TEXAS A&M UNIVERSITY	WORKSHEET: REVIEW TOOL - Consent Process		
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	HRP-336	5/30/2017	1 of 3

The purpose of this review tool worksheet is to provide support for a member of the IRB, HRPP or designee when observing the consent process of a research participant. This worksheet does not need to be retained, but observations can be used as examples or findings in any letter sent to the Principal Investigator.

IRB Number	
Name of Person Completing Worksheet	
Date Worksheet Completed	

Note: If the potential research participant does not provide permission for a member of the IRB or HRPP staff to be present for the consent process, then their wishes prevail.

1. Consent form Documentation (check if yes):

☐	a. Is informed consent obtained from each subject prior to the start of any study procedures? (including screening procedures to determine eligibility)
☐	b. Is the IRB approved consent form (approval stamp on the consent form) used to consent each subject?
☐	c. Is the original dated and signed consent form on file for each subject?
☐	d. Did all consented subjects receive a copy of their signed and dated consent form?
☐	e. Are participant files documented to indicate each subject received a copy of their signed and dated consent form?
☐	f. Was a copy of each subject's signed consent form placed in subject's medical record? (if appropriate).

g. Where are signed consent forms kept for this study?

h. What is the process to assure the study team is using the IRB currently approved consent form?

i. How does the study team know they are using the IRB currently approved form?

j. Who presents the consent form to the individuals?

2. Consent Observation Checklist

a. Who is administering the consent? _____
   i. Are they authorized to do so by the PI ☐ Yes ☐ No
   ii. Is the delegation to obtain consent documented? ☐ Yes ☐ No

b. Location: Where is the consent Process Occurring: _____

c. Is a Study Code or ID Number of Subject being assigned? ☐ Yes ☐ No

d. Are the following key elements part of the consenting of a potential study participant (other issues may also be needed):

i.	Is the consent form the most recent IRB-approved version?	☐ Yes	☐ No	
ii.	Does the consenter mention that the study involves "research?"	☐ Yes	☐ No	
iii.	If the study involves an unapproved agent (i.e., not FDA approved), does the consenter explain this?	☐ Yes	☐ No	
iv.	Does the consenter discuss/summarize or allow the subject time to read about and question the consenter regarding the following:			
1.	Study purpose	☐ Yes	☐ No	
2.	Randomization	☐ Yes	☐ No	☐ NA
3.	Blinding	☐ Yes	☐ No	☐ NA
4.	Study Procedures and interventions	☐ Yes	☐ No	
5.	Risks	☐ Yes	☐ No	
6.	Benefits	☐ Yes	☐ No	
7.	Alternatives	☐ Yes	☐ No	☐ NA
8.	Confidentiality and/or HIPAA authorization	☐ Yes	☐ No	
9.	Cost and compensation	☐ Yes	☐ No	
10.	PI contact information for study related questions or concerns	☐ Yes	☐ No	
11.	IRB contact information to discuss any concerns about human subject rights	☐ Yes	☐ No	
12.	Voluntary nature of study (right to refuse/withdraw without affecting individual's present or future care)	☐ Yes	☐ No	
13.	Research-related injury compensation and pregnancy issues (if appropriate)	☐ Yes	☐ No	☐ NA
14.	Does the consenter solicit and sufficiently answer questions?	☐ Yes	☐ No	

e. Does the consenter communicate using understandable language and avoid using scientific jargon that the subject clearly did not understand? ☐ Yes ☐ No

f. Is the consent form properly signed and dated? ☐ Yes ☐ No

g. Is a copy of the signed consent form (and HIPAA authorization when applicable) given to the participant? ☐ Yes ☐ No

h. Is the consenting "environment" suitable? ☐ Yes ☐ No

i. Did the consenter spend sufficient time obtaining informed consent? ☐ Yes ☐ No

Additional Comments (provide a brief explanation for each "No"):