St. Joseph Health
Center for Clinical Research

IRB NEWSLETTER

December 2018

Greetings IRB Members!
Please read below for current updates on the
SJH Human Research Protection Program.

HRPP Updates

HAPPY HOLIDAYS!

The St. Joseph Health Center for Clinical Research and the Human Research Protection Program would like to wish you and your families a Merry Christmas and a Happy New Year! Thank you for all of your hard work and dedication this past year. As we prepare for this holiday season, we would like to share a special Christmas Blessing:

"O sweet Child of Bethlehem,
grant that we may share with all our hearts
in this profound mystery of Christmas.
Out into the hearts of men and women this peace
for which they sometimes seek so desperately
and which you alone can give to them.
Help them to know one another better,
and to live as brothers and sisters,
children of the same Father.
Reveal to them also your beauty, holiness and purity.
Awaken in their hearts
love and gratitude for your infinite goodness.
Join them all together in your love.
And give us your heavenly peace. Amen."
(Pope John XXIII)

Revised Common Rule

As discussed previously, the revised "Federal Policy for the Protection of Human Subjects," also known as the Common Rule, is due to go into effect on January 21, 2019. The HRPP Office will be providing an overview of the revised rule during the January IRB meetings – so please be sure to attend if you are able. In the meantime, for a summary of the changes entailed in the revised rule, please review the attached reference guide.

If you have any questions regarding the revised Common Rule, please contact Adam Pucci, HRPP Manager, at Adam.Pucci@stjoe.org.

Overview of Changes to the Common Rule

Providence St. Joseph Health

Category	Topic	Details	Location
IRB Operations	Single IRBs for multisite research ("cooperative research")	Single IRBs generally required; however, some flexibility is provided in determining and documenting when a single IRB is not appropriate.	46.114
	External IRBs	Reliance arrangement with non-institutional IRB must be documented; more stringent requirements proposed in the NPRM are not included	46.103
	Checking the box	Institutions may no longer indicate on their Federalwide Assurance that the Common Rule applies to all of their research, regardless of funding.	46.109, 46.115
	Continuing Review	Continuing review of research is no longer required under various circumstances. NOTE: SJH intends to implement a process for an annual check-in with the HRPP for such research	46.116
Informed Consent	New language/clarity	Consent forms must be clearer and more focused; many changes added to emphasize that information provided must facilitate a potential subjects' understanding of why one would participate or not	46.116
	Basic and additional elements of informed consent	New basic element on collection of identifiable private information or identifiable biospecimens; three new additional elements on commercial profit, return of clinically relevant research results and whole genome sequencing	46.116
	Broad Consent	Broad consent is an option for storage, maintenance, and secondary research use of identifiable private information and biospecimens. NOTE: SJH does not intend to implement this option at this time	46.111, 46.116
	Recruitment/screening waivers	Allows waiver of informed consent for subject recruitment or screening, under certain conditions	46.116
	Clinical trials consent forms	Some clinical trials must post consent forms online	46.116
	Electronic consent	Electronic consent is allowable; participants must provide written copy. NOTE: The SJH HRPP will evaluate and provide guidance on the use of electronic consent in the future	46.117
	Legally authorized representatives	If no law, institution can designate a representative	46.102

**Taken from PRIM&R Common Rule Quick Reference Table*

Overview of Changes to the Common Rule

Providence St. Joseph Health

Category	Topic	Details	Location
Scope	Definition: Research	Defines what's NOT research; certain journalistic, public health surveillance, and criminal justice or intelligence activities	46.102
	Definition: Human Subjects	Includes "information or biospecimens" obtained from through intervention and interaction OR "identifiable private information or identifiable biospecimens"	46.102
	Definition: Identifiable biospecimen/identifiable private information	Will be re-examined within one year and every four years after	46.102
	Definition: Vulnerable populations	Pregnant women and "handicapped" removed; replaces "mentally disabled" with "individuals with impaired decision-making capacity"	46.111
	Tribal law	Tribal law applies where applicable; added throughout	46.101, 46.114, 46.116
New guidelines for exemptions	Additional exemptions for low-risk studies	New exemptions added, including exemptions for benign behavioral interventions with adults, secondary research on identifiable private information and identifiable biospecimens under various circumstances; various regulatory requirements, such as limited IRB review, may apply.	46.104 (see also 46.103, 46.109, 46.110, 46.111)
Compliance dates	1/21/19; Single IRBs for multisite research: 1/20/20	Previous rule applies to research approved prior to 1/21/19; new rule to approvals 1/21/19 or later	46.101

**Taken from PRIM&R Common Rule Quick Reference Table*