

IRC maintains several numbering systems.

IRC PROTOCOL/STUDYNUMBERS

IRC study numbers are used for internal tracking of actions. All study numbers consist of 5 digits followed by 2 or 3 digits.

Sample	96102-03D	
	96	Approved initially during 1996
	96102	One hundred second study approved during 1996
	96102-03	Renewed for the third year (or third renewal period)
	96102-03D	Fourth action approved during the third year (or approval period)

IRC PRINCIPAL INVESTIGATOR NUMBERS

Each investigator is assigned a four-digit number upon his or her first approval. That number remains connected to that individual. Within a multi-site study, each investigator enters in sequence.

Sample	0987-003	
	0987	The 987th investigator granted approval
	0987-003	The third investigator included within a particular study.

This investigator could be 0987-012 were she the 12th investigator to be approved for another study.

NON-SIGNIFICANT RISK (NSR) Devices

When an NSR decision is given, it represents a major element of an "Abbreviated IDE." The NSR is granted for a specific, named, identifiable device. Were FDA to audit the sponsor or the IRB we would be able to agree on the device being reviewed. It is also granted for the use of that device within the context of that protocol.

Sample	DIR-23	
	D	Device
	DAB	Device from sponsor Abacus
	DAB-23	Twenty third device from sponsor Abacus

FWA - FEDERAL WIDE ASSURANCE

These are maintained according to the number assigned by OHRP.

IRC CLIENT AND CONTRACT NUMBERS

Clients are given sequential numbers.

Contracts/indemnification forms are given sequential numbers.

IRC EXEMPTION AND DEFERRAL NUMBERS

Exemptions are EXE plus a log number. Deferrals are DEF plus a log number.

