

2018 Common Rule	
CHW's Transition Plan for Implementing Revisions to the	Volume 5, Number 1 – January 2019
Common Rule	
Delay in implementation	Volume 4, Number 3 – July 2018
	Volume 4, Number 1 – January 2018
	Volume 4, Number 2 – April 2018
Notice of proposed rulemaking	Volume 1, Number 4 – October 2015
	Volume 2, Number 1 – February 2016
Revisions published	Volume 3, Number 1 – January 2017
Summary of Revisions to the Common Rule	Volume 5, Number 1 – January 2019
What is CHW IRB Working on to Prepare?	Volume 5, Number 1 – January 2019
Back to Basics	
The HRPP v. the IRB	Volume 5, Number 3 – July 2019
What is the "Common Rule?"	Volume 5, Number 2 – April 2019
Communications from the HRPP/IRB Office	Volume 5, Number 4 – October 2019
Certificates of Confidentiality	
Amendment submissions in response to new NIH policy	Volume 4, Number 1 – January 2018
NIH policy revision (CoC Automatic)	Volume 3, Number 4 – October 2017
Overview	Volume 3, Number 3 – July 2017
Clinical Trials.Gov	
Clinical trials registration and results submission – CT.gov	Volume 3, Number 1 – January 2017
Community Rep Reflections	
Tyler Pease – Board 1	Volume 5, Number 3 – July 2019
Stan Garbasz – Board 2	Volume 5, Number 5 – July 2019
Corporate Compliance- Compliance Corner	
Alteration of HIPAA Authorization	Volume 5, Number 3 – July 2019
"Cloud" Based Platforms to Store Research Data	Volume 5, Number 3 – July 2019
Data Use Agreements	Volume 5, Number 2 – April 2019
General Data Protection Regulation (UPDATE)	Volume 4, Number 2 – April 2018
Maintaining Epic Access	Volume 5, Number 1 – January 2019
Conduct of Research	
Certificates of Confidentiality	Volume 3, Number 3 – July 2017
Closure of Study	Volume 4, Number 3 – July 2018
Collaborators engaged in research at CHW	Volume 1, Number 4 – October 2015
Consent – age of majority	Volume 1, Number 3 – August 2015
Consent – Finding and Using the Correct IC Document	Volume 4, Number 4 – October 2018
Consent – obtaining v. documenting	Volume 2, Number 4 – October 2016
Consent – parent of child is a minor	Volume 1, Number 2 – May 2015
Deferrals and reliance agreements	Volume 3, Number 3 – July 2017
-0	Volume 3, Number 1 – January 2017
Grant congruency checks	Volume 3, Number 3 – July 2017



Grants (federal) awarded directly to researchers	Volume 1, Number 4 – October 2015
Human subject research determinations	Volume 3, Number 2 – April 2017
International Research – new policy	Volume 2, Number 1 – February 2016
Modification for increase in enrollment	Volume 1, Number 4 – October 2015
Monitor access to EPIC	Volume 1, Number 3 – August 2015
Newborn screening research using dried blood spots	Volume 1, Number 1 – February 2015
Note to File – Appropriate Use	Volume 4, Number 3 – July 2018
OCRICC Approval – Use of Froedtert Resources/Subjects	Volume 4, Number 4 – October 2018
Pediatric risk level – placebo arm of study	Volume 1, Number 3 – August 2015
Preparatory to research form	Volume 1, Number 3 – August 2015
Principal investigator – planning for absences	Volume 3, Number 3 – July 2017
Principal investigator – who can serve as PI at CHW	Volume 3, Number 1 – January 2017
Quality improvement project and intent to publish	Volume 1, Number 3 – August 2015
Reportable Events – new form and process	Volume 3, Number 4 – October 2017
Social Security Numbers and Research Stipends	Volume 4, Number 3 – July 2018
Study staff updates - timeliness	Volume 3, Number 2 – April 2017
Temporary change in Principal investigator	Volume 4, Number 1 – January 2018
Testing drugs on pediatric patients – FDA guidance	Volume 1, Number 1 – February 2015
Training requirements for study staff outside CHW	Volume 4, Number 1 – January 2018
When an investigator leaves the institution	Volume 3, Number 1 – January 2017
Consent	
Certificates of Confidentiality - Overview	Volume 3, Number 3 – July 2017
Continued participation at ate of majority	Volume 1, Number 3 – August 2015
FDA/OHRP final guidance on use of electronic consent in	Volume 3, Number 1 – January 2017
clinical investigations	
Consent – Finding and Using the Correct IC Document	Volume 4, Number 4 – October 2018
Obtaining v. documenting consent	Volume 2, Number 4 – October 2016
Parent of the child is a minor	Volume 1, Number 2 – May 2015
Short form – new translations available	Volume 2, Number 4 – October 2016
Use of footer in ICF documents – Position Statement	Volume 3, Number 1 – January 2017
Follow up – New ICF template	Volume 5, Number 2 – April 2019
Continuing Review	
No modifications at the time of CR	Volume 3, Number 2 – April 2017
Submission deadline	Volume 4, Number 1 – January 2018
Auto Reminders for CR submission/Due Date updated	Volume 5, Number 4 – October 2019
Deferrals and reliance agreements	
Collaborators engaged in research at CHW	Volume 1, Number 4 – October 2015
IRB reliance takes time – even with Smart IRB	Volume 4, Number 1 – January 2018
Reliance form update	Volume 3, Number 1 – January 2017
Overview	Volume 3, Number 3 – July 2017
Reliance Process Update	Volume 5, Number 3 – July 2019
Institutional Form for Reliance Agreements Updated	Volume 5, Number 4 – October 2019
Education	



Alerting IRB office of new staff for training	Volume 2, Number 4 – October 2016
Banking education module on D2L	Volume 2, Number 4 – October 2010 Volume 3, Number 2 – April 2017
Luminaries lecture series - OHRP	Volume 2, Number 2 – April 2017 Volume 2, Number 4 – October 2016
Podcast – Rethinking the vulnerability of children in	Volume 1, Number 2 – May 2015
comparative effectiveness research	
Introduction to the CHW IRB – Monthly Session	Volume 5, Number 4 – October 2019
EPIC	Volume 5, Number 4 October 2015
2015 upgrade	Volume 2, Number 4 – October 2016
Epic Billing Reminder	Volume 5, Number 1 – January 2019
Maintaining Epic Access	Volume 5, Number 1 – January 2019
FDA/OHRP	Volume 5, Number 1 – January 2015
Draft guidance (OHRP) – appropriate disclosure of risks	Volume 1, Number 1 – February 2015
Draft guidance (FDA) – individual patient expanded access	Volume 1, Number 1 – Tebruary 2015 Volume 1, Number 2 – May 2015
Draft guidance (FDA) – individual patient expanded access	Volume 1, Number 1 – February 2015
Guidance (FDA/OHRP) - on use of electronic consent in	Volume 1, Number 1 – Pebruary 2015 Volume 3, Number 1 – January 2017
clinical investigations	Volume 5, Number 1 – January 2017
International compilation of research standards - 2018	Volume 4, Number 1 – January 2018
Luminaries lecture series	Volume 2, Number 4 – October 2016
Public outreach website	Volume 3, Number 1 – January 2017
Videos on prisoner research - OHRP	Volume 3, Number 2 – April 2017
Forms	
Continuing review form – new form	Volume 2, Number 1 – February 2016
Decedent form – use of PHI of decedents in research	Volume 3, Number 1 – January 2017
HIPAA Authorization – do not list CHW	Volume 3, Number 2 – April 2017
HIPAA Waiver Request – Listing Staff	Volume 3, Number 1 – January 2017
Institutional Form for Reliance Agreements Updated	Volume 5, Number 4 – October 2019
PHI on IRB forms	Volume 1, Number 4 – October 2015
Preparatory to research form	Volume 1, Number 3 – August 2015
Registration Page Update	Volume 4, Number 3 – July 2018
Reviewer checklists	Volume 1, Number 4 – October 2015
Short form consent – new translations available	Volume 2, Number 4 – October 2016
Temporary change in PI request form	Volume 4, Number 1 – January 2018
IRB Consultation Request form	Volume 5, Number 2 – April 2019
Follow up – New ICF Template	Volume 5, Number 2 – April 2019
ICF Template - Black language Change Request form	Volume 5, Number 2 – April 2019
IRBNet	
Access to grant when sharing projects	Volume 3, Number 1 – January 2017
	Volume 4, Number 2 – April 2018
	Volume 4, Number 4 – October 2018
Alerting IRB office of new staff for training	Volume 2, Number 4 – October 2016
Auto Reminders for CR submission/Due Date updated	Volume 5, Number 4 – October 2019
Deadline for enforcement of correct way to revise	Volume 3, Number 3 – July 2017
documents in a project	



Effective Date v. Approval Date	Volume 4, Number 2 – April 2018
Filtering email notifications	Volume 2, Number 2 – May 2016
ID Number for IRBNet projects	Volume 3, Number 1 – January 2017
Login Credentials – policy on not sharing	Volume 2, Number 1 – Jundary 2017
Managing documents in IRBNet	<u>Volume 2, Number 2 – May 2016</u>
Modifications at CR not allowed	Volume 3, Number 2 – April 2017
Principal Investigator required sign off in IRBNet	Volume 3, Number 2 – April 2017
Remove access when staff leaves	Volume 4, Number 1 – January 2018
Sign offs in IRBNet	Volume 2, Number 3 – August 2016
Training resources	Volume 2, Number 2 – May 2016
"Unassigned" status in IRBNet	Volume 4, Number 2 – April 2018
Misc and IRB Office Updates/Process Updates	
ICF Template – Black Language Change Request Process	Volume 5, Number 2 – April 2019
IRB Office – Drop In Office Hours for Study Teams	Volume 5, Number 2 – April 2019
IRB Office – Office Hours Update	Volume 5, Number 3 – July 2019
IRB Office – Office Hours Expanded	Volume 5, Number 4 – October 2019
Chair update – IRB #2	Volume 1, Number 1 – February 2015
Communication of form and template updates	Volume 3, Number 1 – January 2017
Congratulations Lori Roesch – Co-Chair CIP Council	Volume 4, Number 1 – January 2018
IRB office main phone line and email	Volume 3, Number 2 – April 2017
IRB office staffing update	Volume 3, Number 3 – July 2017
IRB passes FDA audit	Volume 3, Number 1 – January 2017
Launch of newsletter - purpose	Volume 1, Number 1 – February 2015
The Immortal Life of Henrietta Lacks – book and movie	Volume 3, Number 2 – April 2017
Staff Change Amendments	Volume 5, Number 2 – April 2019
Website – new HRPP web pages	Volume 2, Number 3 – August 2016
Website reorganization	Volume 3, Number 2 – April 2017
Policies	
Appeal of IRB Decisions – new policy	Volume 5, Number4 – October 2019
Closure of Research with CHW IRB – new policy	Volume 5, Number 4 – October 2019
International research – new policy	Volume 2, Number 1 – February 2016
Login credentials – no sharing	Volume 2, Number 4 – October 2016
Position Statements	
Use of footer in ICF documents	Volume 3, Number 4 – October 2017
Submission of documents for stamping	Volume 3, Number 4 – October 2017
Pregnant Subjects and Pregnant Partners of Subjects	Volume 4, Number 4 – October 2018
Regulatory News	
Draft guidance (OHRP) – appropriate disclosure of risks	Volume 1, Number 1 – February 2015
Draft guidance (FDA) – individual patient expanded access	<u>Volume 1, Number 2 – May 2015</u>
Draft guidance (FDA) – testing drugs in pediatrics	Volume 1, Number 1 – February 2015
Guidance (FDA/OHRP) - on use of electronic consent in	Volume 3, Number 1 – January 2017
clinical investigations	
International compilation of research standards -2018	Volume 4, Number 1 – January 2018



Newborn screening research using dried blood spots	Volume 1, Number 1 – February 2015
Research Ambassador's Angle	
Introduction to the Program and the Ambassadors	Volume 5, Number 3 – July 2019
Clinical Trials.gov Registration and Compliance	Volume 5, Number 4 – October 2019
Spotlight on the IRB Members	
Tyler Pease – Board 1	Volume 5, Number 3 – July 2019
Louella Amos, MD – Chair – Board 2	Volume 5, Number 4 – October 2019
Submissions to the IRB	
Amendments – check if study staff up to date	Volume 3, Number 2 – April 2017
Amendment – documents to submit	Volume 4, Number 1 – January 2018
Amendments – increase in enrollment	Volume 1, Number 4 – October 2015
Barcode (HIM) on consent documents	Volume 4, Number 2 – April 2018
Continuing review – documents to submit	Volume 4, Number 1 – January 2018
Continuing review – managing documents	Volume 2, Number 3 – August 2016
Continuing review – submission deadline	Volume 4, Number 1 – January 2018
Document footer clarification	Volume 4, Number 1 – January 2018
Improving quality of submissions to the IRB	Volume 5, Number 2 – April 2019
Modifications in CR submission not allowed	Volume 3, Number 2 – April 2017
PHI on IRB forms	Volume 1, Number 4 – October 2015
Reportable events – new form and process	Volume 3, Number 4, October 2017
Response packages – only changes requested by the IRB	Volume 3, Number 2 – April 2017
	Volume 4, Number 2 – April 2018
Response packages – referencing package to which responding	Volume 2, Number 4 – October 2016
Review of Documents outside of a particular package	Volume 4, Number 2, April 2018
Study staff updates - timeliness	Volume 3, Number 2 – April 2017
Submission Checklist and Guides	Volume 4, Number 2 – April 2018
Submission of documents for stamping	Volume 3, Number 1 – January 2017
Unlocking a package v. Response Package needed	Volume 4, Number 2 – April 2018
Use of Imaging in Research Studies	Volume 5, Number 3 – July 2019
Use of Imaging in Research Studies – Follow Up	Volume 4, Number 4 – October 2019
TRU – Pediatric Translational Research Unit	
EPIC 2015 upgrade	Volume 2, Number 4 – October 2016
Moving	Volume 3, Number 1 – January 2017
	Volume 4, Number 1 – January 2018
Overview	Volume 1, Number 1 – February 2015
Research support	Volume 2, Number 3 – August 2016
Storyboard Transition – EPIC	Volume 5, Number 4 – October 2019