The Network for Public Health Law

HIPAA Authorization/42 CFR Part 2 Consent Checklist

	HIPAA (health information) 45 CFR 164.508 "Authorization"	**42 CFR Part 2 (substance use disorders), 42 CFR 2.31, 2.32 "Consent"**
Whose information	Must include name of patient	Must include name of patient
What information may be disclosed	Generally: Must describe information in a "specific and meaningful" way Remuneration: If purpose involves remuneration (e.g. marketing, sale of data), must state that disclosure will result in remuneration to covered entity	Must describe how much and what kind of information may be disclosed, including an explicit description of what substance use disorder information may be disclosed; must be limited to that information necessary to carry out the purpose of the disclosure
Who may disclose the information	Must include the name or other specific identification of person(s), or classes of persons, authorized to make the disclosure	Must include the specific name(s) or general designation(s) of Part 2 program(s), entity(ies), or individual(s)
Who may receive the information	Must include the name or other specific identification of person(s), or classes of persons, to whom disclosure it to be made	Must include the names of the individual(s) or the name(s) of the entity(-ies) to which a disclosure is to be made. If the recipient entity facilitates the exchange of health information or is a research institution, a written consent must include the name(s) of the entity(-ies) **and** (A) The name(s) of individual or entity participant(s); **or** (B) A general designation of an individual or entity participant(s) or class of participants that must be limited to a participant(s) who has a treating provider relationship with the patient whose information is being disclosed. When using a general designation, a statement must be included on the consent form that the patient (or other individual authorized to sign in lieu of the patient), confirms their understanding that, upon their request and consistent with this part, they must be provided a list of entities to which their information has been disclosed pursuant to the general designation.
Purpose(s) for which the information may be disclosed	Must describe each purpose of disclosure When authorization is initiated by individual, "at the request of the individual" is a sufficient statement	Must describe each purpose of disclosure.
Signature of patient or individual	Must include signature of patient or authorized representative; if	Must include signature of patient or authorized representative. Electronic signatures are permitted to the extent

	representative signs, must also include description of authority to act	that they are not prohibited by any applicable law.
Signature of witness	None required	None required
Format	Must be written in plain language. Paper or electronic, provided any electronic signature is valid under applicable law.	Paper or electronic
Date signed	Must include date signed	Must include date signed
Revocation of consent	Must inform patient of: • Right to revoke in writing • How to revoke • Any exceptions to revocation Alternatively: May refer patient to revocation information in Notice of Privacy Practices	Must inform patient of right to revoke at any time, except to the extent the program has already acted on it
Refusal to consent	Must inform patient about covered entity's ability or inability to condition treatment, payment, enrollment or eligibility for benefits on providing authorization	(regulations don't address)
Expiration of consent	Must inform patient regarding expiration of authorization. May expire: • On specific date • After specific amount of time • Upon specific event For research: may state "end of research study," "none" or similar language	Must include the date, event, or condition upon which the consent will expire if not revoked before. This date, event, or condition must ensure that the consent will last no longer than reasonably necessary to serve the purpose for which it is provided.
Redisclosure of information	Must inform patient that information disclosed may be redisclosed by the recipient and no longer protected	Must provide exact language of **either** of the following statements to data recipient: 1)This record which has been disclosed to you is protected by federal confidentiality rules (42 CFR part 2). The federal rules prohibit you from making any further disclosure of this record unless further disclosure is expressly permitted by the written consent of the individual whose information is being disclosed in this record or, is otherwise permitted by 42 CFR part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose (see § 2.31). The federal rules restrict any use of the information to investigate or prosecute with regard to a crime any patient with a substance use disorder, except as provided at §§ 2.12(c)(5) and 2.65; **or** 2) 42 CFR part 2 prohibits unauthorized disclosure of these records.
Right to copy of authorization or consent	Must provide patient with copy of authorization form	(regulations don't address)
Compound authorization	May be combined with Part 2 consent	