

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...."