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News from the Advocate Aurora Health Research Subject Protection Program (RSPP) Institutional Review Board (IRB)

January 2020

Contents

RSPP/IRB Integration Update

Michelle Maternowski, Director of the RSPP office of Advocate Aurora Health

Best laid plans often go awry, and IRB integration at Advocate Aurora Health is a good example of that adage. Back when we started RSPP/IRB integration plans (about a year ago), I never would have thought that they would not be completed by the end of 2019. But here we are in late December … the RSPP/IRB offices for the legacy institutions have completed integrated (the RSPP is one unit for both legacy Advocate and Aurora), but IRB integration is not completed.
We have made progress – we have group of individuals from both Advocate and Aurora who have agreed to serve on the integrated IRB, and the RSPP has created an integrated meeting schedule, etc. However, we have experienced delays in fully integrating and naming the resulting IRB. Due to these delays, we have not been able to transition currently approved studies to the oversight of the integrated IRB.

So as not to jeopardize study approvals, we have chosen to delay integration and transfer of studies a bit longer. If all goes well and according to our new plan of action, the IRB of Advocate Aurora Health will be integrated in February 2020.

There is a lot of work that needs to occur behind the scenes to make this plan happen. But once done, PIs/research teams will receive a letter from the RSPP office noting the name of the integrated Advocate Aurora IRB that will have oversight responsibility for the approved research study. You will need to share this change in IRB with your study sponsor as well as any federal agency that requires notification (e.g. FDA).

Integrated RSPP forms and SOPs – educational sessions

In the meantime, we are working to getting submission and post-approval forms ready to use when IRB integration is final. Once IRB integration is final, we will begin to work under one set of RSPP forms and SOPs.

To this end, we are scheduling forms/SOP education meetings **in the month of January**. These sessions will inform researchers/team members about the integrated forms and SOPs. These forms and SOPs are essentially those that are

currently in use at legacy Aurora. Those individuals that have experience in using the Aurora IRB for study oversight will not notice much change. However, **researchers at legacy Advocate** who do not have experience using the current Aurora forms/SOPs, these sessions are for you! I don't foresee a lot of differences in content in the new forms and SOPs. However the 'look' of the new forms will definitely be different. The current Advocate documents were created by Huron Consulting who base their forms/SOPs solely upon the federal regulations. The questions on their forms are very open-ended – the submitter provides the information that they think that the IRB may want to know. The Aurora forms and SOPs are also based on the federal regulations, but because we are an accredited institution/IRB, we sometimes need to go the extra step in getting information to fulfill accreditation standards. At Aurora, we tend to include very specific questions on our forms so that information is not forgotten.

Once the education meeting dates have been set in January (we are expecting them to occur at 0800 in the 2nd and 3rd weeks of the month) Outlook invites will be sent to everyone in our researcher list-serve (both Advocate and Aurora). It's up to you to decide whether you wish to listen to the presentation(s) – they will be the same content. A copy of the presentation slides will be made available prior to the session.

Remember, the new forms/SOPs will go into effect with the integration of the IRB and transfer of currently approved studies to that IRB. Again, it is hoped that this will occur in February 2020. Once the IRB is integrated, the RSPP forms will be uploaded into the Advocate IRB Net forms library. These new forms will replace those forms that currently reside in this electronic submission platform. We will send a global email blast to our list-serve notifying everyone when the new forms will be required to be used, and the RSPP SOPs implemented.

<u>Electronic submission platform</u>

One other delay that we have experienced is getting one submission platform for all Advocate Aurora Health research. Our plan is to create a new IRB Net submission platform that will service the entire organization. Contracting roadblocks have delayed the start of the new IRB Net to most likely May 2020.

Because of this delay, we ask that researchers from legacy Advocate sites continue to use the current Advocate IRB Net system. Again, the forms that are to be used will be changing, but the process of logging in and uploading your IRB submission will remain the same. For those researchers/research teams at legacy Aurora sites, we ask that you continue to use Cyber IRB to upload your IRB submission. Again, the forms that you will be using/uploading will not be changing.

<u>New IRB numbering convention</u>

With the start of 2020, all submissions to the Advocate Aurora RSPP will begin using the same numbering convention. Beginning on January 01, 2020, the IRB number for all submissions to the RSPP office (whether in Wisconsin or Illinois) will be in the following format: *20-XXX*. The first two numbers designate the year of submission. The three-digit number that follows will start at 001, and increase consecutively with each study submitted in the year. There may be letters associated with your IRB number. These will designate the type of study that was submitted ('E'=expedited; 'ET'=exempt; 'WC'= ceded study; 'H' =HUD; etc.). This numbering convention is one that we have been using in Wisconsin for over 20 years. It may not seem like much, but this numbering convention can provide the IRB with a snapshot of information that can be time-saving.

For those of you in Illinois that are used to having a research generated study ID (SID) number associated with your research study, don't worry, that number will still be collected in the IRB Net system and stored in the RSPP database. It will merely not appear in the IRB number or on study correspondence.

RSPP Staff Directory

With the recent RSPP merger there has been some confusion about who to reach out to with questions related to Human Subject Research at Advocate Aurora Health. During the merger process, individuals should continue to contact the RSPP office as they have in the past. Individuals from either Wisconsin or Illinois that have any questions or comments about the IRB process or for the IRB office, should not hesitate to contact us at 414-219-7744 or toll-free at 877-219-7744. This central phone number will service both the Illinois and Wisconsin locations. You can also email us at irb.office@aurora.org. This email box will service both Illinois and Wisconsin locations, and is a great way to ensure that you get in touch with the appropriate individual at the Advocate Aurora Health RSPP offices. Using the main phone or email address will typically get you a much quicker response – but if you are working with one of the RSPP staff on a question/issue feel free to communicate with that individual directly! A complete list of Advocate Aurora staff and contact information follows:

Milwaukee location	**Illinois location**	
Director of RSPP Michelle Maternowski, BS Email: **michelle.maternowski@aurora.org** Phone: **414-219-7703**		**Institutional Official** Dennis Baumgardner, MD Email: **dennis.baumgardner@aurora.org** Phone: **414-219-5191**
IRB Administrative Assistant Linda Beaumont Email: **linda.beaumont@aurora.org** Phone: **414-219-7744**	**IRB Administrative Assistant** Andree Lanera Email:Andree.lanera@advocatehealth.com Phone: **630-929-6148**	
IRB Coordinator Debi Christianson Email: **debi.christianson@aurora.org** Phone: **414-219-7629**		
Research Compliance Analysts:	**Research Compliance Analysts:**	
Linda Stahovic, MSW, MBA Email: **linda.stahovic@aurora.org** Phone: **414-219-7431** Brooke Mechelke, BS Email: brooke.mechelke@aurora.org Phone: **414-219-5981** Angela Carpenter Email: **angela.carpenter@aurora.org** Phone: **414-219-7280** Patti Allard Email: patti.allard@aurora.org Phone: **414-219-7714**	Jasmine Taylor, BA, CIP Email:jasmine.taylor2@advocatehealth.com Phone: **630-929-6151** Susan Fargo, BA, CIP Email: susan.fargo@advocatehealth.com Phone**: 630-929-6152** Terry Cole Email: teresa.cole@advocatehealth.com Phone**: 630-929-6148**	

2020 Single IRB Review Requirements

The revised federal "Common Rule" includes a new requirement for single IRB review for studies that involve multiple institutions. This requirement **goes into effect January 21, 2020**. Here is a link (https://www.hhs.gov/ohrp/regulations-and-policy/single-irb-requirement) to information on this new Common Rule requirement. Note that it is different from the NIH policy on single IRB review implemented on January 25, 2018.

There will be some changes to the Request to Rely form and the submission processes relative to the single IRB reliance system for Advocate Aurora Health (this process will be universal for Wisconsin and Illinois sites with finalization of RSPP/IRB integration). The changes are mostly centered around us fine-tuning our processes for ceding of IRB oversight or acceptance of IRB oversight for multi-center research. Watch for more guidance from the AAH RSPP soon.

Informed Consent Series Part 4 – Managing Informed Consent Errors (CTCC Newsletter October 2019 Issue 69)
By Tracy Graham, RN, Research Educator

Every year, informed consent (IC) related issues appear in the top 5 findings on FDA inspection and internal quality monitoring. This five-part series on IC will review common findings and strategies for avoiding these errors in your daily work. In part 3 of this series, strategies for avoiding common IC mistakes was reviewed. Part 4 will now cover steps to take once an IC error has occurred.

Subject Consented with Wrong IC Version / Failure to Re-consent Subject with Updated ICF

- Notify the investigator, sponsor, and IRB of this noncompliance
- Provide the missing information to the subject as soon as possible in a manner agreed upon by the investigator, sponsor, and IRB. Whether to inform the subject about the error and missing information in person or by phone depends on the potential impact of the missing information on the participants desire to remain in the study.
- Consent the subject with the correct informed consent form (ICF) version as soon as possible.
- Document all facts surrounding the error in the EMR or subject record
- If subject was consented with the wrong IC version, retain both ICFs in the subject record and EMR

Wrong/missing date on ICF, signature on wrong ICF line or missing, missing ICF pages, or sub-study preference not indicated on ICF

- If errors are noticed immediately and parties involved are still present, omissions and corrections should be made directly on the ICF. Strike through errors and enter correct information accompanied by the initials and date of the person(s) making any change.
- If the error(s) are not discovered immediately, notify the investigator, sponsor, and IRB of this noncompliance and identify any procedures to be followed.
- Document the facts surrounding the error(s)/omission(s) and steps taken to reconcile the problem(s) in a note. When possible, have those whose who made errors/omissions sign and date the note.
- Attach the signed note to the ICF and provide a copy of the note to the subject.
- Do not make a note directly on the ICF or retrospectively sign or back-date the ICF.

Missing original ICF

- If possible, attempt to retrieve a copy from medical records or the subject
- If no copy of the ICF can be located, consider re-consenting the subject if the subject is still active in the study and document details surrounding need for re-consent in the Electronic Medical Record.
- Report any noncompliance to the investigator, sponsor, and the IRB
- Document the facts, extent of the problem (is more than one original ICF missing?), and steps taken to resolve the problem in the trial records.
- If there is no evidence of subject consent, sponsor will need to determine if subject data can be used.

If IC errors involve multiple subjects or studies, management should be notified and a root cause analysis with corrective and preventive action plan implemented.

Non-English Speaking Subjects and Short Form Consent Translations

When you unexpectedly encounter a prospective subject who does not speak or understand English, the RSPP has the Advocate Aurora Short Form consent document translated into the following 22 languages:

Arabic	**Hindi**	**Russian**
Assyrian	**Hmong**	**Serbian**
Bosnian	**Italian**	**Simplified Chinese**
Croatian	**Japanese**	**Spanish**
French	**Korean**	**Traditional Chinese**
Greek	**Lao**	**Urdu**
Gujarati	**Malayalam**	**Vietnamese**
	Polish	

The translated short form consent contains the basic elements of informed consent in a language understood by the potential subject. In addition to the translated short form consent, the potential subject must be provided with a 'summary' of the research study. In most cases it is acceptable to use the IRB approved English version of the full consent document as the 'summary' document. The summary will provide the potential subject with information about the study procedures and the possible risks/benefits that they may encounter while a research subject. In addition the potential subject must be provided with all necessary elements of a valid HIPAA authorization. The elements of a valid authorization are included in your IRB approved English consent document or the Privacy Board approved stand-alone authorization. The English 'summary' document and if necessary, the stand-alone HIPAA authorization must be verbally presented to the potential subject by a qualified interpreter (per Advocate Aurora system policy).

Note that whenever a Non-English speaking individual is enrolled into a research study at Advocate Aurora Health, it is required that all future research visits be facilitated by a qualified interpreter. It is also expected that any study-required subject materials will be translated into the foreign language at your/study sponsor's cost. Contact the study sponsor for assistance in this regard. Remember that any translated subject materials require IRB approval.

In order to obtain a copy of the short form consent document translated into one of the above languages, you will need to submit a modification/Change of your IRB approved research study office BEFORE using the short form consent/process to enroll the subject. The IRB considers the use of the short form consent process to be a Single Patient Change to the approval granted by the IRB, and must therefore determine the appropriateness of the use in the study/situation. Once the modification/Change form is approved by the IRB (OHRP states that an expedited review process is appropriate in most cases) you will be provided with the translated short form consent document that may be used to enroll the individual into the study.

In order to ensure that the RSPP/IRB is aware of the request to use the short form process and can review the request in an expeditous fashion, we ask that you contact the RSPP office to make us aware of the submission of the modification/Change form. If the RSPP is not notified of the submission of the request in advance, it will go through the normal triage/review process that all modifications are afforded – and may not be reviewed in the time frame of your liking.

Note that in most cases, the encounter of a Non-English speaking potential subject and need for use of a translated short form document is not considered an emergency use situation. Therefore, in most cases, you should have time to submit the modification/Change form to the RSPP office before the enrollment of the subject into the study. As noted above, if the RSPP office is made aware of the submission of the modification/Change form requesting the use of the short form consent process, we will work to review/approve the request in the most expeditious manner possible.

Failure to follow the RSPP processes in obtaining prospective approval from the IRB for the use of the short form consent process will result in the event qualifying as Noncompliance. You will need to report the incident per RSPP SOP/policy.

If you have a need for a short form translation in a language besides one of those listed above, it is recommended that you contact the study sponsor to see if they can provide you any help in obtaining a translated short form consent document in that language. [Note that the AAH RSPP has an English version of the short form consent document that should be used to generate the translation.] You may also contact the RSPP office for possible assistance, although this cannot be guaranteed.

Website Updates

Please make sure to bookmark the searchable RSPP website: https://www.aurorahealthcare.org/rspp-irb. If you encounter difficulties while navigating through this website, please contact Angela Carpenter at: angela.carpenter@aurora.org

RESEARCH NEWS AND HOT TOPICS

OHRP's latest informational video for the general public explores the basic differences between medical research and medical care to help potential participants make the right decision for themselves about whether to join a medical research study. The Spanish language version of this video is now available!

Find "How is Medical Research Different from Medical Care?" in English HERE.
Find the *NEW* Spanish Language version HERE.

REMINDERS

Significant Interest Disclosures

Interest Disclosures: Per legacy Aurora System Policy 269, Investigators/key personnel must update their annual disclosure within 30 days of discovering or acquiring a new significant interest, and Investigators/key personnel have an obligation to notify appropriate reviewing bodies (including the IRB) and funding agencies of significant interests they believe are related to a project on which they are named. Significant Interests are those related to a research project that could directly and significantly affect a covered party's designing, conducting, or reporting of the research or Aurora's conduct, review, and/or oversight of the research. The disclosure questionnaire is available through Policy Tech, Aurora's on-line system. Please contact the RSPP office if you have questions on how to access the questionnaire to process a new or changed Significant Interest. In addition, if you wish to notify the IRB of a Significant Interest that you hold and you believe is related to a study on which you are participating, please send to the RSPP office email. Please do not include specific monetary values in the email.