# INFORMED CONSENT CHECKLIST

**Protocol Title:**

**Principal Investigator:**

**Institution:**

**Study Title and Overview All must be true**

* Name of the study is clearly stated and matches the protocol title
* There is ‘Inclusion and exclusion criteria’ for participation
* Maximum number of subjects anticipated is stated.

**Study Purpose All must be true**

* There is a statement that the study involves research. Study procedures are described in a non-technical lay language (detailed and clear description of what participant is required to do, for e.g. include description of types of questions that will be asked, step by step process for physical procedures.)
* The number of times that a procedure or study component will be performed and the duration of each session of participation is explained.
* The participants’ overall time commitment is stated.

**Voluntary Participation**  **All must be true**

* Statement to indicate that participation is voluntary.
* Refusal to participate will not result in loss of benefits or penalty
* Individual can withdraw at any time.
* There is a disclosure of appropriate alternatives to participating in this research study

**Risks and Discomforts All must be true**

* There is a description of **foreseeable** risk or discomforts (for e.g. social, physical, psychological, economic, legal, privacy)
* There is a description of **unforeseeable** risks or discomforts
* For more than minimal risk studies, there is a statement regarding compensation and/or medical treatment for research-related injury. There is language regarding who to contact in case of research-related injury.

**Participant Confidentiality All must be true**

* If applicable, statement describing who will have access to participant’s identifying information and the efforts to maintain confidentiality.
* A statement describing how and where data will be stored, for how long, as well as if data will be shared.

**Participant Benefits  All must be true**

* Description of any benefits to participant or others
* If applicable, statement that there will be no tangible benefits to the participant

**Participant Compensation All must be true**

* Statement clearly describing if the participant will be compensated for participating in the research
* A description of the amount and type of compensation
* The compensation will not constitute ‘coercion’ or ‘undue influence’.
* If applicable, statement that the participant will not be compensated

**Researcher Contact Information All must be true**

* Name and telephone number of someone to contact with questions about the research
* Name and telephone number of someone to contact about a research-related injury, mistreatment, and/or with concerns about participant rights

**Participant or Legal Representative signature (unless documentation of consent is waived)**

**All must be true**

* Statement that the individual will receive a copy of the consent form that s/he signs.
* There is no language that causes the individual to waive, or appear to waive any legal rights by signing the document.

**Exculpatory Language All must be true**

There is no language releasing the investigator, sponsor, institution, or its agents from liability for negligence.

|  |
| --- |
|  |

**Resources to Guide Review**

* [CRCAIH Glossary of Human Subjects Protections Terms](http://crcaih.org/assets/Human_Subjects_Protections_Glossary.pdf)
* [45 CFR part 46.116, 46.117 , General Requirements for Informed Consent](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116)