**UConn Health Guidance for Investigators Using Quorum IRB (** [**http://www.quorumreview.com/**](http://www.quorumreview.com/) **)**

**when UConn Health is Added as a Site to a Multi-Center Trial**

(11/13/2018, 9/5/2017**,** 1/17/2017, 10/13/2016)

The following guidance may be used when UConn Health is being added as a study site to a multi-center trial. This guidance is intended to cover the most typical situation, but variation in the process may occur. Investigators may also contact Joe Derr (jderr@quorumreview.com, 206-436-3239) at Quorum IRB if further guidance is needed in making a submission to Quorum IRB.

Regardless of the specific steps in the process, a study for which Quorum will act as the IRB of Record cannot commence until Quorum IRB has issued the final approval AND UConn Health has issued the Final Letter of Acceptance of Quorum as the IRB of Record. UConn Health will not issue the final letter of acceptance until the Clinical Trial Agreement is fully executed and all other local requirements are met. After initial acceptance, changes to UConn Health study personnel will continue to require administrative review by the local IRB in addition to any requirements for review by Quorum IRB.

**General Guidance for Utilizing Quorum as IRB of Record:**

**1. Notifying UConn Health IRB**

* B**efore submitting to Quorum IRB** the investigator submits a request for facilitated review to the UConn Health IRB through the iRIS system. The initial request will serve as an administrative action to inform the UConn Health IRB that approval for a specific study will be sought from Quorum.
	+ The investigator (or designee) creates a new application in iRIS
	+ The application at UConn Health must name all key study personnel individually and be routed to them for sign-off.
	+ The type of review requested is facilitated
	+ The question that asks if the submission is an industry sponsored study is answered “yes”
	+ Quorum is noted as the requested IRB of Record.
	+ Attach the Quorum Cover page (provided below) to the submission so that UConn Health can sign-off on that form acknowledging that the Quorum will conduct the official review.
		- The application form and Quorum Cover page are the only required documents at this time.\*
* The UConn Health IRB will return the signed cover page and issue the contingent acceptance of Quorum as the IRB of record. Because this is an administrative acknowledgement, a Regulatory Specialist within the IRB may grant the contingent acceptance. This letter should be provided to Quorum as part of the submission to them.

**2. Submitting to Quorum and Obtaining IRB Approval from Quorum.**

* The investigator follows Quorum’s submission requirements and UConn Health consent requirements to obtain IRB approval from Quorum. Include the contingent acceptance letter form the UConn Health IRB in the submission.
	+ Detailed consent requirements are provided later in this document.
	+ It will be important to ensure that all local UConn Health consent requirements are addressed during this approval process (e.g. correct subject injury language, no HIPAA language in the consent, etc.).
		- If not, the UConn Health IRB may require that a request for modification be submitted to Quorum.

**3. Obtaining Final Acceptance from UConn Health**

* After obtaining approval from Quorum, the investigator returns to the UConn Health iRIS system and provides responses to the previous contingent acceptance of Quorum as the IRB and attaches all required documents as noted on the UConn Health submission checklist for facilitated review.
* UConn Health will follow its procedures for conducing facilitated reviews.
* When all local requirements are met UConn Health will issue the Final Acceptance of Quorum as IRB of Record letter to PI with copy to Quorum IRB.

\* - Investigators may opt to submit other ancillary documents (e.g. pharmacy review, conflict disclosures) to the UConn Health IRB with the initial request, at the time the final acceptance is requested or by responding to the initial contingent acceptance while Quorum is processing its review. The study specific documents (e.g. consent, protocol etc.) should not be submitted until after approval from Quorum IRB is obtained. The preference of UConn Health IRB is that all documents are submitted when seeking the final acceptance from UConn Health.

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| Quorum_logo_horiz_black copy | **Quorum Review** **Institution Cover Page** | **uconnhealth_stacked_black** |
| **For prompt assessment and Board review, Institution site submissions are submitted with the Site Information Questionnaire (SIQ) and should contain general elements as noted in the Site Submission Checklist found on Quorum’s website at** [**www.quorumreview.com**](http://www.quorumreview.com)**. Including the Institution Cover Page will ensure proper handling of your initial site submission.**  |
| NAME OF INSTITUTION | UConn Health |
| UConn Health IRB # |       |
| PRINCIPAL INVESTIGATOR |       |
| PROTOCOL NUMBER |       |
| SPONSOR NAME |       |
| **Investigator Unique / Modified Consent Forms**If you are a site participating in a central study for which Quorum is the central IRB, the Study Manager, or sponsor for the above protocol, can provide you with the current approved copy of the model consent form for review. *Please indicate below how your consent form should be handled for the above study.* [x]  This Institution **HAS** client template consent language with Quorum. For this study, my Institution requests to:1. [ ]  Use the model consent form and have PI incorporate our institution’s template consent language.
2. [ ]  Use the model consent form and have Quorum incorporate our institution’s template consent language. There is no need to submit a consent form with your submission; Quorum will add the template language.

*Please note that Sponsor approval will be needed prior to finalization of the consent form and issuing any approval documents. Quorum will facilitate this process.* |
| UConn Health Finance has approved payments in the form of checks made payable to cash [ ]  Yes [ ]  No |
| **Disclosure of Financial Interests**         [ ]  No conflict of interest is present[ ]  A conflict of interest has been reported to UConn Research Management Committee.  Please note you **must** attach the management plan that has been approved by the Committee, or the determination that one is not required (or as a separate attachment).  Please also note that the investigator is **required to promptly notify** Quorum Review, if changes to the approved management plan are made or a management plan is required due to a change in the study team members.Please also check “Yes” on Quorum’s Site Information Questionnaire (SIQ) Q. 7 and **attach** a completed Quorum Review Conflict of Interest Statement: Disclosure of Financial Interests and Management Plan Form.  |
| **Acknowledgement by UConn Health**The Investigator(s) named at the beginning of this form are authorized to conduct the above referenced investigational research study in this institution under the jurisdiction of Quorum Review.Signature of Richard Simon, MD or authorized Designee: Date:       Please give portal account access to the following individuals for compliance/oversight reasons:**HRPP Director and Deputy Director:** Richard Simon, MD: simon@uchc.edu; Deborah Gibb: gibb@uchc.edu **Regulatory Specialists:** Pamela Colwell: engelson@uchc.edu; Patricia Gneiting: gneiting@uchc.edu; Stephen MacKinnon: mackinnon@uchc.edu **Compliance Monitor:** Julia Schmidt: jaschmidt@uchc.edu **Financial Compliance:** Diane Clavette: clavette@uchc.edu  |
| **THIS SECTION DESCRIBES CURRENT HANDLING REQUIREMENTS FOR THE INSTITUTION ABOVE AND IS FOR QUORUM USE ONLY**Please see the Account Special Handling Document (ASHD) attached to the account record of UConn Health |

Version 2, dated 07/13/17

**UConn Health**

**Client Template Language**

1. ***Font size****: The institution prefers* ***12****-point font size.*
2. ***Number of participants****: Include the number planned to be enrolled at UConn Health (see Site Information Questionnaire for site’s target enrollment number) after the statement about how many participants will be in the study:*We estimate that <<number>> people will enroll at UConn Health.
3. ***Subject Injury:*** *Include the following language* ***after*** *the section describing the sponsor’s provisions for subject injury:*

**UConn Health Injury Language:**

UConn Health does not provide insurance coverage to compensate for injuries incurred during this research. However, compensation may still be available. A claim may be filed against the State of Connecticut seeking compensation. For a description of this process contact a representative of the UConn Health Institutional Review Board at 860-679-1019 or 860-679-4851 or 860-679-4849.

UConn Health does not offer free care. However, treatment for a research related injury can be obtained at UConn Health for the usual fee <<*If the sponsor will cover research-related injuries:* , although the sponsor may cover this fee for you if your injury is determined to be related to the research>>.

*<<Include the following, as long as this does not contradict the sponsor’s injury language:* Financial compensation for such things as lost wages, disability or discomfort due to the injury is not offered by the sponsor.

***<<If the sponsor specifically states in the consent that they will pay for costs of research-related injury that remain after insurance is billed add the following*:** As described earlier, the sponsor will pay for the medical expenses that are denied by your insurance. This will not apply to participants with Medicare/Medicaid because Medicare/Medicaid cannot be billed before the sponsor. For participants with Medicare/ Medicaid, the sponsor will be responsible for the cost of the treatment for injury. You should bring any itemized bill you receive to a study staff member and s/he will arrange for the sponsor to make payment. The study staff can explain this process to you and they may be reached at the phone number listed on page 1 of this form.***>>***

1. *UConn Health always uses a* ***stand-alone HIPAA authorization****. If the model form contains HIPAA elements, remove them and ensure consent confidentiality requirements are still met by the form. Quorum does not review stand-alone HIPAA authorizations.*
2. *In the section regarding* ***confidentiality/protection of personal information*** *add the following statements (****unless equivalent statements are already present in the form****):*
	1. *That confidentiality cannot be guaranteed:*We will do our best to protect the confidentiality of the information we gather from you but we cannot guarantee confidentialit*y.*
	2. *A statement that individuals will not be identified in any publications or presentations based on the research*
	3. At the conclusion of this study the researchers may publish their findings. Information will be presented in summary format and you will not be identified in any publications or presentations.
	4. *Include UConn Health's Institutional Review Board and Human Subject Protection Program as entities that may have access to information:*

Administrative oversight areas of UConn Health, including representatives of the Institutional Review Board and Human Subjects Protection Program, may also inspect your records to ensure the study is being done correctly.

* 1. ***If a study will likely yield such information and no Certificate of Confidentiality is in place****, include the following language:*

If during the course of this study we learn of *<<include as applicable to the study, for example a PTSD study in returning veterans:* child abuse, elder abuse, spousal abuse, communicable diseases>> we are required to report it to State officials.

1. **For industry sponsored studies of drugs, device or biologics insert the following**: This research may lead to the development of a commercial product. This product may have a financial benefit to the sponsor. If such a product is developed, it is not intended for you to share in the financial benefit.
2. ***Contact Information:*** *Include the following language after Quorum’s standard contact section:*

If you have questions about your rights as a research subject you may also contact a coordinator at the Institutional Review Board at UConn Health at 860-679-1019, 860-679-4851, or 860-679-4849.

1. ***Attestation for participation:*** *Replace the existing attestation language with the following:*

By signing this form, I (*include as applicable to the form:* the participant, legally authorized representative, parent(s) or guardian) acknowledge that I have read, or have had read to me, this informed consent document, have talked with research personnel about this study, have been given the opportunity to ask questions and have them satisfactorily answered, and voluntarily consent to participate in this project as described in this form.

I do not give up any of my legal rights. I will receive a signed copy of this consent form.

1. ***Attestation for person conducting consent discussion:***

By signing this form I, the individual obtaining consent, am confirming that the above information has been explained to the subject <<*include as applicable to the form:* (and/or legally authorized representative, parent(s) or guardian)>> and that a copy of this document, signed and dated by both the person giving consent and by me, along with a copy of the Research Participant Feedback Form, will be provided to the participant <<and/or representative>>. The individual providing consent had an opportunity to ask questions and voluntarily agreed to participation in this study. *<<****If the study involves genetic research also include the following statement, otherwise delete it:>>*** The handout regarding the Genetic Information Non-Discrimination Act has also been provided to the individual providing consent.

**Consent Form Supplement**

Conflict of Interest

*Sample consent form language describing any conflict of interest between the sponsor and the Principal Investigator, any member of the study staff, and/or immediate family members (including spouses and dependent children) of the PI or study staff.*

**Guidance**

* Below is a list of sample language that Quorum Review may insert in to a site-specific consent form if a site indicates a conflict of interest on the Site Information Questionnaire.
* **Language added to the site’s consent form would be based on the text below but adapted to reflect the site’s particular situation.**
* Please note that Quorum would only propose the addition of such language in a site's consent if the language was applicable to the site, based on the information that the site has provided Quorum about the Principal Investigator’s/study staff’s/family member’s financial relationship with the sponsor. Language that is not applicable to the site would not be included in the site-specific consent form.
* The model form for a central study will include only a bracketed statement: *<<Quorum may add site-specific conflict-of-interest language to the form based on information the site reports to Quorum.>>*
* Please speak with your Study Manager if you have questions about this information.

**Sample language**

<<<<The study doctor, A study staff member, *describe if other*>> has <<a financial relationship>> associated with the sponsor in which the payment for doing the study could be influenced by the results of the study. If you have concerns about this relationship, ask the study doctor for more information.>>

<<<<The study doctor, A study staff member, *describe if other*>> receives a significant payment from the sponsor, such as <<grants from the sponsor, fees for services <<the study doctor, the study staff member, etc.>> provides to the sponsor, money for research or equipment, compensation as a consultant to the sponsor, reimbursement for travel or other expenses, <<and/or>> speaking or other fees>>. If you have concerns about this payment, ask the study doctor for more information.>>

<<<<The study doctor, A study staff member, *describe if other*>> has a financial interest in the study <<drug, device, vaccine, product, etc.>> and may receive money depending on the results of this study. If you have concerns about this financial interest, ask the study doctor for more information.>>

<<<<The study doctor, A study staff member, *describe if other*>> has a significant amount of stock or other ownership in the sponsor of the study. If you have concerns about this ownership, ask the study doctor for more information.>>

<<<<The study doctor, A study staff member, *describe if other*>> is an employee or executive of the sponsor. If you have concerns about this employment, ask the study doctor for more information.>>

<<<<The study doctor, A study staff member*, describe if other*>> may receive a bonus based on the number of participants enrolled in the study. If you have concerns about this payment, ask the study doctor for more information.>>