SUNY Upstate Medical University
Research Administration
Quality Assessment & Improvement Program (QAIP) Compliance Tips

Common Mistakes:	Compliance Tips:
Regulatory documentation: Failure to maintain copies of signed original and all revised versions of the protocol	Never discard out-dated protocol(s). All protocol versions should be saved either in hard copy or electronically on IRBNet
Failure to establish or complete the subject enrollment log	A well-organized computer spread sheet or paper and pen form can serve as the subject enrollment log. This log could capture subject name or number, date of consent and/or assent (if applicable), person obtaining consent, eligibility, etc. Reasons for exclusion and/or withdrawal can also be documented in this log.
Failure to maintain adequate records of monitoring activities	Any form of study monitoring activity can be recorded in the form of a monitoring log. The log should include the date of review, name and signature of the person conducting the review and any findings resulting in a need for corrective action. It is suggested that the PI monitor study documents periodically to ensure compliance.
No staff signature log	Create a staff signature log to document signatures and initials of all persons collecting and recording data and/or study-related information in subject files. Investigators' delegation of responsibility can also be recorded in this log. Anyone assisting the PI in the conduct of the study should be listed on the IRB application as a study team member.

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Informed consent process: Having unauthorized study staff obtain informed consent	Informing a potential subject about the study is not equivalent to obtaining their legally effective consent. If the plan is to have designated study team members rather than the PI obtain consent, be sure that all applicable study staff are identified on the IRB application or registration form.
Use of invalid consent forms	Never make any changes on the consent form without prior IRB approval. Always print the most current version of the IRB approved stamped consent form from IRBNet. Do not use a consent form that has expired.
Missing signatures and/or dates on consent form	Make sure all lines on the consent form are completed. Never forward or back-date. Include a signed and dated note-to-file explaining any discrepancies in dates. Report to the IRB as appropriate.
Failure to provide or document the subject's receipt of a copy of the signed consent form (and the Upstate Notice of Privacy Practices, if not waived)	Each subject must receive a signed copy of the fully executed consent form (and the Upstate Notice of Privacy Practices, if not waived). A check-box on the enrollment log or a narrative note can document the subject's receipt of these items.
Failure to keep the original signed consent form	Maintain <u>all</u> pages of the original fully-executed consent form(s) for each subject enrolled.

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Common Mistakes:	QAIP Tips:
Source documentation/case report form	
Discrepancies between source documents and case report forms	Verify all data. If mistakes are found, make sure to initial and date any corrections. Use a single-line cross-out that does not obscure the original entry.
Subject selection criteria	
Inadequate documentation of eligibility determination	Develop an eligibility checklist with all approved protocol-specific inclusion and exclusion criteria. Make sure that the checklist is signed and dated by the person completing it, and place in the subject's study file.
Study files	
General organization lacking in study documentation	For each enrolled subject create a study file which includes all subject-specific documentation.
Remember: Blank lines on signed consent forms are unacceptable	Make sure all lines on consent forms are filled in. Have each person date their own signature. If a witness line is included on a consent form, it must be utilized.