

Appendix E

THE BASIC 8 ELEMENTS OF INFORMED CONSENT FOR MINIMAL RISK ACTIVITIES

There are eight basic pieces of information you must disclose when you are recruiting subjects in verbal scripts/cover letters, and in consent letters (for activities not exceeding minimal risk)

1. Who you are
2. What you are doing
3. Why you are doing it
4. What subjects are asked to do and how long it will take
5. Participation is voluntary
6. No penalty for nonparticipation/withdrawal from study
7. How confidentiality/anonymity will be handled
8. Who to call if any questions regarding research design

ADDITIONAL ELEMENTS IF RISK EXCEEDS MINIMAL LEVEL

Additional Elements are required, as appropriate, if activities exceed minimal risk. See HS application form for additional documentation that may be required.