



Non-Compliance Issues for DSHS-IRB Approved Studies

Topic	Specific Non-Compliance Issue
Patient Contact Studies	Contacting patients after 3 months have lapsed resulting in contacts with newly added patients on the TCR "Do Not Contact" (DNC) list.
	Contacting patients on the DNC list after receiving notification not to contact the patient from the TCR
	Contacting patients without allowing at least 3 weeks to pass after sending an initial recruitment letter
	Not reporting DNC requests or complaints to TCR within 2 business days
	Failing to provide a recruitment report every 3 months while actively recruiting
TCR/IRB Applications and Forms	Finalized version of the IRB renewal application not submitted by study expiration date
	IRB close-out report and TCR data destruction certificate not submitted within one month after study expires/closes
Data Security	PI sharing data with others without IRB approval
	Retention of data without IRB approval