

HIPAA Compliance and language checklist

Core Authorization Elements & Applicable Regulation

- **The Information** – Specific and meaningful description of what will be used or disclosed.
45 CFR 164.508(c)(1)(i)
- **Who may use or disclose the information** – The name or other specific identification of the person, or class of persons, authorized to make the use or disclosure
45 CFR 164.508(c)(1)(ii)
- **To whom the information will be disclosed** - The name or other specific identification of the person, or class of persons, to whom the covered entity may make the requested use or disclosure
45 CFR 164.508(c)(1)(iii)
- **Purpose of use or disclosure** – A description of each purpose of the requested use or disclosure.
45 CFR 164.508(c)(1)(iv)
- **Expiration date or expiration event** – An expiration date/expiration event that relates to the individual or the purpose of the use or disclosure.
45 CFR 164.508(c)(1)(v)
- **Individual's signature and date** – If the authorization is signed by a personal representative, a description of the representative's authority must be provided.
45 CFR 164.508(c)(1)(vi)

Required Authorization Statements

- **Right to revoke authorization** – Outline the right for the individual to revoke their authorization in writing.
45 CFR 164.508(b)(5) and 45 CFR 164.508(c)(2)(i)
- **Right to refuse to sign authorization**
45 CFR 164.508(c)(2)(ii)
- **Conditional terms** - Ability or inability to condition treatment, payment, enrollment or eligibility for benefits on the authorization.
45 CFR 164.508(b)(4)(i) and 45 CFR 164.508(c)(2)(ii)
- **Redisclosure** - Information may be disclosed to others not subject to the Privacy Rule (cannot promise that information will definitely be protected)
45 CFR 164.508(c)(2)(iii)
- **Plain Language Requirement** The authorization must be written in plain language.
45 CFR 164.508(c)(3)
- **Copy to the Individual** The covered entity must provide a copy of the signed authorization form to the Individual.
45 CFR 164.508(c)(4)
- **Additional Elements, if applicable** - Right of Access
45 CFR 164.524(a)(1)
- **Temporary denial of access**
45 CFR 164.524(a)(2)(iii)
- **Adverse Event Reporting**
45 CFR 164.512(b)(1)(iii)(A)
- **Documentation Retention**
45 CFR 164.508(b)(6) and 45 CFR 164.530(j)(2)
- **Action in Reliance** - Written revocation of authorization, with withdrawal of existing research data, is permitted except when the investigator has relied on the data during the conduct of the study. Examples of reliance include having sent the data to the sponsor or assessing an adverse event.
45 CFR 164.508(b)(5)(i)