IRB UpDATE

**DATE: December 2018**

**TO: Research Community**

**FROM: SUNY Downstate Medical Center IRB & Privacy Board**

**RE: Updates to IRB Forms, Templates, Guidance, and Policy IRB-01**

**Dear Research Community:**

Happy Continued Holidays! The following information provides key information regarding revisions to IRB forms, templates, guidance, and Policy IRB-01 for the SUNY Downstate Medical Center IRB. If you have questions, suggestions, or wish to request training, please contact the IRB Office at (718) 613-8480 or [IRB@downstate.edu](mailto:IRB@downstate.edu)

**Informational Sessions:**

The IRB will host the following informational presentations regarding the revised Common Rule and Policy IRB-01. All are invited!

|  |  |  |
| --- | --- | --- |
| **Date** | **Time** | **Location** |
| **January 10, 2019**  (Thursday) | **Noon Presentation**  Q&A session follows | **Special Functions**   |  | | --- | | (HSEB 1-025/ E138) | |
| **January 14, 2019**  (Monday) | **2 PM Presentation**  Q&A session follows | **Lecture Hall 1A**  (HSEB) |
| **January 16, 2019**  (Wednesday) | **10 AM Presentation**  Q&A session follows | **Classroom 1A**  (HSEB) |

**Policy IRB-01:**

The IRB has posted revisions to IRB-01 Policy, **effective January 21, 2019**. Although there are many updates and clarifications, the primary purpose of this update is to comply with U.S. Department of Health and Human Services and fifteen other Federal Departments and Agencies’ revisions to the Federal Policy for the Protection of Human Subjects (Common Rule), with a compliance date of **January 21, 2019**.

These revisions are an effort to modernize, simplify, and enhance the current system of oversight.

The following are available on the [Policies and Procedures web site](http://research.downstate.edu/irb/irb-policies.html):

* + - IRB Update (this memo)
    - IRB-01: SUNY Downstate Medical Center Human Research Protections Program [(WORD)](http://research.downstate.edu/irb/documents/IRB-01Revised12.20.2018-LOCKED.docx) [(PDF)](http://research.downstate.edu/irb/documents/IRB-01Revised12.20.2018.pdf)
    - IRB-01: Major Changes Highlighted [(WORD)](http://research.downstate.edu/irb/documents/IRB-01Revised12.20.2018-MajorChangesHighlighted.docx) [(PDF)](http://research.downstate.edu/irb/documents/IRB-01Revised12.20.2018-MajorChangesHighlighted.pdf)
    - IRB-01: Summary of Changes [(WORD)](http://research.downstate.edu/irb/documents/SummaryofChangestoIRB-01Policy12.26.2018LOCKED.docx) [(PDF)](http://research.downstate.edu/irb/documents/SummaryofChangestoIRB-01Policy12.26.2018.pdf)

**IRB REVIEWS IN PROCESS:**

The IRB will continue to use the current forms for reviews that are in progress; however, the IRB will let you know if additional information is required in order to approve a study **on or after January 21, 2019** based on federal regulations or revision to IRB-01 policy.

**Exempt IRB applications:**

There are three (3) versions of the IRB Exempt application during the transition to the revised Common Rule, as described below.

*NOTE: Each form describes applicable exemption categories.*

A. **CURRENT** Application for Exempt Review (version date 3.14.2018; available until 1.21.2019)

* Use for current research submissions.
* On 1.21.2019, research on this form qualifies for the new exemption categories except exemption category #1.
* For research that is exempt under only category #1, it is best to use the NEW form (version 12.17.2018).

*Note: The IRB will accept submissions (including DOJ/DIJ funded research) on the current form; however, the IRB may request additional information to grant approvals under category #1, effective 1.21.2019.*

B. **NEW:** Application for Exempt Review (version 12.17.2018 or later)

* This form has new expanded exemption categories under the revised Common Rule, effective 1.21.2019.
* Use this version now only for exemption category #1 (including DOJ/DIJ funded research).
* Use this version for all other exemptions research for approvals on or after 1.21.2019.

C. **DOJ/DIJ:** Application for Exempt Review - DOJ/DIJ Funded Research Only (version 12.21.2018 or later)

* Use this form now for any DOJ/DIJ funded research.
* DOJ is not a signatory to the revised Common Rule.

**ALL OTHER IRB APPLICATIONS:**

* Use all other applications (version date of 12.17.2018 or later) at any time.
* These newer forms are compatible with the both the current and revised Common Rule.
* The IRB will continue to use prior forms for reviews that are in progress; however, the IRB will let you know if additional information is required in order to approve a study on or after January 21, based on federal regulations or revision to IRB-01 policy.

**IRB Decision Aid- application for a determination letter to state irb approval is not required:**

There are two (2) new versions of the [IRB Decision Aid](http://research.downstate.edu/irb/irb-electronic-submissions.html). Use the version that applies to the project.

Use form designated for Health Care Operations Activities Only, when there is no intention of developing or creating generalizable knowledge, and the proposed activity is limited to one of the following:

* Health care operations activity (e.g., performance improvement),
* Case report or case series (up to three individuals),
* Operational activity,
* Pilot activity, feasibility activity, or evidence-based practice activity, or Training or educational activity, or
* Not engaged in human research.

Use the other version for any request, including those listed above.

**Informed Consent Templates, INFORMATION SHEETS, HIPAA Authorizations:**

* Please use the above noted [forms](http://research.downstate.edu/irb/irb-electronic-submissions.html) with a version date of 12.27.2018 (or later) at any time. These newer forms are compatible with the current and revised Common Rule.
* It is acceptable to use forms dated prior to 12.27.2018; however, any NEW research approval on or after 1.21.2019 may require additional modifications based on regulatory requirements.

**SHORT FORMS:**

* Please use the [Short Forms](http://research.downstate.edu/irb/irb-electronic-submissions.html) with version date of 11.14.2018, for corresponding Downstate consent forms with a version date of 12.17.18 (or later) and for research initially approved by the IRB on or after 1.21.19 or for previously approved research that transitions to the requirements of the revised Common Rule; otherwise, use Short Forms with version 05.18.2016.

**FORMS for HIPAA Waiver(s) and Waivers of Informed Consent Requirements:**

* Please use the above noted [forms](http://research.downstate.edu/irb/irb-electronic-submissions.html) with a version date of 12.19.2018 (or later) at any time; however, the IRB requires these versions for approvals on or after 1.21.2019.
* The IRB may approve prior versions of these forms prior to 1.21.2019.

**independent HONEST BROKER assurance agreement:**

* Submit this [new form](http://research.downstate.edu/irb/irb-electronic-submissions.html) (version 12.17.2018 or later) with an IRB Decision Aid or IRB Application, as applicable to the project.
* An independent honest broker is a Downstate employee who has access to desired research data or specimens by virtue of his or her responsibilities as a member of the workforce and provides coded data or coded specimens for a project.

**Location of Forms:**

The IRB is removing all forms from the IRBNet library during this transition. Please refer to the IRB website for all forms, templates, and guidance:

* Electronic Submissions: <http://research.downstate.edu/irb/irb-electronic-submissions.html>
* Training and Conflict of Interest: <http://research.downstate.edu/irb/irb-training.html>
* Policy & Guidance: <http://research.downstate.edu/irb/irb-policies.html>

**Anticipated Updates:**

The IRB website annotates materials that are currently undergoing revisions. You may use any of the materials on the website; the IRB anticipates revisions or clarifications to the following documents. Changes will proceed in the approximate priority order below:

1. Responsibilities (highest priority)
2. Application for Amendment
3. Application for Reportable Event
4. Scientific Review Committee (SRC) Committee Membership Information
5. SRC Review Form
6. IRB Guidance on Scientific (Scholastic) Review (under development)
7. Application for Progress Report (Continuing Review)
8. Application for Progress Report (Continuing Review) for External IRB Oversight
9. [IRB FAQs](http://research.downstate.edu/irb/irb-faq.html)
10. Obtaining Legally Effective Informed Consent and HIPAA Research Authorization (draft guidance posted)
11. Data Security (draft guidance posted)
12. Application for Check-In Report (This is a new form that will be required in about 3 years) (lowest priority)

If you have additional questions regarding pending updates or are in urgent need of a document before it is available on the IRB web site, please contact the IRB so that we may be of service.

**OHRP Guidance:**

The US Department of Health and Human services Office of Human Research Protections (OHRP) is in the process of developing new guidance on the new regulations.

Our goal is to provide as much guidance as possible to support our investigators. However, we may need to contact federal authorities for some guidance for specific or unusual concerns not directly described in the regulations. If we cannot answer any questions or are not clear on how to interpret the regulations, we will contact OHRP or the applicable agency and let you know their response.

**Additional Resources:**

For those of you wishing to take deeper dive, we provide the following links:

* [FDA Guidance: Impact of Revised Common Rule on Clinical Investigations](https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM623211.pdf?utm_campaign=Impact%20Guidance&utm_medium=email&utm_source=Eloqua&elqTrackId=B10F41E07EB29CFEE1F2ED0B62E45601&elq=883e244b2d0c4f71bc5eb26d1a72d482&elqaid=5431&elqat=1&elqCampaignId=4386)
* [OHRP Unofficial Revised Common Rule Regulatory Text](https://www.hhs.gov/ohrp/sites/default/files/2018-Common-Rule-reg-text-July2018.pdf)
* [OHRP Official Version of the 2018 Rule](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML)
* [OHRP draft guidance documents related to the revised (2018) Common Rule](https://www.hhs.gov/ohrp/availability-3-draft-documents-announced-federal-register.html)
* [OHRP revised common rule education materials](https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/index.html)
* [2018 Requirements](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/revised-common-rule-regulatory-text/index.html) (effective 1.21.2019)
* [PRIM&R Focus on the Common Rule](https://www.primr.org/commonrule/)
* [SACHRP Recommendations](https://www.hhs.gov/ohrp/sachrp-committee/recommendations/sachrp-recommendations/index.html)