



## Special Edition Newsletter Aurora Research Subject Protection Program (RSPP) Institutional Review Board (IRB) January 2019

This is the last Special Edition of our newsletter discussing the regulatory changes included in the revised Federal Policy for the Protection of Human Subjects (aka the HSS “Common Rule”). The changes included in the revised Rule are scheduled to go into effect on January 21, 2019.

This Special Edition will discuss changes to **Informed Consent**. The Aurora RSPP, along with other IRBs, has been waiting for the authors of the revised Common Rule to provide guidance on this topic to no avail. We will provide updated information as it becomes available.

### Informed consent changes under the Revised Common Rule

Initial Submissions of research approved or transitioned after January 21, 2019 must consider, when applicable, the following as part of an informed consent process:

- \*Concise summary of the research - provided at the beginning of the consent document
- New consent elements – one required and 3 additional/applicable
- Changes to waiver of informed consent criteria and documentation
- \*Posting of consent documents on a federal website (TBD) for federally funded clinical trials
- †Broad consent option for unspecified future use of identifiable data/biospecimens (exempt categories 7 & 8)

\*The Aurora system policy on *Research Involving Humans or their Identifiable Data or Biospecimens* (#811 in Policy Tech) includes carve-outs/exceptions for the concise summary and posting of consent documents for **unregulated research**<sup>1</sup>. This means that the requirement for a concise summary and posting of consent documents is not required for unregulated research.

† Per Aurora system policy 811, the use of Broad Consent will not be available to researchers until a system-wide process is in place to address the requirement to track those who decline or fail to respond to a request to provide broad consent. Should a tracking system become available, information will be provided on the potential use of broad consent in research.

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<sup>1</sup> Human Subject Research not regulated by federal regulation [i.e. DHHS regulation (“Common Rule”)]

## Concise summary of key information

Per the revised Common Rule the “informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject (or legally authorized representative) in understanding the reasons why one might or might not want to participate in the research.” This summary must be presented in an organized fashion that facilitates understanding, and “includes information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.”

The preamble to the revised Common Rule lists 5 points that are suggested as key information that would likely assist a potential subject in understanding the nature of the research and making a determination on participation. These include:



Modified from [www.citiprogram.com](http://www.citiprogram.com)

How a study team opts to apply this requirement will depend greatly on the complexity of the research project. The Aurora IRB informed consent template (located on the [RSPSP website](#)) includes some tips and instructions on creating the concise summary. These tips/instructions include a recommendation on the length of the concise summary (it should be no longer than 3 pages), the need to repeat the information included in the concise summary in the appropriate location in the informed consent document, what to include in your summary if your entire consent document is brief in length, etc. Remember that the concise summary, in addition to the entire consent document, should be written as plain language, at an appropriate reading level understandable to your potential subject population.

If your study is ceded to an external IRB, you are reminded to follow that IRB’s instructions when creating the concise summary.

## New consent elements

The table below outlines the new elements of informed consent that must be included in your research consent document as applicable. These elements have been included in the consent template posted on the RSPSP website.

When your project will involve...	Include in the informed consent...
<b>REQUIRED ELEMENT</b>	
The collection of identifiable private information or identifiable biospecimens	<p>A statement indicating whether:</p> <ul style="list-style-type: none"> <li>• identifiers may be removed, and</li> <li>• <b>de-identified</b> information or biospecimens <b>may or may not be</b> used or shared for future research</li> </ul>
<b>ADDITIONAL ELEMENTS</b>	
Use of biospecimens	<p>A statement indicating whether:</p> <ul style="list-style-type: none"> <li>• biospecimens may be used for commercial profit, and</li> <li>• the subject will share in that profit</li> </ul>
Clinically relevant results	A statement indicating whether the clinical results, including individual research results, will be returned to the subject, and if so, under what conditions
<p>Whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen)</p>	A statement indicating that the research will or might include whole genome sequencing

### Use of short form consent to enroll subjects who do not speak English

For regulated research studies approved after January 21, 2019, or those approved before this date but transitioned to the revised Common Rule regulations, and in which you would like to use a short form consent process to enroll a potential subject who does not speak English, you will be required to provide the concise summary to the potential subject. The concise summary may be verbally communicated to the potential subject by an Aurora-approved interpreter. However, it **MUST** be communicated to the potential subject before the translated short form consent document is provided to the potential subject. See Aurora RSPP

guidance on *Enrolling Subject Who Do Not Speak English* for more information. Also remember that the translated short form consent MUST include the new elements of informed consent.

### Transitioning

If your study was approved by the Aurora IRB prior to January 21, 2019, you will not be required to include the applicable consent changes in your already-approved consent document –even if the study/informed consent document requires amendment/modification – as long as your study has not undergone transitioning. As stated in an earlier edition of this newsletter, the Aurora RSPP will be transitioning all research studies under the oversight of the Aurora IRB to the revised Common Rule by mid-2022. If your study is still open to enrollment of new subjects at the point of transitioning, you will be required to appropriately revise your informed consent document. The Aurora RSPP will work with study teams to ensure that the consent document is appropriately revised.

### Waivers of informed Consent

- The Aurora *IRB Application* has been revised to ask for justification as to why the use of identifiers is necessary to carry out research requiring the secondary use of identifiable private information/biospecimens.
- Use of identifiable information/biospecimens to identify potential subjects (i.e., screening for recruitment purposes) is allowed under the revised Common Rule without informed consent. Therefore, a waiver of informed consent will no longer be needed for screening activities. The *Waiver/Alteration of Authorization* form (502.3) – located on the [RSPP website](#) – has been revised to remove this requirement. NOTE that HIPAA regulations still apply, and a waiver/alteration of authorization is still required for screening activities.

### Posting of informed consent documents

A copy of the informed consent document for federally funded clinical trials must be posted to a publically available, federal website following the completion of enrollment, but no later than 60 days after the last subject's visit. The federal website to be used has yet to be determined.

This activity will be overseen by the Aurora Research Institute. We will provide more information as it becomes available.