

# Summary of Major Changes to the Informed Consent Policy for OSU Hospitals and James Cancer Hospital

(August 2007)

Preamble/Policy – list of procedures and treatments requiring informed consent will be added to OneSource under the “Clinical Care” tab once approved

## Section 1 –

- 1.a: Only the attending physician or a designee may obtain informed consent.
- 1.b: Designees include ONLY:
  - Housestaff knowledgeable about the patient and the procedure
  - Licensed independent practitioners (LIPs) (e.g., NP, PA, CRNA, etc.) who have clinical privileges to perform the procedure
  - Registered nurses may not get informed consent except for RN’s who place PICC lines who may get informed consent for PICC lines only
- 1.d: Medical students may not obtain informed consent for anything

## Section 2 –

- 2.a-e: All consent forms or statements of consent in a progress note must be signed by the patient or legal representative
- 2.e: Clarified ability to do phone or faxed consent in urgent situation

## Section 3 –

- 3.a: Clarification of process for consent when multiple procedures are contemplated on the same day
- 3.b: Clarifies the “optimal” discussion with the patient when getting informed consent
  - Description of procedure including indication, risks, benefits, and alternatives
  - Consequences of declining consent
  - Whether other physicians, LIP’s or students will be performing significant tasks related to the procedure
  - Whether the attending physician is reasonably expected not to be present in the same room for some or all of the tasks performed by others
- 3.d: Consent must be documented prior to beginning procedure

## Section 4 –

- 4.a – Clarifies what must be included in the signed informed consent document or progress note
- 4.b: Signature of a witness is optional

## Section 5 –

- 5.a: HIV testing – no major changes
- 5.b: Blood and blood products
  - Informed consent for blood/blood products reverts to paper based process
  - CAPI attestation will remain but will not suffice for consent
  - Unless there is a significant change in the risks, benefits, or alternatives for transfusion,
    1. For inpatients, consent lasts for length of admission for any product already consented to
    2. For outpatients, consent lasts for one year for any product already consented to
  - Presence of signed informed consent will be checked with ID double check prior to transfusion
- 5.c and 5.d: research/clinical trials/investigational drugs and sterilization added to reflect current policy
- 5.e: new language from CMS related to specific issues in transplant consent

Sections 6-9 – Minor editorial changes and clarifications