**HOW TO USE THE ADDITIONAL CONSENT LANGUAGE:**

Beyond the [basic elements of informed consent](https://www.ecfr.gov/cgi-bin/text-idx?SID=198c038a030e38789bb1e93dfa8c5a1b&pitd=20180719&node=pt45.1.46&rgn=div5#se45.1.46_1116), there may be additional elements that should be included based on the study design or research population.

Each additional consent language topic is listed under its section header from the [Brown consent template](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/guidance-human-subjects-research/consent-process/consent-templates), with definitions and examples of when/why they may be appropriate.

This list is not all inclusive and will be updated often. There may also be additional language required by other institutions/organizations involved in a research study.

1. Instructions are marked by [brackets].
2. Language to be included is marked by <angle brackets> (for example, <name of study drug> or <time involved>).
3. Examples are provided in (parentheses).
4. All plain text with “quotation marks” should be included in your consent document without modification.

The informed consent must be written at an 8th grade reading level and presented in lay language.