Guidelines for Use of PHI in Research – Summary Table

Activity	Researcher	RSRB	Research Privacy Officer/designee	Data Manager
Individual Authorization	• Submits protocol to IRB for approval • Obtains individual subject's authorization; may be combined with research consent form • Offers subject Notice of Privacy Practices; obtains acknowledgment of receipt • Retains authorization and acknowledgment documents for 6 years following end of study	• Reviews and approves or disapproves protocol • Retains copy for 6 years following the end of study	• Not applicable	*Before releasing PHI to the researcher, the data manager:* • Obtains copy of protocol approval or exemption letter from researcher • Obtains list of consenting subjects from researcher
Waiver of Individual Authorization	• Submits Waiver of Authorization to Privacy Officer/designee (Form 25.2) or IRB using the RSRB application process. • Maintains copy of waiver for 6 years following end of study • If disclosures are made, completes on-line Log of Disclosure of PHI or completes hard copy of Log of disclosure of PHI form and submits to the facility's HIM Dept. • HIM provides accounting of disclosures if requested	• Reviews and approves or disapproves waiver • May approve partial waiver • Maintains copy of waiver for 6 years following the end of the study Reviews waivers for: • Records Research • Subject recruitment • All other research not reviewed by Privacy Officer/designee	• Reviews and approves or disapproves waiver • Maintains copy of waiver for 6 years following the end of the study Reviews waivers for: • Case Reports • Case Studies • Methods Training • Student Training Projects	• Obtains copy of protocol approval or exemption letter from researcher • Obtains copy of approved inclusion/exclusion criteria from researcher • If disclosures are made, completes on-line Log of Disclosure of PHI or completes hard copy of Log of disclosure of PHI form and submits to the facility's HIM Dept. • *Disclosures could be made, for example, to pharmaceutical reps and non-URMC and Affiliates researchers including faculty from River Campus schools*

Activity	Researcher	RSRB	Research Privacy Officer/designee	Data Manager
Reviews Preparatory to Research	• Completes Research Certification for each study (Form 25.3) (*Note: If you are looking only at information on patients of your care team, you need not complete the Researcher Certification)* • If no approved study i.e., in cases of doing pre study feasibility reviews, completes Researcher Certification for each review process • For multiple accessions of same data for same study or feasibility review note subsequent access dates on original form • Retain copy of each Researcher Certification for 6 years following end of study • If disclosures are made, completes on-line Log of Disclosure of PHI or completes hard copy of Log of disclosure of PHI form and submits to the facility's HIM Dept. • *Disclosures could be made, for example, to pharmaceutical reps and non-URMC and Affiliates researchers including faculty from River Campus schools* • HIM provides accounting of disclosures if requested	• Not applicable	• Not applicable	• Obtains copy of Researcher Certification from researcher • Retains for 6 years following end of study • If accessing a central system through privileges previously granted then the researcher functions as the 'data manager' and retains copies of the required documentation. • If disclosures are made, completes on-line Log of Disclosure of PHI or completes hard copy of Log of disclosure of PHI form and submits to the facility's HIM Dept. • *Disclosures could be made, for example, to pharmaceutical reps and non-URMC and Affiliates researchers including faculty from River Campus schools*
Research on a Decedent's Information	• Completes Researcher Certification for each study (Form 25.4) • If preparatory to research, completes Researcher Certification for each review process • For multiple accessions of same data for same study or feasibility review note subsequent access dates on original form • Submit Researcher Certification form to RSRB for review and approval prior to doing the research if study involves both living and decedent information • Retain copy of each Researcher Certification for 6 years following end of study • If disclosures are made, completes on-line Log of Disclosure of PHI or completes hard copy of Log of disclosure of PHI form and submits to the facility's HIM Dept. • HIM provides accounting of disclosures if requested	• Reviews studies that include data on both living and deceased persons • Notifies researcher	• No Privacy Officer/designee review or approval required if only decedent information is involved • May request documentation of the death of decedents listed on form 25.4	• Obtains copy of Researcher Certification from researcher • If accessing a central system through privileges previously granted researcher functions as the "data manager' and retains copies of the required documentation. • If disclosures are made, completes on-line Log of Disclosure of PHI or completes hard copy of Log of disclosure of PHI form and submits to the facility's HIM Dept. • *Disclosures could be made, for example, to pharmaceutical reps and non-URMC and Affiliates researchers including faculty from River Campus schools* • May request documentation of the death of decedents listed on form 25.4

Activity	Researcher	RSRB	Research Privacy Officer/designee	Data Manager
De-identified Information	• Completes one of the following: 1. De-identification Form (25.5.1) 2. Qualified Statistician Form (25.5.2) • Retains copy of each Research Certification for 6 years from end of study	• NA	• NA	• Request copy of RSRB approval or Form 25.5.1 or 25.5.2 if non-RSRB activity
Limited Data Set **Data Use Agreement**	• Complete Limited Data Set certification (Form 25.6.1) • Complete Data Use Agreement (Form 25.6.2) • Signs Data Use Agreement if standard form used • Submit to **ORPA** or **Privacy Officer** if changes to form or outside form used • Retain copies of both forms for 6 years following end of study	**ORPA** • Reviews and approves/disapproves request • Notify researcher OK or not OK to sign • Retain copies of both forms for 6 years following end of study	• Reviews and approves/disapproves request involving unfunded research, healthcare operations, private registries and public health • Notify researcher OK or not OK to sign • Retain copies of both forms for 6 years following end of study	• Request copy of approved Data Use Agreement before releasing PHI

Research Databases	• Submits research application to RSRB to:
	  • Establish a database/ repository
	  • Add data to a database / repository
	  • Use/disclose data from database/repository
	• Signed by researcher or unit chief or department chair if database involves several researchers
	• Adds data subject to conditions of RSRB approval
	• Provide copy of RSRB approval to data manager as appropriate
	• Retains form for 6 years following end of study
		• Reviews and approves/ disapproves request
		• Notifies researcher
		• Retains copy for 6 years from end of study
			•
			• Not applicable
				• If data is to be acquired from a central database, request RSRB approval from researcher

Note: **Items for RSRB are submitted to** http://rsrb01.urmc.rochester.edu/rsrb/
Items for Research Privacy Officer/designee are submitted to http://intranet.urmc-sh.rochester.edu/policy/HIPAA/Research.asp