**Guidance for Investigators Using WCG when UConn Health**

**is 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 multi-center trial that has been approved by WCG. This guidance is intended to cover the most typical situation, but variation in process may. Investigators may also contact WCG (see below) if further guidance is needed in making a submission to WCG.

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

General Guidance for utilizing WCG as IRB of Record

**1. Notifying UConn Health IRB**

* B**efore submitting to WCG** 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 WCG.
	+ 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”
	+ WCG 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 contingent acceptance of WCG as the IRB of record. Because this is an administrative acknowledgement, a Regulatory Specialist within the IRB may grant the contingent acceptance.

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

* Investigator checks with Sponsor to see if WCG has conducted a review of the protocol. If so, contact WCG Account Manager Glori Schmeckpeper at Gschmeckpeper@wcgclinical.com, (360)252-2429 or Client Services at 1-855-818-2289. Ask WCG to send the WCG approved Sponsor Template ICF and the WCG Template Key for required consent language, and to give you access to Connexus, the system used by WCG. They’ll explain what submission form to use and answer any of your questions.
* If the Sponsor does not have a current arrangement with WCG for review of the protocol and the investigator wants to proceed with submission to WCG, the Sponsor must provide the investigator with a letter of commitment that sponsor will pay WCG for all IRB review services.
* The investigator follows WCG’s submission requirements and UConn Health consent requirements to obtain IRB approval from WCG.
	+ 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.).
		- The study team is advised to consult with OCTR/Contracts staff on injury language in the ICF to ensure consistency with the clinical trial agreement **before** submitting the ICF to WCG.
		- If not, the UConn Health IRB may require that a request for modification be submitted to WCG.
	+ WCG requires all HIPAA Waiver requests (partial or full) to be listed in their submission form and requires HIPAA Authorizations to be submitted as “subject material” for review. Study teams are responsible for using the UConn Health HIPAA template to ensure the required State of Connecticut language and UConn Health language is included.
	+ For reference the institutional number assigned to UConn Health by WCG is 90947

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

* After obtaining approval from WCG, the investigator returns to the UConn Health iRIS system and provides responses to the previous contingent acceptance of WCG 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 WCG as IRB of Record letter to PI with copy to WCG.

\* - 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 WCG is processing its review. The study specific documents (e.g. consent, protocol etc.) should not be submitted until after approval from WCG is obtained. The preference of UConn Health IRB is that all documents are submitted when seeking the final acceptance from UConn Health.

**\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*University of Connecticut Health Center Required Consent Language\*\*\*\*\*\*\*\*\*\*\*\*\*\*\***

Note: The following document contains only the language requirements for the institution.

It is not a complete consent template.

**TEMPLATE KEY**

Black Text Black text is part of the body of the document. Typically, black text will be grey shaded where required.

Red Text Red text is being used to help section headings stand out.

Blue Text Blue text represents instructions specifically for WCG staff. These need to be reviewed and followed by all staff members working with the template.

Purple Text Purple text represents suggested language and/or instructions meant for the site or other parties outside of WCG. Typically, this text can be ignored by WCG staff.

[Blue Text in Brackets] Blue text in brackets represents a fill-in field meant to be completed by WCG staff.

[Purple Text in Brackets] Purple text in brackets represents a fill-in field meant to be completed by the site. If this information has not been provided by the site, the EPC instructions will indicate whether staff should hold to request this information or consider the information not applicable to the submission.

Grey Shading Grey shading indicates language that is required verbatim.

 Purple text in grey shading indicates language that will be submitted by the site if applicable. If submitted, this language must be verbatim. If this language is not submitted by the site, WCG staff will not add it.

 Blue text in grey shading indicates instructions for WCG staff that must be followed but may not involve verbatim language requirements.

\*\*\*\*\*\*\*\*\*\*\* A line of red asterisks is used to separate sections of the template. When you reach such a line, any preceding instructions and requirements should be considered to have reached their end.

Check the submitted consent form, protocol level WCG approved consent form template, or the sponsor’s template for the sections that need additional language.  If the language is not in those documents, contact the site for the information.

This institution requires a separate HIPAA Form. Do not include HIPAA language in the consent form(s).

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Include the following line immediately after WCG’s standard headings:

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

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This institution requires that the consent form contain the expected number of participant that will enroll at the institution and nationally. The following language is an example of the text that may be submitted. Variations to this language are acceptable.

We estimate that [##] people will enroll at this site. This study is being conducted at several other places too. We estimate that the total number of people enrolled at all places will be [####].

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**Payment for Participation**

Include WCG standard language or submitted text – plus

The site will include the following text after the payment paragraph, if they are issuing checks payable to cash. Variations to this text are allowed.

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.

The following language will be submitted by the site if appropriate to the research:

You can also choose not to receive any compensation. If that is your preference, please initial below:

I prefer not to receive compensation for this study.

OR – If a subject is not being paid:

You will not be paid for participation in this study.

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**Commercial Products**

If there is no “Commercial Products” language in the standard template or sponsor’s template, include the following text immediately following payment for participation:

This research may lead to the development of a commercial product. This product may have a financial benefit. If such a product is developed, it [is or is not] intended for you to share in the financial benefit.

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**Privacy and Confidentiality**

The site will submit language regarding privacy and confidentiality. The consent form must disclose whether the research data will be placed in the medical record, the research record or some combination thereof. Check the submitted consent form for the language. This institution also requires that all consent forms that include the sponsor and UConn Health as entities that are receiving information. If the site does not submit a consent form, add WCG’s ‘conf’ autotext.

The site will add the following language if the study makes use of medical record:

Clinical information collected during this study [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.

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**Injury from Participation**

Use WCG standard, submitted or sponsor’s injury language – plus add the following as the last two paragraphs of the section.

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’s Institutional Review Board at 860-679-8729 or 860-679-4849.

UConn Health does not offer free care. However, treatment for a research related injury can be obtained at the UCHC for the usual fee.

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**Questions**

Use WCG standard, submitted, or sponsor’s questions text - plus add the following before WCG “rights”

If you have questions about your rights as a research subject you may contact a coordinator at the UConn Health Institutional Review Board at 860-679-8729, or 860-679-4849. [The site will include the following information if the study is supported by the Clinical Research Center: You may also contact the Research Subject Advocate at 860-679-3276.] You may also call a coordinator at the Institutional Review Board if you want to talk to someone who is not a member of the research team in order to pass along any suggestions, complaints, concerns or compliments about your involvement in the research, or to ask general questions or obtain information about participation in clinical research studies.

Please do not call the IRB number for medical related issues or to schedule or cancel an appointment.

AND

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**Consent To Participation**

Required Language, delete reference to LAR, parent or guardian in if not applicable to the study:

By signing 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>.

Required Language, revise for reference to LAR, parent or guardian as applicable to the study:

By signing 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 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, will be provided to the participant [and/or representative]. [The site will include the following statement if the study involves genetic research:] The handout regarding the Genetic Information Non-Discrimination Act has also been provided to the subject.

Include WCG standard or submitted signature lines.