PREPARED FOR RADIATION ONCOLOGY FACULTY

DEFINITIONS:

IRB Forms 2, 2a, or 3	Consent to research Contains HIPAA language so that the consent document also serves as HIPAA authorization
IRB Form K1 Full Waiver	No active participation by subject Full Waiver of Consent/Authorization e.g., Retrospective Study You will use either K1 or K5 - not both Full access to PHI
IRB Form K-5 Partial Waiver	Must Enroll subjects with Consent Form screening/recruitment purposes Access to PHI to Identify eligible participants IRB gives investigator partial waiver Can record list of names and info Active participation by subjects You will use either K1 or K5 - not both Physician does not need for own patients Full access to PHI
HIPAA Notice of Privacy	Must present to subject if not already received Subject signs acknowledgement at end of Consent Form
Business Assoc Agreement	Not submitted to IRB When person or business is doing something on your behalf NOT a sponsor of research If a pharmacy is a sponsor for a study, their lab is their business associate If specified in authorization, no BAA is needed If outsourcing work, and not in authorization, need BAA Key Personnel in grant are part of research team - not BAA If central lab is in the authorization by name as someone to whom you are disclosing PHI, you do not need a business associate agreement.
Code Access Agreement for De-identified Data	Submit to IRB when PI will never be able to identify individuals When research team will receive coded data

	When research team will share coded data If coding data but are not sharing, do not need CAA If getting authorization from patient, and PI intends to code, must be in Consent Form and must complete CAA If in authorization "sharing with sponsor" can send coded with no CAA
Data Use Agreement	Not submitted to IRB When receiving or sharing limited data set
Confidentiality Agreement	Not submitted to IRB between PI and research staff
Category 4 Exemption of IRB	Data must be de-identified to obtain
PHI 19 elements	Can use all 19 elements if you have authorization or waiver Can do any analysis with de-identified data
Sponsor defined	Sponsor of research as well as business associates of sponsor: Study monitors Some data monitoring committees Some laboratories
Research Team in patient authorization defined	Staff - not sponsor or colleagues or other research sites PI Collaborators Study Coordinator Subject Advocate Clinical Administrative Staff Fellows/Residents/Students Key Personnel in Grant
Not part of ResearchTeam:	sponsor other research sites outside labs independent statistician colleagues (must be named in authorization to receive data; or use Limited Data Set or Data Set Agreement or Business Associates agreement)
Limited Data Set	Includes only: zip codes geocodes dates of birth

other date info

Excludes:
- names
- initials
- street address
- telephone number
- fax num,ber
- e-mail address
- social security number
- medical record number
- health plan beneficiary #
- account number
- certificate/license number
- vehicle identifiers/serial #s
- device identifiers/srial #s
- web URLs
- IP address numbers
- biometric identifiers
- full face photographs and other images
- any other number, characteristic or code that could be used to identify Individual