INFORMED CONSENT CHECKLIST

☐ Title  ☐ PI  ☐ Sponsor

☐ Request/invitation for participation in a research study

☐ Purpose of study/aims/background/rationale (brief)  ☐ How many subjects

☐ Description of procedures (in lay language)/identification of experimental procedures
   brief study design included
   If applicable special statement if drawing over 450 cc blood in an 8-week period
   If non-therapeutic MRI, make sure we have SOP and recommended language in consent
   ☐ incidental findings language
   ☐ Disclosure when sharing tissue or data for different research purpose

☐ Anticipated duration of participation - time involved (schedule)

☐ Risks and/or discomforts (if none, so state)
   HIV testing language if applicable
   GINA language if applicable (section 4.i. on cover form)

☐ Benefits to subject and/or society (if none, so state)

☐ Alternative treatments (if applicable)

☐ Additional costs to subjects resulting from research procedures

☐ Compensation and prorating  ☐ Taxable statement if applicable

☐ Circumstances for involuntary withdrawal – PI reserves right to discontinue participation

☐ Confidentiality protection
   ☐ If applicable special statement for disposition of videotape/photographs/voice recordings
   ☐ Procurement information if applicable (SS # template language)
   ☐ Mandated reporting language if applicable
   ☐ Clinical Trials Registration statement

☐ Compensation and/or medical treatment available in event of injury

☐ UVM/FAHC disclaimer (new language)/UVM contact person  ☐ Not Applicable
   (the new language only applies to interventional studies with more than minimal risk)

☐ Financial interest sections if applicable

☐ Name and phone number of person to contact with questions

☐ Participation is voluntary and freedom to withdraw without prejudice

☐ "You agree to participate and you understand that you will receive a signed copy of this form."

☐ Subject signature and date line (parent/guardian for minors)

☐ Signature line for minors indicating "assent" (if applicable)

☐ Name, address, and phone number of principal investigator also “This form is valid only if the Committees….”