| **Met** | **Not Met** | **N/A or waived** | **Element** | **Regulatory reference** |
| --- | --- | --- | --- | --- |
|  |  |  | Study Title |  |
|  |  |  | Protocol Director |  |
|  |  |  | A statement that the study involves **research**, | **45 CFR 46.116(a)(1)** |
|  |  |  | An explanation of the **purposes** of the research, | **45 CFR 46.116(a)(1)** |
|  |  |  | A description of the **procedures** to be followed, | **45 CFR 46.116(a)(1)** |
|  |  |  | A description of any reasonably foreseeable **risks** or discomforts to the subject; | **45 CFR 46.116(a)(2)** |
|  |  |  | A description of any **benefits** to the participant or to others which may reasonably be expected from the research; | **45 CFR 46.116 (a) (3)** |
|  |  |  | The consent form begins with the key information that a reasonable person would want to have in order to make an informed decision. | **(new Common Rule)** |
|  |  |  | An explanation of the expected **duration** of subject’s participation, | **45 CFR 46.116(a)(1)** |
|  |  |  | A statement that participant will be **paid** (or not paid) for participation | **45 CFR 46.116(a)(6)** |
|  |  |  | A statement that refusal to participate wi9ll involve no penalty or loss of benefits to which the subject is otherwise entitled |  |
|  |  |  | A statement that participation is **voluntary**. | **45 CFR 46.116(a)(8)** |
|  |  |  | A statement that the participant **may withdraw or discontinue participation** at any time without penalty or loss of benefits to which the subject is otherwise entitled. | **45 CFR 46.116(b)(4)** |
|  |  |  | The consequences of a subject’s decision to withdraw from the research (if applicable). | **45 CFR 46.116(b)(4)** |
|  |  |  | A statement that the participant has the right to refuse to answer **particular questions**. | **45 CFR 46.116(b)(4)** |
|  |  |  | A statement describing the extent, if any, to which **confidentiality** of records identifying the participant will be maintained; | **45 CFR 46.116(a)(5)** |
|  |  |  | Language stating either that **identifiers will be removed and data may be used for future research** without additional consent OR that the **data will not be used in the future even if identifiers are removed** | **(new Common Rule)** |
|  |  |  | An explanation of **whom to contact** for answers to pertinent questions about the research, including concerns or complaints. | **45 CFR 46.116(a)(7)** |
|  |  |  | **Injury Notification** (if applicable): If you feel you have been hurt by being a part of this study…who to contact | **45 CFR 46.116(a)(7)** |
|  |  |  | A statement describing **how to contact someone independent of the research team** for concerns, complaints, or general questions about the research, as well as when participants wish to talk to someone other than the research staff. | **45 CFR 46.116(a)(7)** |
|  |  |  | A **copy** shall be given to the person signing the form. | **45 CFR 46.117(a)** |
|  |  |  |  |  |
|  |  |  | **Documentation of Informed Consent**  Informed consent shall be documented by the use of a written consent form approved by the IRB and **signed by subject**, or subject’s legally authorized representative. | **45 CFR 46.117(a)** |
|  |  |  | Parental permission signature lines / Authority to sign for participant | **45 CFR 46.408** |
|  |  |  | Include protocol approval and expiration dates. |  |
|  |  |  | Protocol includes a **Waiver of Documentation** of Informed Consent (Online consent or Information sheet) – not required outside research | **45 CFR 46.117(c)(2)** |
|  |  |  | Protocol includes a **Waiver of Documentation** of Informed Consent (Online consent or Information sheet) –only link | **45 CFR 46.117(c)(1)** |
|  |  |  | Protocol includes a **Waiver of Informed Consent.** | **45 CFR 46.116(d)** |
|  |  |  | Protocol includes an **Alteration of Informed Consent** (e.g. Research uses Deception) | **45 CFR 46.116(d)** |
|  |  |  | A disclosure of appropriate **alternative procedures** or courses of treatment, if any, that might be advantageous to the subject. | **45 CFR 116(a)(4)** |
|  |  |  | For research involving more than minimal risk, an explanation as to whether any **compensation** and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information can be obtained. | **45 CFR 46.116(a)(6)** |
|  |  |  | A statement that the particular treatment or procedure may involve risks to the subject which are currently **unforeseeable.** | **45 CFR 46.116(b)(1)** |
|  |  |  | Anticipated circumstances under which the subject’s participation may be **terminated by the investigator** without regard to the subject’s consent. | **45 CFR 46.116(b)(2)** |
|  |  |  | Any **additional costs** to the subject that may result from participation in the research. | **45 CFR 46.116(b)(3)** |
|  |  |  | A statement that **significant new findings** developed during the course of the research which may relate to the subject’s willingness to continue participation will be provided to the subject. | **45 CFR 46.116(b)(5)** |
|  |  |  | The approximate **number of subjects** involved in the study. | **45 CFR 46.116(b)(6)** |

| **Met** | **Not Met** | **N/A or Waived** | **Additional Items as Appropriate** |
| --- | --- | --- | --- |
|  |  |  | If the study involves video or audio taping, does the consent include a statement as to what will become of tapes after use, e.g., shown at scientific meetings, erased. |
|  |  |  | Place for subject to indicate/initial explicit consent to be taped. |
|  |  |  | Place for subject to indicate/initial explicit consent for tapes to be used. |
|  |  |  | Place for subject to indicate/initial explicit consent for identity to be made known from the audio or video tapes. |
|  |  |  | If applicable, is an assent document included? |
|  |  |  | If interpreter will be used, description of how confidentiality of interpreter will be maintained, who interpreter works for, and how interpreter will be recruited for the study |
|  |  |  | Translated consent for non-English speakers required |
|  |  |  |  |