

ELEMENTS OF INFORMED CONSENT

- The consent should be written in the second person (“*You are invited to take part...*”), as first person may be considered too suggestive or coercive
- The name of the researcher and his or her affiliation must be clearly stated
- The study and its purpose should be briefly explained
- All procedures and activities to be conducted during the course of the research by participants, including their duration, frequency and locale must be explained
- There must be a statement about risks and safeguards, including those mentioned in the application, in the consent document—even if risks are expected to be minimal
- Benefits to participation, whether direct or indirect, should be outlined. Compensation cannot be listed as a benefit to participation
- A statement indicating that participation is voluntary must be explicitly stated
- A statement that the subject may withdraw at any time without penalty should be included
- The extent to which confidentiality can or will be maintained should be clearly defined
 - Any mandatory reporting requirements must be included
 - For focus group data collection activities, a statement that confidentiality cannot be guaranteed in a group setting must be included (consider using phrasing such as “Confidentiality cannot be guaranteed in a group setting; please respect each other’s privacy by not repeating what was said or who attended this meeting”)
- Contact info, including address and telephone number, for both the researcher *and* the HSRRC must be included (do not use a personal home address)
- There must be an indication that the subject will receive a copy of the form for his/her own records
- If the researcher is working with children or a vulnerable population, “Special Topics” must be consulted for additional informed consent elements
- The entire consent must be written in language that is readily understandable to the average subject (for adults, this usually means the 7th grade level). Avoid jargon, use simple sentences and neutral language

*** Faculty and staff should consider printing informed consents and cover letters on organizational letterhead