Urea Cycle Disorders Consortium
INDUSTRY COLLABORATION POLICY AND PROCEDURES

Version December 2, 2016
Policy Abbreviation: UCDC-ICPP

1. Scope:

This policy addresses Urea Cycle Disorders Consortium (UCDC) collaboration and interaction with pharmaceutical and biotechnology companies (industry). The procedures explain how industry collaboration should occur.

2. Objectives:

2.1. Describe the process that will be followed by the UCDC when collaborating with industry.

2.2. Describe reporting expectations of the UCDC for individual UCDC investigators engaging in relationships with industry partners that could lead to real, or perceived, conflict of interest (COI).

3. Definitions:

3.1. Children's Research Institute (CRI) - Refers to a corporation duly incorporated under the laws of Washington, D.C., with offices at 111 Michigan Avenue, NW, Washington, D.C. 20010. CRI is a subsidiary of Children's National Medical Center and is the lead institution of the Urea Cycle Disorders Consortium.

3.2. Company – For-profit pharmaceutical or biotechnology company.

3.3. Conflict of Interest (COI) – any arrangement or agreement that could potentially interfere, or create the appearance of a possible interference, with the good faith commitment to act on behalf of the UCDC and the patients that we serve.

3.4. Data –data generated by the UCDC and maintained by the Data Management and Coordinating Center (DMCC) at the University of South Florida or the Biostatistics Unit at Children's National Medical Center. Data also includes records, documents and related information. Examples of data include: (1) clinical trial data, (2) data contained in the UCDC database; (3) data obtained from assays, tests, or procedures, (3) data from patients or research subjects.

3.5. Industry or Industry Partner – see Company

3.6. Industry Collaboration Authorization Agreement (ICAA) – An agreement entered into by CRI, as the lead institution, and UCDC member

institutions, giving CRI authority to negotiate with companies on behalf or the UCDC.

3.7. Industry Relations Committee (IRC) – A committee appointed by the UCDC principal investigator to review requests or proposals for collaborations from the private sector and make recommendations to the executive leadership of the UCDC.

3.8. Sponsor – Organization funding research. This can be a governmental (eg. NIH), non-governmental (eg. philanthropic donor), or industry (for-profit company) sponsor.

3.9. UCDC Executive Leadership (Exec Committee) – Consortium principal investigator, co-PIs, including the administrative director.

3.10. UCDC Steering Committee – UCDC leadership, site PIs, NIH scientific and administrative officers.

4. Guiding Principles

4.1. Collaborations with Industry partners are essential to fulfill the mission of the UCDC.

4.2. Policy and processes for industry collaborations will be transparent and equitable.

4.3. All collaborative activities must have a potential benefit for patients and families with UCD

4.4. The Industry Relations Committee (IRC) will be empowered to negotiate with potential industry partners and make recommendations to the UCDC leadership and NIH officers who will have the final authority for approval.

4.5. Confidentiality and intellectual property protection are essential and will be agreed upon and respected.

4.6. Intellectual Property developed through these collaborations belongs to the individuals and or institutions, which deliver them.

4.7. The UCDC does not seek any profit from these activities.

4.8. Work undertaken on behalf of an Industry partner must not be supported by federal funds awarded to the UCDC.

5. Policy:

5.1. <u>UCDC Collaboration Criteria</u> - the UCDC will collaborate on projects that meet the following criteria:

5.1.1. Potentially beneficial for UCD patients;

5.1.2. Not duplicating or in conflict with current RDCRN UCDC protocols, including not diverting patients from existing UCDC studies.

5.2. Individual Investigator Collaboration with Industry - Nothing in these guidelines prevents individual investigators of the UCDC from interacting independently with industry, however, both formal and informal interactions related to UCD should be disclosed to the UCDC leadership to assist in mediating any real or perceived conflict of interest, fiduciary or financial.

5.2.1. The IRC will review these disclosures, and if a potential COI is identified will work with the individual UCD investigator to mediate the potential conflict.

5.3. Confidentiality – each member of the consortium will keep UCDC algorithms and data confidential. All UCDC members can use UCDC data for analyses at any time following notification of UCDC leadership according to the Data Use Policy. UCDC members cannot release data without a CRI services agreement and UCDC leadership approval.

5.4. CRI Negotiates with Companies on Behalf of UCDC – As the lead institution, Children's Research Institute of Children's National Medical Center, will negotiate with companies on behalf of the UCDC.

5.4.1. Industry Collaboration Authorization Agreement – Most, but not all, of the parent institutions of US sites of the UCDC have signed the industry collaboration authorization agreement, which states that CRI will act as the lead institution and appoint CRI as the agent to perform, carry out, execute, amend, grant consents and waivers of consent, and to enter into legally and contractually binding agreements with industry collaborator(s) and third parties in relation to industry collaboration(s).

5.4.2. UCDC member institutions, regardless of funding source, agree to follow all policies and procedures of the UCDC, including those that allow the UCDC to share data with industry. The UCDC will strictly adhere to HIPAA and will ensure that participant confidentiality is protected. Only de-identified data will be provided; or a limited dataset may be provided from participants who have agreed to share a limited dataset.[1]

6. Procedures related to UCDC collaborations with Industry Partners:

6.1. Initial Contact with the private sector – Companies interested in working with the UCDC should be directed to the Chair of the IRC, who will bring such proposals to the committee for discussion and determination if a

[1] A de-identified dataset is stripped of all 18 pieces of protected health information (PHI). A limited dataset may contain dates of birth, death, admission, and discharge.

collaboration between the UCDC and the company would meet the criteria listed in section 5.1 and is consistent with the Guiding Principles.

6.2. Non-Disclosure Agreement (NDA) – It is the policy of the UCDC not to sign an NDA for initial exploratory contact between the IRC chair and the company. If further discussions take place between the UCDC and the company and sensitive information will be shared an NDA may be signed between the investigator and the company.

6.3. IRC Review – The IRC Chair will bring proposed projects or collaborations to the IRC to determine whether collaboration criteria are met (see 5.2). The Committee will make a recommendation on such proposals to the executive leadership of the UCDC, which will have the final authority of approval.

6.4. NIH review – May need to occur prior to entering into a formal agreement (depending on the type of collaboration).

6.5. Work Product – If collaboration between the UCDC and a company is approved per UCDC policies outlined above, the work scope will be determined. The work may consist of providing data from the Longitudinal Study or other UCDC studies, and/or conducting a study for the company within the RDCRN-UCDC. The UCDC does not provide consultation services. Individual UCDC investigators may enter into independent agreements with a company to provide consulting services. Such relationships should be reported to the IRC of the UCDC at the time of initiation for mediation of any potential conflict of interest.

6.6. Services Agreement/Data Use Agreement/Contract

6.6.1. A services or data use agreement will be developed for each collaborative project conducted with industry. If more than one project is expected, a Master Services Agreement (MSA) or Master Data Use Agreement (MDUA) will be developed containing all the terms of the collaboration and each subsequent project will be added as an addendum to the MSA/MDUA with a specific scope of work and fee schedule.

6.6.1.1. A data access fee, reflecting the intrinsic commercial value of the dataset, will be assessed at the time of initiation of a data use agreement.

6.6.1.2. Invoiceable expenses for time spent by UCDC or DMCC staff to facilitate projects under a data use agreement will be based on fair market value and agreed at the time of initiation of the MSA/MDUA.

6.6.2. Contracts/Billing Agreements between CRI and UCDC Member Institutions - If a project involves contribution from UCDC institutions beyond the NIH and philanthropic funding commitments (i.e. additional IRB applications, additional case report forms, etc.), CRI will either:

6.6.2.1. Develop a separate agreement with the participating institutions for said project that will include key elements of the agreement with industry (flow-down terms). The institution will invoice CRI who will then invoice the company for the additional agreed upon costs.

6.6.2.2. Add the project as an addendum to the Industry Collaboration Authorization Agreement (ICAA). The full contract with the company will be supplied to the UCDC sites that have entered into the ICAA. The UCDC will coordinate the agreements and distribution of funds to the various sites involved. Sites will not be required to take part in these ancillary studies.

6.6.3. The UCDC program manager will facilitate the process, working with the CRI contracts attorney and the company's attorney.

6.6.4. Each Services Agreement or Data Use Agreement will address the following elements. Each element is listed with the standard assumption; however, these elements may be modified on an agreement-by-agreement basis.

6.6.4.1. Data use – Refer to the current version of the UCDC Data Use Policy. UCDC data may only be used in the U.S., Europe, Canada and Japan.

6.6.4.2. UCDC rights to data – The UCDC retains all rights to data that are collected under UCDC protocols unless the protocol is created specifically to collect data for a company, in which case data ownership will be negotiated as part of the Service Agreement.

6.6.4.3. Company rights to data – The company will have rights to data collected solely for the company according to the services agreement and scope of work. The UCDC may also have some rights to use the data as negotiated and defined in the Service Agreement.

6.6.4.4. Confidentiality – UCDC agreements, algorithms and data will be confidential. If protocols, policies, procedures, agreements, or data are to be shared, the terms will be defined in the services agreement.

6.6.4.5. Publication rights – Refer to the UCDC publication policy. Terms will be described in the services agreement.

6.6.4.6. Intellectual property – To be described in the services agreement.

6.7. Scope of Work and Timeline

6.7.1. The scope of work will describe in detail the services being provided, deliverables that are expected and a timeline for the

project. If the project is a consulting agreement or a clinical trial, delivery of work product may be on-going for a number of years. Incremental deliverables (eg. annual report, quarterly data downloads, etc.) will be defined.

6.7.2. If the Work Product is a clinical trial, the responsibilities and rights of the company/sponsor and those of any affiliated CROs will be described in detail.

6.8. Fee Schedule – The UCDC program manager will help develop a budget and fee schedule appropriate for the scope of work. The timing of invoices instructions for sending invoices will be defined in the fee schedule.

6.8.1. Payments made for consulting and data request projects will be deposited into the UCDC general industry/consulting cost center. A new cost center will be created for clinical trials.

6.9. Deliver Work Product – The work product will be delivered to the company according to the timeline listed in the Scope of Work.

6.10. Invoice Company – The Company will be invoiced through the CRI Grants and Contracts Office at least every 6 months for on-going projects or as defined in the Fee Schedule. UCDC member institutions will be reimbursed for effort in an industry project in accordance with the agreement between CRI and the institution.

6.11. Track Invoice and Receipt of Payment – Payments will be received by the CRI Grants and Contracts Office. Funds received for consulting and data requests will be applied to the UCDC industry cost center, which will be used to support UCDC infrastructure and administration. Payments received for conducting projects will be applied to their respective cost centers, which will be used to reimburse the UCDC sites and UCDC administration for their respective efforts.

7. Procedures related to UCDC COI reporting and mediation:

7.1. Individual investigators are expected to report any new industry collaboration or activity related to urea cycle disorders prior to initiation of the activity.

7.1.1. Such activities may include, but are not limited to, involvement in a non-UCDC clinical research protocol, service on any type of advisory board, speaking engagements on behalf of the industry collaborator, paid travel for any reason, or any activity that generates a direct payment or honorarium to the investigator (or to an institution or charity on behalf of the investigator).

7.1.2. UCDC investigators are under no obligation to collaborate outside of the UCDC with any industry partner. If a UCDC investigator wishes to interact with other UCDC investigators on behalf of a

company, the investigator working with industry will ensure that the other investigator(s) is(are) aware that the contact or request is on behalf of the company and not the UCDC. Participation in work for industry is voluntary and outside of any agreements that UCDC investigators have with the UCDC.

7.2. The IRC will survey all UCDC investigators for new or on-going potential COI on an annual basis.

7.3. The IRC will review COI reports and work with investigators to mediate potential conflicts in a timely manner.

8. References:

8.1. Publication Policy

8.2. Data Use Policy

9. Revision History

Version 04MAR2016 – First version of this policy

Version 02DEC2016 - Added expectation that an investigator working on behalf of a company will inform other UCDC investigators that their contact/request is on behalf of the company and not the UCDC.