Drake University Institutional Review Board (IRB)

Protocol Reviewer Checklist

Note: The following checklist is designed for protocol reviewers (for any type of protocol: full board review, expedited, or other) as a aid in making sure studies involving human subjects research adhere to current federal regulations. This are not intended to be either all inclusive, nor to take the place of critical review. Rather, they are intended as a shorthand guide to aid reviewers in complete and thorough assessment of studies reviewed.

## Overall Criteria for IRB Approval of Research

◊ Risks are minimized

◊ Risks to subjects are reasonable in relation to anticipated benefits

◊ Subject selection is equitable

◊ Informed consent is sought from each subject (when applicable)

◊ Informed consent is documented

◊ Data is monitored to ensure subject safety

◊ Privacy and Confidentiality are protected (see HIPPA notes below)

◊ Additional safeguards for vulnerable populations (e.g. minors)

◊ Subjects are able to give autonomous consent

## Informed Consent Document Review

◊ Remember: Consent is a PROCESS, the consent form is a RECORD of the information contained and the subject's willingness to participate.

◊ Must be understandable: written at generally a 8$^{th}$ grade level, jargon minimized, in appropriate language for subject. Investigator leading consent process in a non-English speaker should be able to speak the native language of the potential subject

◊ No exculpatory language can be in the consent document

◊ Required Elements of Consent Document:

◊ A statement that the study involves research, the purposes of that research, the expected duration of the subject's participation, a description of the procedures involved in the research and which procedures are experimental

◊ Description of reasonably foreseeable risks or discomforts

◊ Description of benefits to subject

◊ Disclosure of appropriate alternative courses of treatment/procedures (if applicable)

◊ Statement concerning subject confidentiality

◊ An explanation as to whether any compensation is available if injury occurs

◊ A statement concerning who the subject can contact about the research and the subject's rights (must include IRB office/email)

◊ A statement that participation is voluntary, refusal to participate will incur no penalty, and the subject may discontinue participation at any time without penalty or loss of benefits

◊ Additional elements on the consent form when appropriate:

◊ A statement that the study procedure may involve risk to the subject that are currently unforeseeable

◊ Anticipated circumstances in which the PI can terminate subject participation

◊ Any additional costs to patient

◊ The consequences of a subject's decision to withdraw from research

◊ Approximate number of subjects involved in study

◊ A statement that significant new findings which may relate to the subject's willingness to participate in the research will be provided to the subject

## HIPPA Authorization Points

◊ HIPPA Authorization core elements include: Subject has right revoke authorization, information disclosed to recipients not covered by HIPPA may be subject to re-disclosure and is no longer protected information, Subject agrees to access for duration of study (if known), does not affect treatment, payment, enrollment or eligibility for benefits

◊ Waiver to HIPPA authorization can be given IF: 1-study involves minimal risk, 2-an adequate plan to destroy identifiers at earliest opportunity is stated, 3-an adequate plan to protect information from improper use and disclosure is stated, 4-A statement that HIPPA protected information will not be used or disclosed to any other person or entity, 5-The research could not be practicably be conducted without waiver of authorization, and 6-The researcher needs HIPPA protected information to conduct the study