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
Staff - not sponsor or colleagues or other research sites
in patient authorization
PI
Collaborators
Study Coordinator
Subject Advocate
Clinical Administrative Staff
Fellows/Residents/Students
Key Personnel in Grant

defined

Not part of Research Team:
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 number
e-mail address
social security number
medical record number
health plan beneficiary #
account number
certificate/license number
vehicle identifiers/serial #s
device identifiers/serial #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