Reference Creatinine - Peak SCr during drug exposure. (must be at least 0.5 mg/dL or 44.2 umol/L for children)

i. Creatinine: ☐☐☐☐.☐☐ ○ mg/dL ○ umol/L

ii. Date/Time: ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy) ☐☐ : ☐☐ (24hr clock)

b. Qualifying Creatinine - Multiply reference creatinine by 0.5: ☐☐☐☐.☐☐ ○ mg/dL ○ umol/L

c. First creatinine that is less than or equal to qualifying creatinine (32b) 24 hours after dose reduction or immedicately after drug stopping:

i. Found occurrence: ○ Yes ○ No

ii. Creatinine: ☐☐☐☐.☐☐ ○ mg/dL ○ umol/L

iii. Data Date/Time: ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy) ☐☐ : ☐☐ (24hr clock)

Please log on to the DIRECT study website at https://www.obriendata.org/DIRECT, enter all the patient and durg information you have gathered here into the database so that the software will help you determine which drugs met the DIRI criteria. Then continue at question 39 on page 7 to complete the screening log.

Glomerular Disease Phenotype - Primary Criteria for DIRI - UA & UC

33. Enter start date/time and stop date/time for the candidate drugs you selected in item 11:

a. Drug 1 (primary drug) Drug ID: [ ][ ][ ] (copy drug ID from item 11a.)

i. Start Date/Time: [ ][ ] / [ ][ ] / [ ][ ][ ][ ] (mm/dd/yyyy) [ ][ ] : [ ][ ] (24hr clock)

ii. Stop Date/Time: [ ][ ] / [ ][ ] / [ ][ ][ ][ ] (mm/dd/yyyy) [ ][ ] : [ ][ ] (24hr clock) ☐ **NA**

b. Drug 2 (optional drug) Drug ID: [ ][ ][ ] (copy drug ID from item 11b.)

i. Start Date/Time: [ ][ ] / [ ][ ] / [ ][ ][ ][ ] (mm/dd/yyyy) [ ][ ] : [ ][ ] (24hr clock)

ii. Stop Date/Time: [ ][ ] / [ ][ ] / [ ][ ][ ][ ] (mm/dd/yyyy) [ ][ ] : [ ][ ] (24hr clock) ☐ **NA**

c. Drug 3 (optional drug) Drug ID: [ ][ ][ ] (copy drug ID from item 11c.)

i. Start Date/Time: [ ][ ] / [ ][ ] / [ ][ ][ ][ ] (mm/dd/yyyy) [ ][ ] : [ ][ ] (24hr clock)

ii. Stop Date/Time: [ ][ ] / [ ][ ] / [ ][ ][ ][ ] (mm/dd/yyyy) [ ][ ] : [ ][ ] (24hr clock) ☐ **NA**

34. ○ Yes ○ No ○ No Data **Did patient have elevated proteinuria that met the following criteria following exposure to drug?**

Adult patient
24-hour urine collection > 1000 mg

Pediatric patient
24-hour urine collection > 100 mg/m2/day
Random urine collection > 4 mg/m2/hr

If Yes, record the incidence in the following:

a. Protein: [ ][ ][ ][ ] ○ mg/day ○ mg/m2/day ○ mg/m2/hr

b. Data Date/Time: [ ][ ] / [ ][ ] / [ ][ ][ ][ ] (mm/dd/yyyy) [ ][ ] : [ ][ ] (24hr clock)

35. ○ Yes ○ No ○ No Data **Did patient's urine protein creatinine ratio (UPC) exceed 0.8 following exposure to drug?**

If Yes, record the incidence in the following:

a. UPC: [ ] . [ ]

b. Data Date/Time: [ ][ ] / [ ][ ] / [ ][ ][ ][ ] (mm/dd/yyyy) [ ][ ] : [ ][ ] (24hr clock)

36. ○ Yes ○ No ○ No Data **Did patient's urinalysis show 2+ protein following exposure to drug?**

If Yes, record the incidence in the following:

a. Protein: ○ Negative ○ Trace ○ 1+ ○ 2+ ○ 3+ ○ 4+ ○ NA

b. Data Date/Time: [ ][ ] / [ ][ ] / [ ][ ][ ][ ] (mm/dd/yyyy) [ ][ ] : [ ][ ] (24hr clock)

37. ○ Yes ○ No ○ No Data **Did patient's urinalysis show > 50 RBC/HPF following exposure to drug?**

If Yes, record the incidence in the following:

a. Data Date/Tiime: [ ][ ] / [ ][ ] / [ ][ ][ ][ ] (mm/dd/yyyy) [ ][ ] : [ ][ ] (24hr clock)

38. ○ Yes ○ No ○ No Data **Did patient's urinalysis show dysmorphic RBC following exposure to drug?**

If Yes, record the incidence in the following:

a. Data Date/Time: [ ][ ] / [ ][ ] / [ ][ ][ ][ ] (mm/dd/yyyy) [ ][ ] : [ ][ ] (24hr clock)

Please log on to the DIRECT study website at https://www.obriendata.org/DIRECT, enter all the patient and durg information you have gathered here into the database so that the software will help you determine which drugs met the DIRI criteria. Then continue at question 39 on page 7 to complete the screening log.

Screening Summary

39. Mark the drugs that met DIRI criteria according to the result of eligibility check on the DIRECT study website:

☐ Drug 1 ☐ Drug 2 ☐ Drug 3 ☐ None

40. Is patient eligible for this study? (Patient is eligible for study if patient passed all inclusion/exclusion criteria and any selected study drug met DIRI criteria.)

○ Yes ○ No

Informed Consent

41. Was informed consent obtained?

Note: A signed informed consent must be obtained in order to enroll the patient unless your IRB has agreed that no consent is needed for this study or the patient has signed a consent waiver.

○ Yes ○ No ○ No Consent Needed

42. If consent was obtained, answer the following questions:

a. Date Consent Signed: | | / | | / | | | | (mm/dd/yyyy)

b. Who signed the consent? ○ Patient ○ Spouse ○ Patient Representative ○ Parent

c. Who obtained the consent? ○ Investigator ○ Coordinator ○ Other MD

43. If consent form was not obtained, mark below the primary reason for not obtaining consent:

○ Patient decision	○ Patient representative decision	○ Physician decision
○ Death	○ Renal recovery	○ Site personnel issues
○ No one to give consent	○ Discharged from hospital	○ Other

APPENDIX 1

CKD Stage 5 Creatinine Table - For Children of Age 2 - 17

Following table shows the lowest creatinine (IDMS traceable) value that would result in eGFR 14 (CKD stage 5) for given height of a patient using Bedside Schwartz equation. This table is valid only for pediatric patients of age 2 - 17.

Height (cm)	Creatinine		Height (cm)	Creatinine		Height (cm)	Creatinine	
	mg/dL	umol/L		mg/dL	umol/L		mg/dL	umol/L
50	1.42	125.5	100	2.83	250.2	150	4.25	375.7
51	1.45	128.2	101	2.86	252.8	151	4.27	377.5
52	1.48	130.8	102	2.89	255.5	152	4.30	380.1
53	1.50	132.6	103	2.92	258.1	153	4.33	382.8
54	1.53	135.3	104	2.95	260.8	154	4.36	385.4
55	1.56	137.9	105	2.97	262.5	155	4.39	388.1
56	1.59	140.6	106	3.00	265.2	156	4.42	390.7
57	1.62	143.2	107	3.03	267.9	157	4.44	392.5
58	1.65	145.9	108	3.06	270.5	158	4.47	395.1
59	1.67	147.6	109	3.09	273.2	159	4.50	397.8
60	1.70	150.3	110	3.12	275.8	160	4.53	400.5
61	1.73	152.9	111	3.14	277.6	161	4.56	403.1
62	1.76	155.6	112	3.17	280.2	162	4.59	405.8
63	1.79	158.2	113	3.20	282.9	163	4.61	407.5
64	1.81	160.0	114	3.23	285.5	164	4.64	410.2
65	1.84	162.7	115	3.26	288.2	165	4.67	412.8
66	1.87	165.3	116	3.29	290.8	166	4.70	415.5
67	1.90	168.0	117	3.31	292.6	167	4.73	418.1
68	1.93	170.6	118	3.34	295.3	168	4.76	420.8
69	1.96	173.3	119	3.37	297.9	169	4.78	422.6
70	1.98	175.0	120	3.40	300.6	170	4.81	425.2
71	2.01	177.7	121	3.43	303.2	171	4.84	427.9
72	2.04	180.3	122	3.45	305.0	172	4.87	430.5
73	2.07	183.0	123	3.48	307.6	173	4.90	433.2
74	2.10	185.6	124	3.51	310.3	174	4.92	434.9
75	2.13	188.3	125	3.54	312.9	175	4.95	437.6
76	2.15	190.1	126	3.57	315.6	176	4.98	440.2
77	2.18	192.7	127	3.60	318.2	177	5.01	442.9
78	2.21	195.4	128	3.62	320.0	178	5.04	445.5
79	2.24	198.0	129	3.65	322.7	179	5.07	448.2
80	2.27	200.7	130	3.68	325.3	180	5.09	450.0
81	2.30	203.3	131	3.71	328.0	181	5.12	452.6
82	2.32	205.1	132	3.74	330.6	182	5.15	455.3
83	2.35	207.7	133	3.77	333.3	183	5.18	457.9
84	2.38	210.4	134	3.79	335.0	184	5.21	460.6
85	2.41	213.0	135	3.82	337.7	185	5.24	463.2
86	2.44	215.7	136	3.85	340.3	186	5.26	465.0
87	2.46	217.5	137	3.88	343.0	187	5.29	467.6
88	2.49	220.1	138	3.91	345.6	188	5.32	470.3
89	2.52	222.8	139	3.94	348.3	189	5.35	472.9
90	2.55	225.4	140	3.96	350.1	190	5.38	475.6
91	2.58	228.1	141	3.99	352.7	191	5.41	478.2
92	2.61	230.7	142	4.02	355.4	192	5.43	480.0
93	2.63	232.5	143	4.05	358.0	193	5.46	482.7
94	2.66	235.1	144	4.08	360.7	194	5.49	485.3
95	2.69	237.8	145	4.11	363.3	195	5.52	488.0
96	2.72	240.4	146	4.13	365.1	196	5.55	490.6
97	2.75	243.1	147	4.16	367.7	197	5.58	493.3
98	2.78	245.8	148	4.19	370.4	198	5.60	495.0
99	2.80	247.5	149	4.22	373.0	199	5.63	497.7

APPENDIX 2

CKD Stage 5 Creatinine Table - For Patients of Age 18 and Older

Following table shows the lowest creatinine (IDMS traceable) value that would result in eGFR 14 (CKD stage 5) for given age, gender, and race of a patient using CKD-EPI equation. This table is valid only for adult patients of age 18 and older.

	Creatinine mg/dl					Creatinine umol/L			
	Male		*Female*			*Male*		*Female*	
Age	Black	Other	Black	Other	*Age*	Black	Other	Black	Other
18	6.02	5.32	4.75	4.20	18	532.2	470.3	419.9	371.3
19	5.98	5.29	4.72	4.18	19	528.6	467.6	417.2	369.5
20	5.95	5.26	4.69	4.16	20	526.0	465.0	414.6	367.7
21	5.91	5.23	4.67	4.13	21	522.4	462.3	412.8	365.1
22	5.88	5.20	4.64	4.11	22	519.8	459.7	410.2	363.3
23	5.84	5.17	4.61	4.08	23	516.3	457.0	407.5	360.7
24	5.81	5.14	4.59	4.06	24	513.6	454.4	405.8	358.9
25	5.78	5.11	4.56	4.04	25	511.0	451.7	403.1	357.1
26	5.74	5.08	4.53	4.01	26	507.4	449.1	400.5	354.5
27	5.71	5.05	4.51	3.99	27	504.8	446.4	398.7	352.7
28	5.68	5.02	4.48	3.97	28	502.1	443.8	396.0	350.9
29	5.64	5.00	4.46	3.94	29	498.6	442.0	394.3	348.3
30	5.61	4.97	4.43	3.92	30	495.9	439.3	391.6	346.5
31	5.58	4.94	4.40	3.90	31	493.3	436.7	389.0	344.8
32	5.55	4.91	4.38	3.88	32	490.6	434.0	387.2	343.0
33	5.51	4.88	4.35	3.85	33	487.1	431.4	384.5	340.3
34	5.48	4.85	4.33	3.83	34	484.4	428.7	382.8	338.6
35	5.45	4.82	4.30	3.81	35	481.8	426.1	380.1	336.8
36	5.42	4.80	4.28	3.79	36	479.1	424.3	378.4	335.0
37	5.39	4.77	4.25	3.77	37	476.5	421.7	375.7	333.3
38	5.36	4.74	4.23	3.74	38	473.8	419.0	373.9	330.6
39	5.33	4.71	4.20	3.72	39	471.2	416.4	371.3	328.8
40	5.29	4.69	4.18	3.70	40	467.6	414.6	369.5	327.1
41	5.26	4.66	4.16	3.68	41	465.0	411.9	367.7	325.3
42	5.23	4.63	4.13	3.66	42	462.3	409.3	365.1	323.5
43	5.20	4.61	4.11	3.64	43	459.7	407.5	363.3	321.8
44	5.17	4.58	4.08	3.62	44	457.0	404.9	360.7	320.0
45	5.14	4.55	4.06	3.59	45	454.4	402.2	358.9	317.4
46	5.11	4.53	4.04	3.57	46	451.7	400.5	357.1	315.6
47	5.08	4.50	4.01	3.55	47	449.1	397.8	354.5	313.8
48	5.05	4.47	3.99	3.53	48	446.4	395.1	352.7	312.1
49	5.02	4.45	3.97	3.51	49	443.8	393.4	350.9	310.3
50	5.00	4.42	3.94	3.49	50	442.0	390.7	348.3	308.5
51	4.97	4.40	3.92	3.47	51	439.3	389.0	346.5	306.7
52	4.94	4.37	3.90	3.45	52	436.7	386.3	344.8	305.0
53	4.91	4.35	3.88	3.43	53	434.0	384.5	343.0	303.2
54	4.88	4.32	3.85	3.41	54	431.4	381.9	340.3	301.4
55	4.85	4.30	3.83	3.39	55	428.7	380.1	338.6	299.7
56	4.82	4.27	3.81	3.37	56	426.1	377.5	336.8	297.9
57	4.80	4.25	3.79	3.35	57	424.3	375.7	335.0	296.1
58	4.77	4.22	3.77	3.33	58	421.7	373.0	333.3	294.4
59	4.74	4.20	3.74	3.31	59	419.0	371.3	330.6	292.6
60	4.71	4.17	3.72	3.29	60	416.4	368.6	328.8	290.8
61	4.69	4.15	3.70	3.28	61	414.6	366.9	327.1	290.0
62	4.66	4.12	3.68	3.26	62	411.9	364.2	325.3	288.2
63	4.63	4.10	3.66	3.24	63	409.3	362.4	323.5	286.4
64	4.61	4.08	3.64	3.22	64	407.5	360.7	321.8	284.6
65	4.58	4.05	3.62	3.20	65	404.9	358.0	320.0	282.9

--- To be continued on next page ---

APPENDIX 2 (*continued from page 11*)

CKD Stage 5 Creatinine Table - For Patients of Age 18 and Older

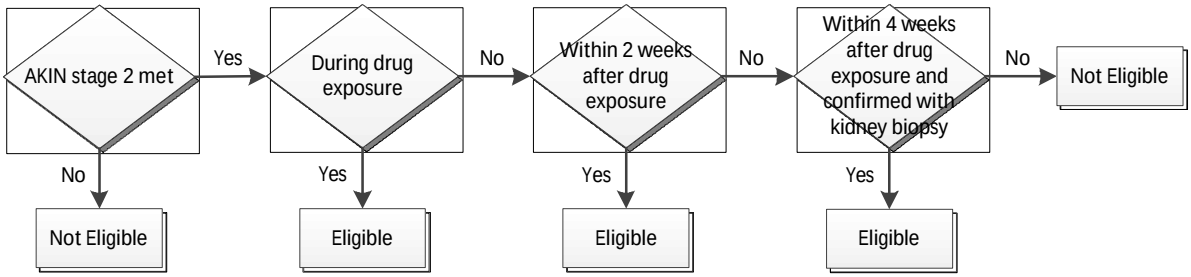
Following table shows the lowest creatinine (IDMS traceable) value that would result in eGFR 14 (CKD stage 5) for given age, gender, and race of a patient using CKD-EPI equation. This table is valid only for adult patients of age 18 and older.

	Creatinine mg/dl					Creatinine umol/L				
	Male		*Female*			*Male*		*Female*		
Age	Black	Other	Black	Other	*Age*	Black	Other	Black	Other
66	4.55	4.03	3.59	3.18	**66**	402.2	356.3	317.4	281.1
67	4.53	4.01	3.57	3.16	**67**	400.5	354.5	315.6	279.3
68	4.50	3.98	3.55	3.15	**68**	397.8	351.8	313.8	278.5
69	4.47	3.96	3.53	3.13	**69**	395.1	350.1	312.1	276.7
70	4.45	3.94	3.51	3.11	**70**	393.4	348.3	310.3	274.9
71	4.42	3.91	3.49	3.09	**71**	390.7	345.6	308.5	273.2
72	4.40	3.89	3.47	3.07	**72**	389.0	343.9	306.7	271.4
73	4.37	3.87	3.45	3.06	**73**	386.3	342.1	305.0	270.5
74	4.35	3.85	3.43	3.04	**74**	384.5	340.3	303.2	268.7
75	4.32	3.83	3.41	3.02	**75**	381.9	338.6	301.4	267.0
76	4.30	3.80	3.39	3.00	**76**	380.1	335.9	299.7	265.2
77	4.27	3.78	3.37	2.99	**77**	377.5	334.2	297.9	264.3
78	4.25	3.76	3.35	2.97	**78**	375.7	332.4	296.1	262.5
79	4.22	3.74	3.33	2.95	**79**	373.0	330.6	294.4	260.8
80	4.20	3.72	3.31	2.93	**80**	371.3	328.8	292.6	259.0
81	4.17	3.69	3.30	2.92	**81**	368.6	326.2	291.7	258.1
82	4.15	3.67	3.28	2.90	**82**	366.9	324.4	290.0	256.4
83	4.12	3.65	3.26	2.88	**83**	364.2	322.7	288.2	254.6
84	4.10	3.63	3.24	2.87	**84**	362.4	320.9	286.4	253.7
85	4.08	3.61	3.22	2.85	**85**	360.7	319.1	284.6	251.9
86	4.05	3.59	3.20	2.83	**86**	358.0	317.4	282.9	250.2
87	4.03	3.57	3.18	2.82	**87**	356.3	315.6	281.1	249.3
88	4.01	3.55	3.16	2.80	**88**	354.5	313.8	279.3	247.5
89	3.98	3.53	3.15	2.78	**89**	351.8	312.1	278.5	245.8
90	3.96	3.51	3.13	2.77	**90**	350.1	310.3	276.7	244.9
91	3.94	3.49	3.11	2.75	**91**	348.3	308.5	274.9	243.1
92	3.92	3.47	3.09	2.74	**92**	346.5	306.7	273.2	242.2
93	3.89	3.45	3.07	2.72	**93**	343.9	305.0	271.4	240.4
94	3.87	3.43	3.06	2.71	**94**	342.1	303.2	270.5	239.6
95	3.85	3.41	3.04	2.69	**95**	340.3	301.4	268.7	237.8
96	3.83	3.39	3.02	2.67	**96**	338.6	299.7	267.0	236.0
97	3.80	3.37	3.00	2.66	**97**	335.9	297.9	265.2	235.1
98	3.78	3.35	2.99	2.64	**98**	334.2	296.1	264.3	233.4
99	3.76	3.33	2.97	2.63	**99**	332.4	294.4	262.5	232.5

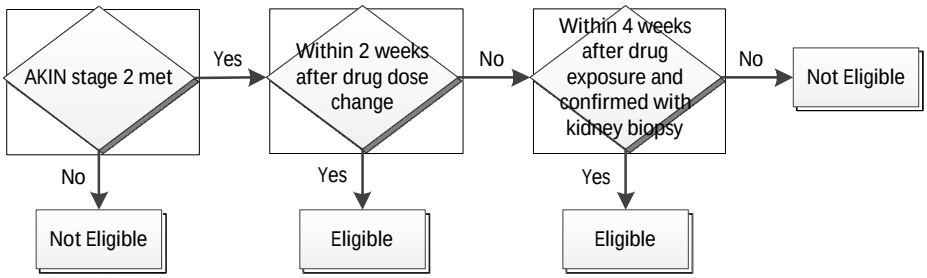
APPENDIX 3

Decision Flow for DIRI Eligibility Check

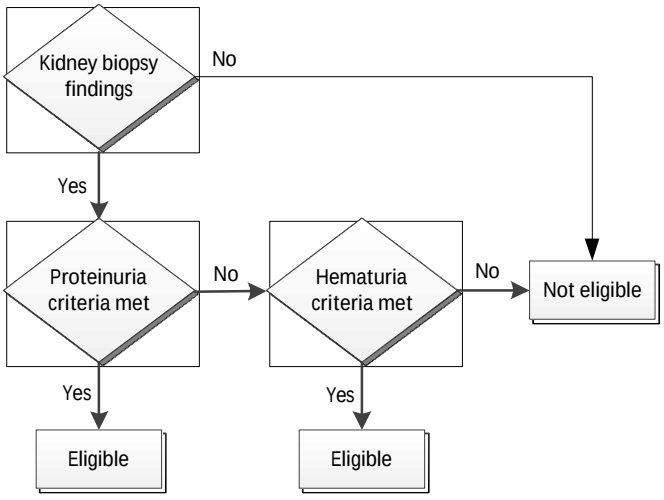
Eligibility assessment for AKI phenotype with AKIN stage 2 criteria based on rising serum creatinine:



Eligibility assessment for AKI phenotype with AKIN stage 2 criteria based on decliining serum creatinine:



Eligibility assessment for Glomerular Disorder phenotype:



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Genomics of Drug Induced Renal Injury (DIRI): Racial Detail

DR1 - CRF 02

Patient ID: | | | | | | |

Coordinator ID: | | | | | |

Form ID: | | | | | | - | | | | | |

Please review the following Race Code table and identify the best matching race categories for patient and patient's parents. This information will help better evaluate the genetic distribution of study participants in terms of race. We understand that racial origin is self reported by patient or documented in patient's medical records. We appreciate it may be difficult to obtain the requested information and would be very grateful for any information provided by the patient.

Self-Reporting Race Identification (Based on Modified CDC Race and Ethnicity Code Set v1.0)

Race Group	Race Code	Description
AMERICAN INDIAN OR ALASKA NATIVE	101	American Indian
	102	Alaska Native
ASIAN	201	Asian Indian
	202	Bangladeshi
	203	Bhutanese
	204	Burmese
	205	Cambodian
	206	Chinese
	207	Taiwanese
	208	Filipino
	209	Hmong
	210	Indonesian
	211	Japanese
	212	Korean
	213	Laotian
	214	Malaysian
	215	Okinawan
	216	Pakistani
	217	Sri Lankan
	218	Thai
	219	Vietnamese
	220	Iwo Jiman
	221	Maldivian
	222	Nepalese
	223	Singaporean
	224	Madagascar
	299	Other Asian
BLACK	301	Black
	302	African American
	303	African (Botswanan, Ethiopian, Liberian, Nambian, Nigerian, Zairean)
	304	Bahamian
	305	Barbadian
	306	Dominican
	307	Dominica Islander
	308	Haitian
BLACK	309	Jamaican
	310	Tobagoan
	311	Trinidadian
	312	West Indian
	399	Other Black
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	401	Polynesian (Native Hawaiian, Samoan, Tahitian, Tongan, Tokelauan)
	402	Micronesian (Guamanian or Chamorro, Guamanian, Chamorro, Mariana Islander, Marshallese, Palauan, Carolinian, Kosraean, Pohnpeian, Saipanese, Kiribati, Chuukese, Yapese)
	403	Melanesian (Fijian, Papua New Guinean, Solomon Islander, New Hebrides)
	404	Other Pacific Islander
WHITE	501	European (Armenian, English, French, German, Irish, Italian, Polish, Spaniard, Scottish)
	502	Middle Eastern or North African (Assyrian, Egyptian, Iranian, Iraqi, Lebanese, Palestinian, Syrian, Afghanistani, Israeili)
	503	Arab
	599	Other White
HISPANIC OR LATINO	602	Mexican
	603	Central American
	604	South American
	605	Latin American
	606	Puerto Rican
	607	Cuban
	608	Dominican
	699	Other Hispanic or Latino
NOT REPORTED	998	Not Reported
OTHER	999	Other Race

1. **Patient Self**
   - a. **Race Code:** | | | |
   - b. **Country of Birth:** | | ☐ NA
   - c. **City of Birth:** | | ☐ NA
2. **Mother's Race Code:** | | | | | | (Up to two race codes may be entered for each parent.)
3. **Father's Race Code:** | | | | | | (Up to two race codes may be entered for each parent.)

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Genomics of Drug Induced Renal Injury (DIRI) : Medical History

Patient ID: | | | | | | | **Coordinator ID:** | | | | | | **Form ID:** | | | | | | - | | | | | |

DR1 - CRF 03

Please enter medical history from hospital admission for inpatient or medical history within three months of DIRI for outpatient.

1. **Date Obtained:** | | / | | / | | | | (mm/dd/yyyy)

2. **Please enter up to 2000 characters in the following box the reason for hospital admission for inpatient, or the chief complaint or reason for followup at clinic for outpatient. Include any nephrologist diagnosis if available.**

3. **Hypertension:** ○ Present ○ Absent ○ No Data

4. **Diabetes Mellitus:** ○ Present ○ Absent ○ No Data

5. **Chronic Obstructive Pulmonary Disease:** ○ Present ○ Absent ○ No Data

6. **Cardiac**
   - a. **Coronary Artery Disease:** ○ Present ○ Absent ○ No Data
   - b. **Congestive Heart Failure:** ○ Present ○ Absent ○ No Data

7. **Peripheral Vascular Disease** ○ Present ○ Absent ○ No Data

8. **Immunocompromised**
   - a. **HIV-Positive/ARC:** ○ Present ○ Absent ○ No Data
   - b. **AIDS:** ○ Present ○ Absent ○ No Data
   - c. **Non-Renal Organ Transplant** ○ Present ○ Absent ○ No Data

     If Yes, specify type of transplant: (Check all that apply.)

     ☐ Liver ☐ Heart ☐ Lung ☐ Other

9. **Liver Disease**
   - a. **Cirrhosis of Liver:** ○ Present ○ Absent ○ No Data
   - b. **Hepatic Failure with Encephalopathy or Coma:** ○ Present ○ Absent ○ No Data
   - c. **Other Liver Disease:** ○ Present ○ Absent ○ No Data

Genomics of Drug Induced Renal Injury (DIRI) : Medical History

Patient ID: | | | | | | | **Coordinator ID:** | | | | | | **Form ID:** | | | | | | - | | | | | |

DR1 - CRF 03

10. Malignancy

- **a. Solid Tumor with Metastasis:** ○ Present ○ Absent ○ No Data
- **b. Hodgkins Lymphoma:** ○ Present ○ Absent ○ No Data
- **c. Non-Hodgkins Lymphoma:** ○ Present ○ Absent ○ No Data
- **d. Leukemia/Myelomas:** ○ Present ○ Absent ○ No Data
- **e. Other Cancers:** ○ Present ○ Absent ○ No Data
- **f. Chemotherapy:** ○ Present ○ Absent ○ No Data
- **g. Radiation Therapy:** ○ Present ○ Absent ○ No Data
- **h. Other Cancer Therapy:** ○ Present ○ Absent ○ No Data

11. Autoimmune Disease: ○ Present ○ Absent ○ No Data

If Yes, please specify: (Check all that apply.)

☐ Lupus ☐ Rheumatoid Arthritis
☐ Scleroderma ☐ Sjogren's Syndrome
☐ Other:

12. Renal

- **a. Kidney Disease with No Dialysis:** ○ Present ○ Absent ○ No Data
- **b. Kidney Disease with Past Dialysis:** ○ Present ○ Absent ○ No Data

If any primarykidney disease, please specify: (check all that apply.)

☐ Glomerular Disease ☐ PCKD
☐ Kidney Stones

13. Allergic Disease: ○ Present ○ Absent ○ No Data

If Yes, please specify: (Check all that apply.)

☐ Asthma ☐ Eczema
☐ Hayfever ☐ Anaphylaxis
☐ Other:

14. Currently taking oral contraceptives? ○ Yes ○ No

15. Smoking Status: ○ Current Smoker ○ Former Smoker ○ Never Smoked ○ No Data

16. Has the patient been on any of the following in the last four weeks? (Check all that apply.)

☐ Diuretics ☐ Antibiotics
☐ NSAIDs (excluding aspirin) ☐ ACEi/ARBs
☐ Aprotinin ☐ Recreational Drugs

17. Has the patient undergone any procedures requiring radio contrast in the last four weeks? ○ Yes ○ No

If Yes, enter the date of last procedure:

| | | / | | | / | | | | | (mm/dd/yyyy)

18. Was the patient given any blood products in the last four weeks? ○ Yes ○ No

If Yes, enter the date of last occurrence:

| | | / | | | / | | | | | (mm/dd/yyyy)

19. Has the patient undergone any of the following in the last four weeks? (Check all that apply.)

☐ Cardiac Surgery ☐ Nephrotoxic Insult
☐ Cardiac Catheterization ☐ Vascular Surgery
☐ Other Major Surgery/Trauma

Genomics of Drug Induced Renal Injury (DIRI): Physical Exam

DR1 - CRF 04

Patient ID: | | | | | | |

Coordinator ID: | | | | | |

Form ID: | | | | | | - | | | | | |

1. Date: | | / | | / | | | | | | (mm/dd/yyyy)

2. Time: | | : | | (24-hour clock)

3. Edema:

○ Generalized ○ Peripheral Only ○ Localized Only (sacral/flank) ○ None ○ Not Recorded

4. Lung rales:

○ Present ○ Absent ○ Not Recorded

5. Heart:

○ Raised JVD ○ Cardiac Murmurs ○ Arrythmias ○ No Abnormalities ○ Not Recorded

6. Ascites:

○ Yes ○ No ○ Not Recorded

7. Jaundice:

○ Yes ○ No ○ Not Recorded

8. Foley Catheter:

○ Yes ○ No ○ Not Recorded

9. Fluid overload noted from chest X-ray:

○ Yes ○ No ○ X-Ray Not Done ○ Inconclusive

10. Surgical status:

○ Emergency ○ Elective ○ None ○ Not Recorded

11. Source of infection?

○ Known ○ Suspected ○ None ○ Not Recorded

12. If infectious source known or suspected, check all that apply:

☐ Urinary Tract ☐ Lung ☐ GI Tract
☐ Blood ☐ CSF ☐ Skin
☐ Joint ☐ Other

13. Cultures done?

○ Yes ○ No

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Genomics of Drug Induced Renal Injury (DIRI): Risk Factors

DR1 - CRF 05

Patient ID: ☐☐☐☐☐☐ Coordinator ID: ☐☐☐☐☐ Form ID: ☐☐☐☐☐ - ☐☐☐☐☐

1. Date: ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy)

2. Time: ☐☐ : ☐☐ (24-hour clock)

3. Did patient have any of the following risk factors for AKI in the last 72 hours or since the last time point? ○ Yes ○ No

If Yes, please answer in detail to each of the following seven risk categories:

a. Procedures requiring intravascular contrast agents:

○ Yes ○ No

If Yes, please check all that apply in the following and for each checked item please also provide the date/time of the procedure and the amount of contrast agents:

☐ 01-01 CONTRAST - INTRAVENOUS
Date: ☐☐ / ☐☐ / ☐☐☐☐
Time: ☐☐ : ☐☐
Amount: ☐☐☐ ml ☐ **NA**

☐ 01-02 CONTRAST - CARDIAC CATH
Date: ☐☐ / ☐☐ / ☐☐☐☐
Time: ☐☐ : ☐☐
Amount: ☐☐☐ ml ☐ **NA**

☐ 01-03 CONTRAST - INTRAARTERIAL
Date: ☐☐ / ☐☐ / ☐☐☐☐
Time: ☐☐ : ☐☐
Amount: ☐☐☐ ml ☐ **NA**

b. Nephrotoxic agents:

○ Yes ○ No

If Yes, please check all that apply in the following:

☐ 02-01 TRANSPLANT MEDS
☐ 02-02 NON-PRESCRIPTION MEDS
☐ 02-03 CHEMOTHERAPY
☐ 02-04 IV DRUG ABUSE
☐ 02-05 AMINOGLYCOSIDES
☐ 02-06 ANTIBIOTICS OTHER THAN AMINOGLYCOSIDES
☐ 02-07 NSAIDS (EXCLUDING ASPIRIN)
☐ 02-08 RHABDOMYOLYSIS
☐ 02-09 IV HEMOLYSIS
☐ 02-10 ANESTHETIC AGENTS
☐ 02-11 ACEi/ARBs
☐ 02-12 OTHER PRESCRIPTION MEDS

c. Surgical procedures requiring general anesthesia:

○ Yes ○ No

If Yes, please check all that apply in the following:

CARDIAC SURGERY
☐ 03-01 CABG ALONE
☐ 03-02 VALVE ALONE
☐ 03-03 COMBINED CABG & VALVE
☐ 03-04 OTHER

VASCULAR CAUSES
☐ 04-01 DISSECTING ANEURYSMS
☐ 04-02 ANEURYSM REPAIR
☐ 04-04 VASCULAR (UNSPECIFIED)
☐ 04-05 VASCULAR SURGERY - CAROTID
☐ 04-06 VASCULAR SURGERY - PERIPHERAL VASCULAR DISEASE

OTHER SURGERY
☐ 05-01 SOLID ORGAN TRANSPLANT
☐ 05-03 OTHER

d. MAP < 65 mmHg for more than 60 minutes if monitored, or SBP < 90 mmHg if not monitored:

○ Yes ○ No

e. Additional risk factors for AKI:

○ Yes ○ No

If Yes, please check all that apply in the following:

INTRAVASCULAR FLUID LOSS
☐ 06-01 HEMORRHAGE
☐ 06-02 DIC
☐ 06-03 BURNS
☐ 06-04 HYPOVOLEMIA
☐ 06-05 HYPOALB (< 3 g/dL or 30 g/L)

INCREASED VASCULAR CAPACITY
☐ 07-01 SEPSIS
☐ 07-02 ANAPHYLACTIC REACTIONS
☐ 07-03 LOSS OF SYMPATHETIC TONE
☐ 07-04 LOSS OF AUTOREGULATION
☐ 07-05 ANESTHESIA
☐ 07-06 HYPOTENSION FROM OTHER CAUSES; MAP < 65

CARDIAC FAILURE
☐ 08-01 MI
☐ 08-02 CHF
☐ 08-03 PUL EMBOLUS
☐ 08-04 VALVE FAILURE
☐ 08-05 CARDIOGENIC SHOCK
☐ 08-06 ARRYTHMIA
☐ 08-07 TAMPONADE

--- Continued from risk category e ---

LIVER DISEASES
☐ 09-01 HEPATORENAL SYNDROME
☐ 09-02 HYPOALB (< 3 g/dL or 30 g/L)
☐ 09-03 CIRRHOSIS
☐ 09-04 HEPATITIS
☐ 09-05 HEPATIC DISEASE (UNSPECIFIED)

ECF LOSSES
☐ 10-01 VOMITING
☐ 10-02 DIARRHEA
☐ 10-03 DIABETES INSIPIDUS
☐ 10-04 ADRENAL INSUFFICIENCY
☐ 10-05 DEHYDRATION

OTHER PROCEDURES
☐ 11-01 SWAN GANZ PLACEMENT
☐ 11-02 CARDIAC PROCEDURES
☐ 11-03 ECMO/ECOR
☐ 11-04 CHEST TUBE PLACEMENT
☐ 11-05 BRONCHOSCOPY
☐ 11-06 THORACENTESIS
☐ 11-07 PARACENTESIS
☐ 11-08 BURN PROCEDURES
☐ 11-09 RADIOLOGIC PROCEDURES
☐ 11-10 HYPERBARIC TREATMENTS
☐ 11-11 INTERNAL ORGAN BIOPSY
☐ 11-12 PLASMAPHERESIS
☐ 11-13 TIPS
☐ 11-14 EGD/COLONOSCOPY
☐ 11-15 LP/ICP MONITORING
☐ 11-16 LVAD
☐ 11-17 PLACEMENT OF PACEMAKER

f. RBC transfusion:

○ Yes ○ No

g. Hyperglycemia:(blood sugar >110mg/dL or 6.05 mmol/L, or patient is on insulin.)

○ Yes ○ No

4749356671

Genomics of Drug Induced Renal Injury (DIRI): Vitals, Labs, I&O

Patient ID: ☐☐☐☐☐☐ **Coordinator ID:** ☐☐☐☐☐ **Form ID:** ☐☐☐☐☐ - ☐☐☐☐☐

DR1 - CRF 06

1. **Date:** ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy)
2. **Time:** ☐☐ : ☐☐ (24-hour clock)
3. **Was patient in ICU on this day?** ○ Yes ○ No

Note: The date and time of entry will be the actual time documented for the BUN and Creatinine results from the lab reports in the patient's medical records. All other lab values may be collected for up to a window of +/- 4 hours from the time of the BUN/Creatinine collection.

NA = Data Not Available/Unknown: This Box must be marked for missing values.

Vital Signs

		NA
4. **Temperature:**	☐☐☐.☐ ○ F ○ C	☐
5. **Systolic BP:**	☐☐☐ mmHg	☐
6. **Diastolic BP:**	☐☐☐ mmHg	☐
7. **Heart Rate:**	☐☐☐ bpm	☐
8. **Respiratory Rate:**	☐☐ bpm	☐
9. **Weight:**	☐☐☐.☐ kg	☐

Vital Signs (For ICU patients only)

		NA
10. **FIO2:**	☐☐☐.☐☐ ○ Frac ○ L/min	☐
11. **CVP:**	☐☐ mmHg	☐
12. **PAWP:**	☐☐☐ mmHg	☐
13. **Cardiac Output:**	☐☐☐.☐ L/min	☐
14. **O2 Apparatus:**	○ Vent ○ Mask ○ Cannula ○ Trach Collar ○ CPAP ○ None ○ Other	
15. **pH:**	☐.☐☐	☐
16. **paO2:**	☐☐☐ mmHg	☐
17. **paCO2:**	☐☐☐ mmHg	☐
18. **Neurological State - Eye:**	☐	☐
19. **Neurological State - Verbal:**	☐	☐
20. **Neurological State - Motor:**	☐	☐

Labs

		NA
21. **Na:**	☐☐☐ mEq/L (mmol/L)	☐
22. **K:**	☐☐.☐ mEq/L (mmol/L)	☐
23. **Cl:**	☐☐☐ mEq/L (mmol/L)	☐
24. **HCO3:**	☐☐.☐ mEq/L (mmol/L)	☐
25. **BUN:**	☐☐☐.☐☐ ○ mg/dL ○ mmol/L	☐
26. **Creatinine:**	☐☐☐☐.☐☐ ○ mg/dL ○ umol/L	☐
27. **Glucose:**	☐☐☐☐.☐☐ ○ mg/dL ○ mmol/L	☐
28. **Total Ca:**	☐☐☐.☐☐ ○ mg/dL ○ mmol/L	☐
29. **Ionized Ca:**	☐☐☐.☐☐ ○ mg/dL ○ mmol/L	☐
30. **PO4:**	☐☐☐.☐☐ ○ mg/dL ○ mmol/L	☐
31. **Mg:**	☐.☐☐ ○ mg/dL ○ mmol/L	☐
32. **Albumin:**	☐☐☐.☐ ○ g/dL ○ g/L	☐
33. **Total Bilirubin:**	☐☐☐.☐ ○ mg/dL ○ umol/L	☐
34. **Direct Bilirubin:**	☐☐☐.☐ ○ mg/dL ○ umol/L	☐

Labs *(--- continued ---)*

		NA
35. **ALT (SGPT):**	☐☐☐☐☐ IU/L	☐
36. **AST (SGOT):**	☐☐☐☐☐ IU/L	☐
37. **ALP:**	☐☐☐☐☐ IU/L	☐
38. **WBC:**	☐☐☐.☐ $10^3/mm^3$ ($10^9/L$)	☐
39. **Bands:**	☐☐☐.☐ %	☐
40. **Eosinophils:**	☐☐☐.☐ %	☐
41. **Hemoglobin:**	☐☐☐.☐ ○ g/dL ○ g/L	☐
42. **HCT:**	☐☐.☐ %	☐
43. **Platelets:**	☐☐☐☐ $10^3/mm^3$ ($10^9/L$)	☐
44. **PT:**	☐☐☐.☐☐ second	☐
45. **PTT:**	☐☐☐.☐☐ second	☐
46. **INR:**	☐☐.☐☐	☐
47. **Lactate Level:**	☐☐.☐ ○ mg/dL ○ mmol/L	☐

Intake & Output

48. Was patient on dialysis today (includes days between intermittent dialysis)?

○ Yes ○ No ○ No Data

49. Was I&O collection done for the day?

○ Yes ○ No

If no I&O collection, please state reason:

50. I&O Collection Times:

Start Date/Time: ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy) ☐☐ : ☐☐ (24-hr clock)

Stop Date/Time: ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy) ☐☐ : ☐☐ (24-hr clock)

Intake			Output		
		NA			NA
51. PO:	☐☐☐☐☐ ml	☐	56. Urine:	☐☐☐☐☐ ml	☐
52. NG:	☐☐☐☐☐ ml	☐	57. Stool:	☐☐☐☐☐ ml	☐
53. IV:	☐☐☐☐☐ ml	☐	58. NG:	☐☐☐☐☐ ml	☐
54. Other Intake:	☐☐☐☐☐ ml	☐	59. Wounds&Drains:	☐☐☐☐☐ ml	☐
55. Total Intake:	☐☐☐☐☐ ml	☐	60. Other Output:	☐☐☐☐☐ ml	☐
			61. Total Output:	☐☐☐☐☐ ml	☐

Genomics of Drug Induced Renal Injury (DIRI): Urinalysis & Urine Chemistry

DR1 - CRF 07

Patient ID: | | | | | | |

Coordinator ID: | | | | | | |

Form ID: | | | | | | | - | | | | | |

1. **Urinalysis done?** ○ Yes ○ No
   If Yes, please enter data in the Urinalysis section.
2. **Urine chemistry done?** ○ Yes ○ No
   If Yes, please enter data in the Urine Chemistry section.

Urinalysis

3. **Date:** | | / | | / | | | | | (mm/dd/yyyy)
4. **Time:** | | : | | (24hr clock)
5. **Specific Gravity:** | . | | | | ☐ **NA**
6. **pH:** | . | | | ☐ **NA**
7. **Protein:** ○ Negative ○ Trace ○ 1+ ○ 2+ ○ 3+ ○ 4+ ○ NA
8. **Glucose:** ○ Negative ○ Trace ○ 1+ ○ 2+ ○ 3+ ○ 4+ ○ NA
9. **WBC:** ○ Rare ○ 0-2 ○ 3-5 ○ 6-10 ○ 11-20 ○ 21-50 ○ >50 ○ NA
10. **RBC:** ○ Rare ○ 0-2 ○ 3-5 ○ 6-10 ○ 11-20 ○ 21-50 ○ >50 ○ NA
11. **Urinary Sediments:** (check all that apply)
    - ☐ Hyaline Cast ☐ Granular Cast ☐ RBC Cast
    - ☐ Cellular Cast ☐ WBC Cast ☐ Hgb Cast
    - ☐ Fatty Cast ☐ Waxy Cast ☐ Tubular Broad Cast
12. **Eosinophils:** ○ Present ○ Absent ○ No Data

Urine Chemistry

13. **Type of Urine Collection:** ○ Timed ○ Spot

Note: (1) For **Timed** collection, enter both the Start and Stop Dates/Times.
(2) For **Spot** collection, enter only the Start date/time.

14. **Urine Collect Start Date/Time:** | | / | | / | | | | (mm/dd/yyyy) | | : | | (24-hour clock)
15. **Urine Collect Stop Date/Time:** | | / | | / | | | | (mm/dd/yyyy) | | : | | (24-hour clock)
16. **Urine Total:** | | | | | | ml ☐ **NA**
17. **Na:** | | | | mEq/L (mmol/L) ☐ **NA**
18. **K:** | | | | mEq/L (mmol/L) ☐ **NA**
19. **Cl:** | | | | mEq/L (mmol/L) ☐ **NA**
20. **Ca:** | | | . | | ○ mg/dL ○ mmol/L ☐ **NA**
21. **PO4:** | | | . | | ○ mg/dL ○ mmol/L ☐ **NA**
22. **Urea Nitrogen:** | | | . | | ○ mg/dL ○ mmol/L ☐ **NA**
23. **Protein:** | | | | | ○ mg/dL ○ mg/L ☐ **NA**
24. **Creatinine:** | | | | . | | ○ mg/dL ○ umol/L ☐ **NA**
25. **Osmolality:** | | | | | mOsm/L ☐ **NA**
26. **Albumin:** | | | . | | ○ mg/dL ○ mg/L ☐ **NA**

Genomics of Drug Induced Renal Injury (DIRI): Renal Replacement Therapy

DR1 - CRF 08

Patient ID: | | | | | | |

Coordinator ID: | | | | | | |

Form ID: | | | | | | - | | | | | |

1. Has the patient received RRT in the last 72 hours or since the last time point if less than 72 hours?

○ Yes ○ No

2. Reasons to start/pursue RRT: (Check all that apply)

- ☐ 01-01 Hyperkalemia
- ☐ 01-02 Acidemia
- ☐ 01-03 Electrolyte Disturbance
- ☐ 01-04 Progressive Azotemia
- ☐ 01-05 Uremic Manifestations
- ☐ 01-06 Oliguria (<400 ml/24h)
- ☐ 01-07 Fluid Overload
- ☐ 01-08 Volume Status Unable to Accomodate Demands for Fluid
- ☐ 01-09 Compromised Cardiac, Respiratory or Liver Status
- ☐ 01-10 Intoxication
- ☐ 01-11 Non-recovery of Renal Function
- ☐ 01-12 Other

3. Type of RRT procedure:

○ IHD ○ CVVH ○ CVVHD ○ CVVHDF

○ SLED ○ UF Only ○ PD

4. RRT Start Date/Time:

| | | / | | | / | | | | | (mm/dd/yyyy)

| | | : | | | (24hr clock)

5. Was CRRTtemporarily stopped in the last 72 hours or since the last time point if less than 72 hours?

○ Yes ○ No

If Yes, answer the following questions:

a. RRT Stop Date/Time:

| | | / | | | / | | | | | (mm/dd/yyyy)

| | | : | | | (24hr clock)

6. Was RRT definitely stopped in the last 72 hours or since the last time point if less than 72 hours?

○ Yes ○ No

If Yes, answer the following questions:

a. RRT Stop Date/Time:

| | | / | | | / | | | | | (mm/dd/yyyy)

| | | : | | | (24hr clock)

b. Reasons for RRT discontinuation: (Check all that apply)

- ☐ 03-01 Renal recovery
- ☐ 03-02 Death
- ☐ 03-03 Withdrawal of treatment
- ☐ 03-04 Other

Genomics of Drug Induced Renal Injury (DIRI): Drug Dosing

DR1 - CRF 09

Patient ID: ☐☐☐☐☐☐ **Coordinator ID:** ☐☐☐☐☐ **Form ID:** ☐☐☐☐☐ - ☐☐☐☐☐

1. Information about this drug as recorded in screening log:

a. Drug ID: ☐☐☐

b. Drug Full Name: ☐

c. Drug Trade Name: ☐

d. Start Date/Time: ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy) ☐☐ : ☐☐ (24hr clock)

e. Dose Reduction or Drug Stop Date/Time: ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy) ☐☐ : ☐☐ (24hr clock) ☐ **NA**

2. Is serum drug concentration available? ○ Yes ○ No

3. Has the patient previously received this drug (in any dose or route) during a previous hospital admission or as part of previous outpatient treatment?

○ Yes ○ No ○ Unknown

If Yes, please answer the following questions:

a. Did the patient experience adverse events related to kidney injury?

○ Yes ○ No ○ Unknown ○ NA

b. Did the patient recover and kidney related AE resolve?

○ Yes ○ No ○ Unknown ○ NA

Drug Dose History (in chronological order)

4. Episode 1

a. Start: ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy) ☐☐ : ☐☐ (24hr clock)

b. End: ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy) ☐☐ : ☐☐ (24hr clock)

c. Dose: ☐☐☐☐☐.☐☐ ○ mg ○ gram ○ mcg ○ Other : _____

d. Freq: ☐☐.☐☐ hr

e. Route: ○ PO ○ IM ○ IV ○ SQ ○ PR ○ Other : _____

f. Concentration: ☐☐.☐ ○ mcg/mL ○ Other : _____

Date : (mm/dd/yyyy) ☐☐ / ☐☐ / ☐☐☐☐

Time : ☐☐ : ☐☐ (24hr clock)

g. Trough Conc: ○ Yes ○ No ○ Unknown

5. Episode 2

a. Start: ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy) ☐☐ : ☐☐ (24hr clock)

b. End: ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy) ☐☐ : ☐☐ (24hr clock)

c. Dose: ☐☐☐☐☐.☐☐ ○ mg ○ gram ○ mcg ○ Other : _____

d. Freq: ☐☐.☐☐ hr

e. Route: ○ PO ○ IM ○ IV ○ SQ ○ PR ○ Other : _____

f. Concentration: ☐☐.☐ ○ mcg/mL ○ Other : _____

Date : (mm/dd/yyyy) ☐☐ / ☐☐ / ☐☐☐☐

Time : ☐☐ : ☐☐ (24hr clock)

g. Trough Conc: ○ Yes ○ No ○ Unknown

6. Episode 3

a. Start: ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy) ☐☐ : ☐☐ (24hr clock)

b. End: ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy) ☐☐ : ☐☐ (24hr clock)

c. Dose: ☐☐☐☐☐.☐☐ ○ mg ○ gram ○ mcg ○ Other : _____

d. Freq: ☐☐.☐☐ hr

e. Route: ○ PO ○ IM ○ IV ○ SQ ○ PR ○ Other : _____

f. Concentration: ☐☐.☐ ○ mcg/mL ○ Other : _____

Date : (mm/dd/yyyy) ☐☐ / ☐☐ / ☐☐☐☐

Time : ☐☐ : ☐☐ (24hr clock)

g. Trough Conc: ○ Yes ○ No ○ Unknown

Genomics of Drug Induced Renal Injury (DIRI): Drug Dosing

Patient ID: ☐☐☐☐☐☐

Form ID: ☐☐☐☐☐ - ☐☐☐☐☐

DR1 - CRF 09

7. Episode 4

a. Start: ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy) ☐☐ : ☐☐ (24hr clock)

b. End: ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy) ☐☐ : ☐☐ (24hr clock)

c. Dose: ☐☐☐☐☐ . ☐☐ ○ mg ○ gram ○ mcg ○ Other : _____

d. Freq: ☐☐ . ☐☐ hr

e. Route: ○ PO ○ IM ○ IV ○ SQ ○ PR ○ Other : _____

f. Concentration: ☐☐ . ☐ ○ mcg/mL ○ Other : _____

Date : (mm/dd/yyyy) ☐☐ / ☐☐ / ☐☐☐☐

Time : ☐☐ : ☐☐ (24hr clock)

g. Trough Conc: ○ Yes ○ No ○ Unknown

8. Episode 5

a. Start: ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy) ☐☐ : ☐☐ (24hr clock)

b. End: ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy) ☐☐ : ☐☐ (24hr clock)

c. Dose: ☐☐☐☐☐ . ☐☐ ○ mg ○ gram ○ mcg ○ Other : _____

d. Freq: ☐☐ . ☐☐ hr

e. Route: ○ PO ○ IM ○ IV ○ SQ ○ PR ○ Other : _____

f. Concentration: ☐☐ . ☐ ○ mcg/mL ○ Other : _____

Date : (mm/dd/yyyy) ☐☐ / ☐☐ / ☐☐☐☐

Time : ☐☐ : ☐☐ (24hr clock)

g. Trough Conc: ○ Yes ○ No ○ Unknown

9. Episode 6

a. Start: ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy) ☐☐ : ☐☐ (24hr clock)

b. End: ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy) ☐☐ : ☐☐ (24hr clock)

c. Dose: ☐☐☐☐☐ . ☐☐ ○ mg ○ gram ○ mcg ○ Other : _____

d. Freq: ☐☐ . ☐☐ hr

e. Route: ○ PO ○ IM ○ IV ○ SQ ○ PR ○ Other : _____

f. Concentration: ☐☐ . ☐ ○ mcg/mL ○ Other : _____

Date : (mm/dd/yyyy) ☐☐ / ☐☐ / ☐☐☐☐

Time : ☐☐ : ☐☐ (24hr clock)

g. Trough Conc: ○ Yes ○ No ○ Unknown

10. Episode 7

a. Start: ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy) ☐☐ : ☐☐ (24hr clock)

b. End: ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy) ☐☐ : ☐☐ (24hr clock)

c. Dose: ☐☐☐☐☐ . ☐☐ ○ mg ○ gram ○ mcg ○ Other : _____

d. Freq: ☐☐ . ☐☐ hr

e. Route: ○ PO ○ IM ○ IV ○ SQ ○ PR ○ Other : _____

f. Concentration: ☐☐ . ☐ ○ mcg/mL ○ Other : _____

Date : (mm/dd/yyyy) ☐☐ / ☐☐ / ☐☐☐☐

Time : ☐☐ : ☐☐ (24hr clock)

g. Trough Conc: ○ Yes ○ No ○ Unknown

11. Episode 8

a. Start: ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy) ☐☐ : ☐☐ (24hr clock)

b. End: ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy) ☐☐ : ☐☐ (24hr clock)

c. Dose: ☐☐☐☐☐ . ☐☐ ○ mg ○ gram ○ mcg ○ Other : _____

d. Freq: ☐☐ . ☐☐ hr

e. Route: ○ PO ○ IM ○ IV ○ SQ ○ PR ○ Other : _____

f. Concentration: ☐☐ . ☐ ○ mcg/mL ○ Other : _____

Date : (mm/dd/yyyy) ☐☐ / ☐☐ / ☐☐☐☐

Time : ☐☐ : ☐☐ (24hr clock)

g. Trough Conc: ○ Yes ○ No ○ Unknown

Genomics of Drug Induced Renal Injury (DIRI): Drug Dosing

Patient ID: ☐☐☐☐☐☐

Form ID: ☐☐☐☐☐ - ☐☐☐☐☐

DR1 - CRF 09

12. Episode 9

a. Start: ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy)
☐☐ : ☐☐ (24hr clock)

b. End: ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy)
☐☐ : ☐☐ (24hr clock)

c. Dose: ☐☐☐☐☐.☐☐ ○ mg ○ gram ○ mcg ○ Other : _____

d. Freq: ☐☐.☐☐ hr

e. Route: ○ PO ○ IM ○ IV ○ SQ ○ PR ○ Other : _____

f. Concentration: ☐☐.☐ ○ mcg/mL ○ Other : _____

Date : (mm/dd/yyyy) ☐☐ / ☐☐ / ☐☐☐☐

Time : ☐☐ : ☐☐ (24hr clock)

g. Trough Conc: ○ Yes ○ No ○ Unknown

13. Episode 10

a. Start: ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy)
☐☐ : ☐☐ (24hr clock)

b. End: ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy)
☐☐ : ☐☐ (24hr clock)

c. Dose: ☐☐☐☐☐.☐☐ ○ mg ○ gram ○ mcg ○ Other : _____

d. Freq: ☐☐.☐☐ hr

e. Route: ○ PO ○ IM ○ IV ○ SQ ○ PR ○ Other : _____

f. Concentration: ☐☐.☐ ○ mcg/mL ○ Other : _____

Date : (mm/dd/yyyy) ☐☐ / ☐☐ / ☐☐☐☐

Time : ☐☐ : ☐☐ (24hr clock)

g. Trough Conc: ○ Yes ○ No ○ Unknown

Genomics of Drug Induced Renal Injury (DIRI): Outcome Info

DR1 - CRF 10

Patient ID: ☐☐☐☐☐☐ **Coordinator ID:** ☐☐☐☐☐ **Form ID:** ☐☐☐☐☐ - ☐☐☐☐☐

1. **Did patient complete full study?**
   ○ Yes ○ No
2. **What was the last time point that was completed?**
   ○ Day of DIRI
   ○ Peak SCr or Peak Severity of Injury
   ○ Drug Stop or Dose Reduction
   ○ Nadir SCr or Resolution of Event
   ○ Hospital Discharge or Last Clinical Visit

Inpatient Hospital Discharge or Outpatient Last Clinic Visit Status

3. **Discharge or Last Visit Date:** ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy)
4. **Alive?** ○ Yes ○ No
5. **Required dialysis?** ○ Yes ○ No
6. **Serum Creatinine:** (Recorded on day closest to discharge) ☐☐☐☐.☐☐ ○ mg/dL ○ umol/L
7. **Creatinine Date:** ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy)

Dialysis Status

8. **Was patient ever on dialysis during this study period?** ○ Yes ○ No

   If Yes, answer the following questions:

   a. **First day of dialysis:** ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy)

   b. **Last day of dialysis:** ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy)

   c. **Type of dialysis:** (Check all that apply.)

   ☐ IHD ☐ CVVH ☐ CVVHD ☐ CVVHDF ☐ SLED ☐ UF Only ☐ PD

Genomics of Drug Induced Renal Injury (DIRI): Follow Up

DR1 - CRF 11

Patient ID: ☐☐☐☐☐☐ Coordinator ID: ☐☐☐☐☐ Form ID: ☐☐☐☐☐ - ☐☐☐☐☐

1. **Date:** ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy)
2. **Which follow-up?**
   - ○ **Day 28** ○ **Day 90**
3. **Who supplied follow-up information?**
   - ○ **Patient** ○ **Surrogate** ○ **Medical Record**
4. **Is patient alive?**
   - ○ **Yes** ○ **No** ○ **Unknown**
5. **If patient is alive, is patient dialysis dependent?**
   - ○ **Yes** ○ **No** ○ **Unknown**

If patient is not dialysis dependent, please enter patient data obtained from patient's recent outpatient medical record or from current physician:

6. **Source of Data:**
   - ○ **Medical Record** ○ **Current Physician**
7. **BUN:** ☐☐☐.☐☐ ○ mg/dL ○ mmol/L ☐ **NA**
8. **Creatinine:** ☐☐☐☐.☐ ○ mg/dL ○ umol/L ☐ **NA**
9. **Date of Data Recorded:** ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy) ☐ **NA**

1. **Patient ID:** ☐☐☐☐☐☐

2. **Coordinator ID:** ☐☐☐☐☐

Affix Kit ID bar code label in box

Lab Kit ID

Sample A - Serum ☐ **Mark if not collected**

3. **Date Collected:** ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy)
4. **Time Collected:** ☐☐ : ☐☐ (24-hour clock)
5. **Volume Collected:** ☐☐ . ☐ ml
6. **Number of Aliquots:** ☐☐
7. **Day Frozen:** ○ Day after Collection Date ○ Same as Collection Date
8. **Time Frozen:** ☐☐ : ☐☐ (24-hour clock)

Sample C - Whole Blood ☐ **Mark if not collected**

9. **Date Collected:** ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy)
10. **Time Collected:** ☐☐ : ☐☐ (24-hour clock)
11. **Volume Collected:** ☐☐ . ☐ ml
12. **Number of Aliquots:** ☐☐
13. **Day Frozen:** ○ Day after Collection Date ○ Same as Collection Date
14. **Time Frozen:** ☐☐ : ☐☐ (24-hour clock)

Sample E - Urine ☐ **Mark if not collected**

15. **Date Collected:** ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy)
16. **Time Collected:** ☐☐ : ☐☐ (24-hour clock)
17. **Volume Collected:** ☐☐☐ ml
18. **Number of Aliquots:** ☐☐
19. **Day Frozen:** ○ Day after Collection Date ○ Same as Collection Date
20. **Time Frozen:** ☐☐ : ☐☐ (24-hour clock)

Genomics of Drug Induced Renal Injury (DIRI) : Clinical Data Review

DR1 - CRF 14

Patient ID: | | | | | | | **Coordinator ID:** | | | | | | | **Form ID:** | | | | | | | - | | | | | |

Case Summary

a. Patient Location: ○ Inpatient ○ Outpatient

b. Gender: ○ Male ○ Female

c. Age: | |

d. Race:

e. DIRI Phenotype: ○ AKI ○ Glomerular Disorder

f. Study drugs that met DIRI criteria:

i.

ii.

iii.

Case Review

1. Date of Review: | | / | | / | | | | (mm/dd/yyyy)

2. Does the patient case have sufficient clinical data for adjudication?

○ Yes ----> **If Yes, please assign adjudicators for this case and accept the patient into official adjudication process.**

○ No ----> **If No, please document all action items required for site coordinator to resolve the issues.**

Adjudicator Assignment

3. Adjudicator 1:

4. Adjudicator 2:

5. Adjudicator 3:

Action Items

6. Action Item 1: ○ Request for resolution ○ Submit for review ☐ **Resolved**

a. **[Review]**

b. **[Response]**

7. Action Item 2: ○ Request for resolution ○ Submit for review ☐ **Resolved**

a. **[Review]**

b. **[Response]**

8. Action Item 3: ○ Request for resolution ○ Submit for review ☐ **Resolved**

a. **[Review]**

b. **[Response]**

9. Action Item 4: ○ Request for resolution ○ Submit for review ☐ **Resolved**

a. **[Review]**

b. **[Response]**

10. Action Item 5: ○ Request for resolution ○ Submit for review ☐ **Resolved**

a. **[Review]**

b. **[Response]**

11. Action Item 6: ○ Request for resolution ○ Submit for review ☐ **Resolved**

a. **[Review]**

b. **[Response]**

12. Action Item 7: ○ Request for resolution ○ Submit for review ☐ **Resolved**

a. **[Review]**

b. **[Response]**

13. Action Item 8: ○ Request for resolution ○ Submit for review ☐ **Resolved**

a. **[Review**

b. **[Response]**

Genomics of Drug Induced Renal Injury (DIRI) : Clinical Data Review

DR1 - CRF 14

Patient ID: | | | | | | |

Form ID: | | | | | | - | | | | | |

14. Action Item 9: ○ Request for resolution ○ Submit for review ☐ **Resolved**

a. **[Review**

b. **[Response]**

15. Action Item 10: ○ Request for resolution ○ Submit for review ☐ **Resolved**

a. **[Review**

b. **[Response]**

Genomics of Drug Induced Renal Injury (DIRI): Adjudication Report

DR1 - CRF 15

Patient ID: ☐☐☐☐☐☐

Form ID: ☐☐☐☐☐ - ☐☐☐☐☐

1. Adjudicator ID: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

2. Date of Review: ☐☐ / ☐☐ / ☐☐☐☐ (mm/dd/yyyy)

3. a. Phenotype and DIRI criteria that was used to determine patient's eligibility for enrollment with this study:

- ○ AKI phenotype with AKIN stage 2 criteria based on rising serum creatinine *(based on time course and magnitude of creatinine change)*
- ○ AKI phenotype with AKIN stage 2 criteria based on declining serum creatinine
- ○ Glomerular disorder phenotype *(based on biopsy)*

b. Study Drugs:

	NA	Drug ID	Drug Name	Met DIRI Criteria
Drug 1	☐	___		○ Y ○ N
Drug 2	☐	___		○ Y ○ N
Drug 3	☐	___		○ Y ○ N

4. Assessment Tools

a. Naranjo Scores (*Naranjo CA, Busto U, Sellers EM, et al. A method for estimating the probability of adverse drug reactions. Clin. Pharmacol. Ther. 1981;30:239-245.)*

Naranjo scores of 9 - 10 indicate that event was "definitely" an ADR; scores of 5 - 8 rate the likelihood as "probable"; scores of 1 - 4 are "possible"; and scores of less than 1 are "doubtful".

To assess the adverse drug reaction, please answer the following questions and give pertinent subscores for each drug.	Question Points			Subscores		
	Yes	No	DoNot Know	Drug 1	Drug 2	Drug 3
(1) Are there previous conclusive reports on this reaction?	+1	0	0	___	___	___
(2) Did the adverse event appear after the suspected drug was administered?	+2	-1	0	___	___	___
(3) Did the adverse reaction improve when the drug was discontinued or a specific antagonist was administered?	+1	0	0	___	___	___
(4) Did the adverse reaction reappear when the drug was re-administered?	+2	-1	0	___	___	___
(5) Are there alternative causes (other than the drug) that could on their own have caused the reaction?	-1	+2	0	___	___	___
(6) Did the reaction reappear when a placebo was given?	-1	+1	0	___	___	___
(7) Was the drug detected in the blood (or other fluids) in concentrations known to be toxic?	+1	0	0	___	___	___
(8) Was the reaction more severe when the dose was increased, or less severe when the dose was decreased?	+1	0	0	___	___	___
(9) Did the patient have a similar reaction to the same or similar drugs in any previous exposure?	+1	0	0	___	___	___
(10) Was the adverse event confirmed by any objective evidence?	+1	0	0	___	___	___
Add subscores from each column to calculate the Naranjo score for respective drug: (Score 0: Unlikely, Score 1-4: Possible, Score 5-8: Probable, Score 9-10: Definite)				___	___	___

Genomics of Drug Induced Renal Injury (DIRI): Adjudication Report

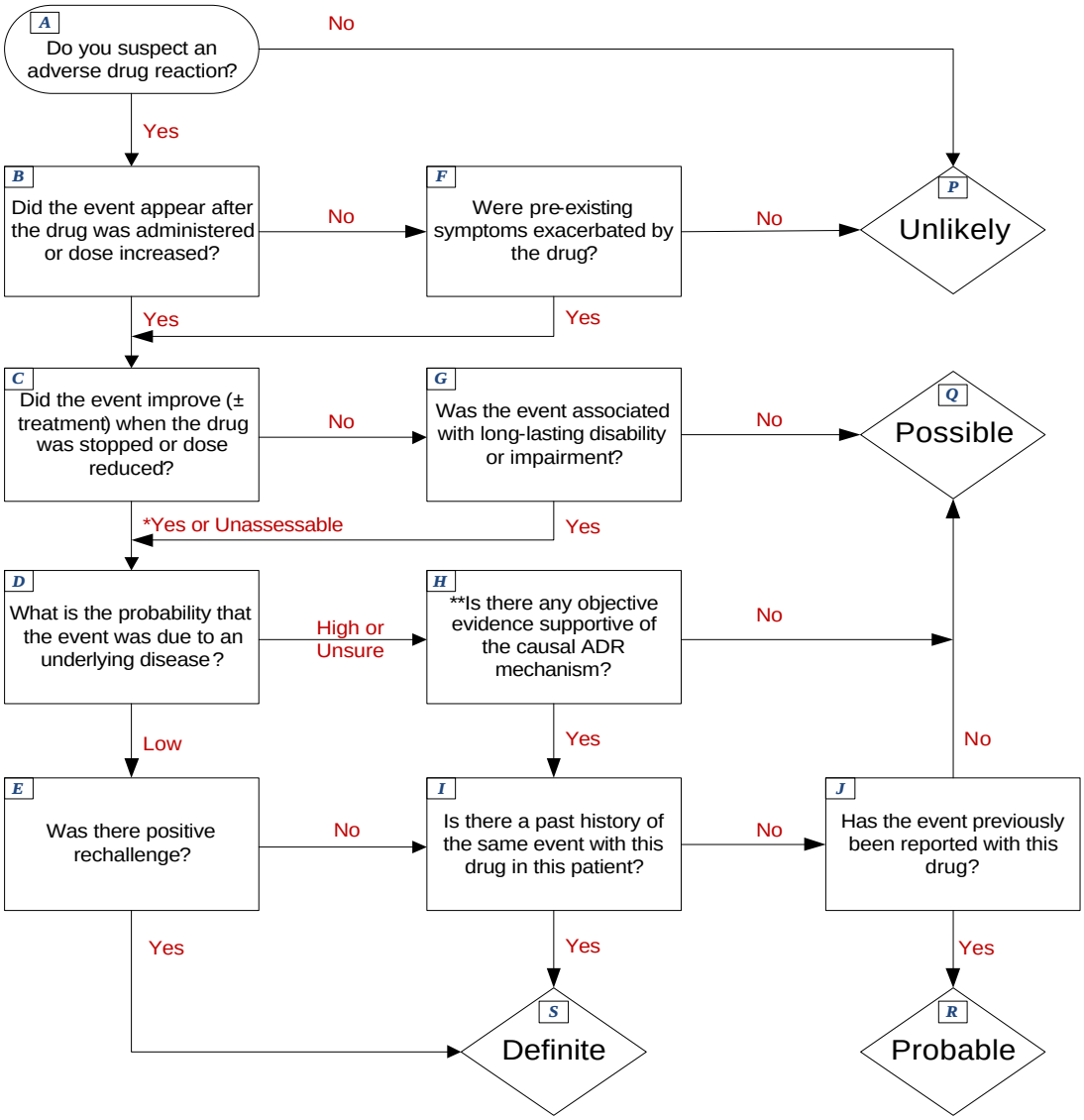
Patient ID: | | | | | | |

DR1 - CRF 15

Form ID: | | | | | | | - | | | | | |

4. Assessment Tools *(--- continued from Page 1 ---)*

b. Liverpool Adverse Drug Reaction Causality Assessment Tool (*DOI: 10.1371/journal.pone.0028096*)



Apply the Liverpool ADR assessment tool to construct the decision paths and determine the likelyhood of ADR associated with the drugs. Decision path is a sequence of tag letters (at the upper left corner of each question box) which represents an unbroken chain of path from box A to one of the final assessment results.

	Decision Path	Result
Drug 1		○ Unlikely ○ Possible ○ Probable ○ Definite
Drug 2		○ Unlikely ○ Possible ○ Probable ○ Definite
Drug 3		○ Unlikely ○ Possible ○ Probable ○ Definite

Genomics of Drug Induced Renal Injury (DIRI): Adjudication Report

Patient ID: | | | | | | |

Form ID: | | | | | | - | | | | | |

DR1 - CRF 15

5. Event attributable to drug and if so what level of certainty (use Naranjo scores and Liverpool assessment tool in #4):

Assessment	Drug 1	Drug 2	Drug 3	Underlying and Concomitant Risk Factors
Likely Cause to ADR	○ Unlikely ○ Possible ○ Probable ○ Definite	○ Unlikely ○ Possible ○ Probable ○ Definite	○ Unlikely ○ Possible ○ Probable ○ Definite	○ Unlikely ○ Possible ○ Probable ○ Definite
Percent Contribution (add to 100%) **Total =** ___ %	___ %	___ %	___ %	___ %
Type of Event **A: Drug Toxicity** **B: Hypersensitivity**	○ Drug Toxicity ○ Hypersensitivity	○ Drug Toxicity ○ Hypersensitivity	○ Drug Toxicity ○ Hypersensitivity	

6. Relative contribution of various categories of risk factors (reported in CRF05) in relation to drug exposure:

Risk Factors	Percent contribution of individual risk factor category to overall risk (total among risk factors should be 100%)
a. Procedures requiring intravascular contrast agents	___ %
b. Nephrotoxic agents	___ %
c. Surgical procedures requiring general anethesia	___ %
d. MAP < 65 mmHg for more than 60 minutes if monitored, or SBP < 90 mmHg if not monitored	___ %
e. Additional risk factors for AKI (intravascular fluid loss, increased vascular capacity,cardiac failure, liver diseases, ECF losses, other procedures)	___ %
f. RBC transfusion	___ %
g. Hyperglycemia	___ %
Total =	___ %

Genomics of Drug Induced Renal Injury (DIRI): Adjudication Report

Patient ID: | | | | | | |

Form ID: | | | | | | - | | | | | |

DR1 - CRF 15

Adjudication Result:

7. DIRI confirmed? ○ Yes ○ No ○ Need More Information

If No, why?

If Need More Information, please list below: