

Community Health Care Credentialing Program

Basic Elements of Informed Consent

Use of informed consent requires approval by Duke Risk Management.

- A statement of the **rationale** for the screening.
- A description of any reasonably **foreseeable risks or discomforts** to the participant.
- A description of any **benefits** to the participant or to others which may reasonably be expected from the screening.
- A disclosure of appropriate **alternative procedures** or courses of treatment, if any, that might be advantageous to the participant.
- A statement that this is a screening and **does not constitute a definitive diagnosis**, and that additional tests or repeat screenings may be necessary.
- A statement describing the extent, if any, to which **confidentiality** of records identifying the subject will be maintained.
- For screening involving more than minimal risk, an explanation as to the **availability of medical treatment** in the case of screening-related injury, including who will pay for the treatment and whether other financial compensation is available.
- An explanation of **whom to contact** for answers to pertinent questions about the screening and whom to contact in the event of a screening-related injury to the participant.
- A statement that **participation is voluntary**, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.
- A statement of the procedure to be used in case the participant has an **out-of-range test**.
- A statement about any **additional costs** to the participant that may result from participation in the screening.