**Guidance for Investigators Using Advarra IRB (** https://www.advarra.com/**)**

(Note: Schulman IRB and Chesapeake IRB merged to form Advarra IRB)

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

The following guidance may be used when UConn Health is being added as a study site to a sponsored multi-center trial. This guidance is intended to cover the most typical situation, but variation in process may occur. Investigators may also contact Caitlin Ziemak (Caitlin.ziemak@advarra.com, 203.628.4387) at Advarra IRB or Institutions@advarra.com if further guidance is needed in making a submission to Advarra IRB.

Regardless of the specific steps in the process, a study for which Advarra will act as the IRB of Record cannot commence until Advarra has issued the final approval AND UConn Health has issued the Final Letter of Acceptance of Advarra 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 Advarra IRB.

**1. Notifying UConn Health IRB**

* B**efore submitting to Advarra 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 Advarra.
	+ 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”
	+ Advarra is noted as the requested IRB of Record.
	+ The application form is the only required documents at this time.\*
* The UConn Health IRB will issue the letter of acknowledgement of the intent to use Advarra as the IRB of record. Because this is an administrative acknowledgement, a Regulatory Specialist or other staff within the IRB may process this submission. This letter is to be provided to Advarra IRB as part of the submission packet.

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

* The investigator follows Advarra’s submission requirements and UConn Health consent requirements to obtain IRB approval from Advarra. The acknowledgement letter issued by the UConn Health IRB is to be included in the submission.
	+ Detailed consent requirements are provided later in this document.
		- In addition, use of the medical record must be disclosed in the consent when applicable
	+ 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 Advarra.

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

* After obtaining approval from Advarra, the investigator returns to the UConn Health iRIS system 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 Advarra as IRB of Record letter to PI with copy to Advarra 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 Advarra is processing its review. The study specific documents (e.g. consent, protocol etc.) should not be submitted until after approval from Advarra IRB is obtained. The preference of UConn Health IRB is that all documents are submitted when seeking the final acceptance from UConn Health.

**ADVARRA MANDATORY LANGUAGE DOCUMENT**

**FOR**

**UCONN HEALTH**

**CONSENT REQUIREMENTS AND PREFERENCES**

|  |  |
| --- | --- |
| **Sponsor / Study Title:** | **Sponsor Name / “Protocol Title”** |
| **Protocol Number:** | **Protocol Number** |
| **Principal Investigator:****(Study Doctor)** | **«PiFullName»** |
| **Telephone:** | **«IcfPhoneNumber»** |
| **Address:** | **«PiLocations»** |

**Name of Research Participant:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Number to enroll:**

The goal is to enroll [insert number] participants in this study; with [insert number] of those being enrolled at UConn Health.

**Subject Injury:**

[**Required Language in addition to any sponsor subject 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 860-679-4849 or 860-679-8729.

[**Required Language in addition to any sponsor subject injury language**] UConn Health does not offer free care. However, treatment for a research related injury can be obtained at UConn Health for the usual fee.

[**Required if Condition is Met**] If the sponsor specifically states in the consent that sponsor will pay for costs of research related injury that remains after insurance is billed, the consent must also specify the following after that statement: <Research Sponsor Name> will pay for medical expenses for the treatment of your injury, or alternatively <Research Sponsor Name> will pay for the medical expenses that are denied by your insurance. This will not apply to Medicare/Medicaid patients because Medicare/Medicaid cannot be billed before the Sponsor. For Medicare/Medicaid patients, the Sponsor will be responsible for the cost of the treatment for injury.

**Subject Payment:**

[**Required if Condition is Met**] if the consent indicates subjects will be paid subjects must be informed about IRS implications and given the option to decline payment:

Because you will be paid for participation in this study you may be asked to complete a W9 form and your name, address and social security number will have to be sent to Accounts Payable. If you receive over $600 from participating in research studies over the course of the calendar year that money must be reported to the IRS as income. *You can also choose not to receive any compensation. Please indicate your preferences by initialing below:*

*Please make the check(s) payable to me.*

*I prefer not to receive compensation for this study.*

*I will pick the check up in person.*

*I would prefer the check be mailed to me.*

[**Required if Condition is Met**] The consent can only indicate that a check for participation will be made payable to cash if the submission to Advarra contains approval to do so from Research Finance at UConn Health or Clinical Research Center at UConn Health. If payable to cash the consent must state:

You may choose to receive a check made payable to cash. To do this, you must either bring identification to pick the check up in person or have it mailed to you by certified mail. If the check is payable to cash, no replacement checks will be issued if it is lost or stolen.

*[Include cash option only if you have permission from AVP]*

*Please make the check(s) payable to cash.*

**Contact Information**

Add the following language to the end of Advarra’s **WHOM TO CONTACT ABOUT THIS STUDY** 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 860-679-4849 or 860-679-8729.

**Conflict of Interest Disclosure Statement**

Advarra will verify that any required financial disclosures noted in UConn Health developed management plans are contained within the consent document.

**Development of Commercial Product: (Required statement for IND or IDE studies)**

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.

**Confidentiality Section**

The consent form must disclose whether research data will be placed in the medical record, the research record or some combination thereof. The wording doesn’t have to be specific as long as the issue is addressed. Sample language follows:

Clinical information collected during this study [insert will or will not] be stored in your medical record. [If selecting will, include language similar to the following] The medical record is confidential and accessible to authorized persons and to insurance companies. In addition, any clinical provider that you see, whether at UConn Health or elsewhere, may potentially have access to the information in your medical record.

**Inspection of Records**

**Required statement, typically placed after the statement that the FDA may inspect records:**

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

**HIPAA Language**

A separate HIPAA Authorization based on UConn Health template is required and Advarra will remove HIPAA language from sponsor consent template

**Consent To Participation:**

The following should always be inserted above the participant signature lines

By signing and dating this form you (the participant, legally authorized representative, parent(s) or guardian) acknowledge that you have read, or have had read to you, 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. You acknowledge that you have the opportunity to voluntarily provide feedback about your experience as a research participant. You may ask for a copy of the Research Participant Feedback Form, you may obtain the form online at https://ovpr.uchc.edu/services/rics/hspp/volunteers/, or you may submit the form online at https://redcap.link/UConnHealth-Feedback-Research .

The following should always be inserted above the person obtaining consent signature lines

By signing and dating this form the individual obtaining consent is confirming that the above information has been explained to the subject (and/or legally authorized representative, parents or legal guardians) and that a copy of this document, signed and dated by both the person giving consent and the person obtaining consent, along with a copy of the Research Participant Feedback Form if requested, will be provided to the participant >and/or representative<. [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 subject.